

# 2013 ACCP Annual Meeting

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### ORIGINAL RESEARCH

#### ADR/Drug Interactions

**1. Adverse drug reaction related hospitalizations in a Chinese hospital: a prospective study.** *Man Zhu, Master<sup>1</sup>, Zhihui Tang, Master<sup>2</sup>, Daihong Guo, Master<sup>2</sup>, Dongxiao Wang, Master<sup>2</sup>, Weilan Wang, Master<sup>2</sup>, Fei Pei, Master<sup>2</sup>*; (1) Department of Pharmaceutical Care, Chinese PLA General Hospital, Beijing, China (2) Chinese PLA General Hospital, Beijing, China

**BACKGROUND:** Adverse Drug Reactions (ADRs) have been regarded as a major public health problem since they represent a sizable percentage of admissions. Unfortunately, there are few data on epidemiology of ADR related admissions in China.

**PURPOSE:** The study undertook a prospective analysis to evaluate the frequency, the adverse reactions and the main suspected drugs of ADRs related admissions and provide data for safe drug use.

**METHODS:** Age, sex, duration, drugs taken before admission, diagnoses, renal and liver function, alcohol abuse and allergic history of all patients admitted in four wards in our hospital from December 2012 to March 2013 were registered by clinical pharmacist. The admissions caused by an ADR, the type of reactions and the suspected drugs were also registered.

**RESULTS:** A total of 1001 consecutive adult patients admitted to the hospital during a 16-week period. Thirty-six patients (3.6%) were hospitalized for ADRs related causes, among which, Oncology (21/379), Endocrinology (10/312), Cardiology (2/185) and Pneumology (3/89). Hypoglycemia, myelosuppression, hypoleukemia were the frequent ADRs, with antidiabetics (7/36) and antitumor drugs (21/36) as the main suspected drugs. Male patients admitted due to ADRs were significantly more than female patients ( $p < 0.05$ ). Patients admitted to due to ADRs with liver failure were significantly more than patients with normal liver function ( $p = 0.0196$ ).

**CONCLUSION:** This study shows that ADRs cause 3.6% of admissions in our hospital. The clinical manifestations of ADR-related admissions are variable. The ADR-related admissions are more frequently exposed to cancer chemotherapy. None of the ADR-related admissions was caused by off-label use.

**2. Association between thromboembolic complications and recombinant factor VIIa when used in non-hemophiliacs.** *Shawn Johnson, Pharm.D., MPH, BCPS, BCNSP<sup>1</sup>, Danielle Blais, Pharm.D., BCPS<sup>1</sup>, Erin Reichert, Pharm.D., BCPS<sup>1</sup>, Pamela Burcham, Pharm.D., BCPS<sup>1</sup>, Anthony Gerlach, Pharm.D., BCPS, FCCM<sup>2</sup>*; (1) The Ohio State University Wexner Medical Center, Columbus, OH (2) Department of Pharmacy, The Ohio State University Wexner Medical Center, Columbus, OH

**PURPOSE:** Recent studies have demonstrated recombinant Factor VIIa (rFVIIa) use may be associated with the development of thromboembolic complications (TECs). It remains unclear whether higher dosages are associated with increased TECs. The primary aim of this investigation is to determine the incidence of TECs associated with rFVIIa use in non-hemophiliacs and if higher dosages results in an increased incidence of TECs.

**METHODS:** A retrospective chart review was conducted on non-hemophiliac patients receiving rFVIIa at our institution from 1/1/2005 to 11/1/2011. Exclusion criteria included patients  $>18$  or  $>89$  year, pregnant women, prisoners, and those with congenital factor VII deficiency. Data collected includes demographics, laboratory data, indication for use, history of thrombosis, hematolog-

ic studies, transfusions, use of anticoagulant or hemostatic agents, cumulative dosage, evidence of ischemia or thromboembolism, and all cause 30-day mortality. Statistical analysis was performed by fisher's exact test for nominal data and Mann-Whitney U test for non-parametric continuous data and presented as median (25–75% interquartile range).

**RESULTS:** One hundred and eighty-five were identified for inclusion and 14.9% (27) patients experienced TEC with 70.4% (19) being arterial and 29.6% (8) venous. There were no differences in demographics, median cumulative dosage rFVIIa administered (37.4 [22–79] versus 45 [21–131] mcg/kg,  $p = 0.42$ ), and concurrent use of anticoagulant or hemostatic agents between those who developed a TEC and those who did not. There was a trend for increased all cause 30-day mortality in those who experienced a TEC (51.9% versus 36.1%,  $p = 0.14$ ).

**CONCLUSION:** Administration of rFVIIa in non-hemophiliacs may lead to an increased development of TECs particularly arterial TECs. Further prospective studies are needed to determine whether total dosage used increases risk.

#### Adult Medicine

**3. Asymptomatic bacteriuria in adult acute care patients: a descriptive analysis.** *Ryan Dull, Pharm.D.<sup>1</sup>, Stacey Friedman, Pharm.D.<sup>2</sup>, Meghan Doyle, Pharm.D. Candidate<sup>2</sup>, Brianna Davis, Pharm.D. Candidate<sup>2</sup>*; (1) Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, NE (2) Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** Asymptomatic bacteriuria (ABU) is a common finding in hospitalized adults. Despite the lack of benefit, many patients with ABU receive antimicrobials. The goal of this research project was to assess those patients admitted to a community hospital with evidence of ABU and treated with antimicrobials.

**METHODS:** Adult patients admitted to our community hospital (157 beds) with bacteriuria obtained within 24 hours of admission between June 2011 and March 2012 were reviewed. ABU was defined as bacteriuria without documented urinary symptoms. Patients were considered symptomatic if urinary urgency or frequency, dysuria, suprapubic tenderness, flank pain, rigors, or gross hematuria were documented in the electronic medical record. Excluded patients were pediatrics ( $<19$  years old), pregnant or immunocompromised patients. Patients undergoing invasive urologic procedures, documented infection at a non-urinary site, delirium or altered mental status were also excluded. Polymicrobial bacterial growth or high quantities of squamous epithelial cells were considered urinary contamination. Descriptive statistics were used for baseline demographics, continuous and discrete variables.

**RESULTS:** Fifty-eight patients were evaluated. The mean age was  $72.9 \pm 18.2$  years and 44 (76%) were female. Forty patients (69%) presented to the emergency room from home. Five patients (9%) had an urinary catheter present on admission. Twenty-two ABU patients (38%) were without symptoms of urinary infection. Of these patients, 16 (73%) received antimicrobial treatment. Ten of 22 (45%) patients had pyuria. Ninety percent of patients with pyuria received antimicrobial therapy. Almost half (47%) of the collected urine specimens had evidence of contamination.

**CONCLUSION:** Patients (73%) admitted to our institution are inappropriately treated with antimicrobial therapy for ABU. Interventions such as prescriber education, prospective audit of antimicrobial use with intervention, and improved urine specimen collection technique may reduce inappropriate antimicrobial use. The results of this analysis will be used to provide evidence for reducing treatment of ABU.

**4. Evaluation of N-acetylcysteine for the prevention of contrast-induced nephropathy.** *Sara K. Richter, Pharm.D.<sup>1</sup>, Andrew J. Crannage, Pharm.D., BCPS<sup>2</sup>*; (1) Division of Pharmacy Practice, St. Louis College of Pharmacy, Mercy Hospital St. Louis, St. Louis, MO (2) St. Louis College of Pharmacy, St. Louis, MO

**PURPOSE:** Currently, there is no protocol in place for the use of N-acetylcysteine (NAC) in the prevention of contrast-induced nephropathy (CIN) at Mercy Hospital St. Louis. The objective of this study was to determine the impact of NAC on the development of CIN.

**METHODS:** Patients receiving intravenous radiocontrast dye admitted between January 1 and December 31, 2011 were included if they had two or more of the following characteristics: baseline serum creatinine >1.2 mg/dL or creatinine clearance <50 mL/min, age  $\geq$  75 years, diabetes mellitus, heart failure, or hypertension. Patients were divided into two groups, those who received NAC and those who did not. The primary outcome was the difference in the proportion of patients in each group who developed CIN.

**RESULTS:** A total of 302 patients were included, 151 received NAC and 151 did not receive NAC. Patients who received NAC had worse baseline renal function than those who did not receive NAC (mean pre-contrast serum creatinine 1.41 versus 0.95 mg/dL,  $p < 0.0001$ ). In the NAC group, 10.2% of patients developed CIN compared to 21.8% who did not receive NAC therapy ( $p = 0.0428$ ). In risk stratification analyses, patients  $\geq 75$  years of age and those with a history of hypertension demonstrated significant benefit from NAC ( $p = 0.0156$  and  $p = 0.0134$ , respectively). In a subgroup analysis, fluids were found to reduce the incidence of CIN, regardless of NAC administration ( $p = 0.0234$ ).

**CONCLUSION:** The use of NAC was associated with a reduction in the incidence of CIN in patients at risk for its development. Based on risk stratification analyses, this study will contribute to the development of a guide or protocol to assist practitioners in the most appropriate utilization of NAC. This will be beneficial for patients and healthcare institutions, especially during this time of nationwide drug shortages.

## Ambulatory Care

**5. Description of fracture risk in postmenopausal women on long-term bisphosphonate therapy in primary care.** *Matthew Kostoff, Pharm.D., BCPS, Laura Borgelt, Pharm.D., FCCP, BCPS, Joseph Saseen, Pharm.D.; Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO*

**PURPOSE:** Drug holidays are recommended for some patients treated with long-term bisphosphonate therapy to mitigate risks, including atypical fracture. Current evidence provides limited guidance for drug holidays, but suggests evaluating patients' fracture risk. No studies have identified how many patients are truly at risk. This study described characteristics of postmenopausal women on long-term bisphosphonate therapy that fall into one of four fracture risk categories (low, mild, moderate, high). The prevalence of women eligible for a drug holiday, estimated cost savings when eligible for drug holiday, and the rate of documentation for calcium and vitamin D supplementation were also determined.

**METHODS:** This was a retrospective electronic health record review in eight primary care clinics. Postmenopausal women age 55–89 years with osteopenia or osteoporosis who were prescribed bisphosphonate therapy for >4 years between 10/1/2002 and 9/30/2012 were evaluated. Data describing patient demographics; risk factors for fracture; bisphosphonate medication, duration, and indication; DXA scan results; and calcium and vitamin D supplementation were collected.

**RESULTS:** A total of 201 women were included. Mean age was 71.4 ( $\pm 8.2$ ) years, mean BMI was 25.3 ( $\pm 5.6$ ) kg/m<sup>2</sup>, and 73.1% were Caucasian; 74/201 (36.8%) were low risk, 10/201 (5.0%) mild risk, 72/201 (35.8%) moderate risk, and 45/201 (22.4%) high risk. Eighty-one women (40.3%) were eligible for a drug holiday or discontinuation. The estimated cost savings per eligible patient was \$574.80. Calcium/vitamin D supplementation was documented in 52.7% of women.

**CONCLUSION:** More than one-third of postmenopausal women taking long-term bisphosphonate therapy had low fracture risk and over 40% of our patients were eligible for a drug holiday or discontinuation. These data suggest that potential cost savings

and possible avoidance of risks may be achieved in many patients on long-term bisphosphonate therapy in primary care. This emphasizes the need to accurately assess risk and benefit in patients treated with bisphosphonate therapy.

**6. Impact of health literacy on aspects of medication nonadherence reported by underserved patients with type 2 diabetes.** *Maria M. Thurston, Pharm.D., BCPS<sup>1</sup>, Sally A. Huston, Ph.D.<sup>2</sup>, Catherine A. Bourg, Pharm.D., BCPS, BCACP<sup>2</sup>, Beth B. Phillips, Pharm.D., FCCP, BCPS<sup>2</sup>, Gina J. Ryan, Pharm.D., BCPS, CDE<sup>3</sup>; (1) Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, GA (2) University of Georgia College of Pharmacy, Athens, GA (3) Mercer University College of Pharmacy and Health Sciences, Atlanta, GA*

**PURPOSE:** Previous research has demonstrated conflicting results when it comes to the relationship between health literacy and medication adherence. The primary objective of this study was to determine whether there is a relationship between health literacy and subjectively and objectively reported medication adherence.

**METHODS:** This was a multicenter, cross-sectional survey study. Patients were  $\geq 18$  years with Type 2 diabetes mellitus and taking  $\geq 1$  anti-diabetic medication for  $\geq 6$  months and with an A1c measure. Two well-validated survey instruments, the Morisky 8-Item Medication Adherence Scale (MMAS-8) (subjective adherence) and the short-form Test of Functional Health Literacy in Adults (s-TOFHLA) were used. Anti-diabetic medication refill data were collected and used to calculate the cumulative medication gap (CMG). Demographic data were also collected. Correlations were examined. Dichotomized health literacy (limited/adequate) was logistically regressed on the eight individual items comprising the MMAS-8 plus demographic covariates.

**RESULTS:** A total of 192 subjects were enrolled. Thirty-three percent of subjects had limited health literacy (s-TOFHLA score  $\leq 22$ ). There were no significant correlations between health literacy (s-TOFHLA) and subjective (MMAS-8) or objective (CMG) adherence. Age was significantly correlated with literacy ( $-0.411$ ,  $p < 0.01$ ), MMAS-8 (0.157,  $p < 0.05$ ), and A1c ( $-0.235$ ,  $p < 0.01$ ). Logistic regression revealed the odds of adequate health literacy were significantly higher for more highly educated individuals and for those who reported little difficulty in remembering their medications (MMAS-8 question 8). The odds of adequate health literacy decreased with increasing age. None of the other individual MMAS-8 questions (1–7) had a significant association with health literacy.

**CONCLUSIONS:** Health literacy level does not appear to be associated with deliberate medication discontinuation as assessed by the first 7 MMAS-8 questions. Adequate health literacy is positively associated with less difficulty in remembering to take medication.

**7. Therapeutic outcomes of a pharmacist-directed attention deficit-hyperactivity disorder program in a medical home.** *Jennifer Reinhold, Pharm.D.<sup>1</sup>, Vincent Willey, Pharm.D.<sup>1</sup>, Kathleen Willey, M.D.<sup>2</sup>, Bonnie Kelly, M.D.<sup>2</sup>, Eun Kim, M.D.<sup>2</sup>, Miriam Mullin, M.D.<sup>2</sup>; (1) Philadelphia College of Pharmacy, Philadelphia, PA (2) Quality Family Physicians, Hockessin, DE*

**PURPOSE:** To evaluate the therapeutic and clinical outcomes associated with a pharmacist-directed, multidisciplinary approach to treating ADHD.

**METHODS:** Evaluation of data was retrospectively analyzed via electronic medical record review of self-identifying patients referred by the physicians into the pharmacist program for evaluation of ADHD from January 2010 until March 2013. Outcomes described included ultimate diagnosis (ADHD, another psychiatric diagnosis, no diagnosis), treatment, follow-up, factors that may influence achievement of remission, and remission rates.

**RESULTS:** A total of 96 patients were referred into the program for evaluation during the study period. Mean age was 31 years and 58.3% were female. Of those initial 96 patients, 50 (52.1%) were diagnosed with ADHD. Of the 46 patients who

did not have ADD, 28 (60.9%) did not leave with any psychiatric diagnosis. Psychiatric diagnoses in the 18 non-ADHD patients included primarily anxiety disorders (33%), mood disorders (22%), or concomitant anxiety and depression (39%). Forty-five of the 50 patients (90%) who were diagnosed with ADHD were prescribed medication, and 31 were seen for follow-up. Of those 31 patients, 74.2% of patients were treated with a long-acting stimulant, 16.1% with a non-stimulant, 6.4% with a short-acting stimulant medication, and 3.3% with combination therapy. The overall response or remission rate (patient either responded to therapy with residual symptoms or experienced complete symptom remission) by the end of the study period was 90.3%.

**CONCLUSIONS:** Only half the patients presenting with self-suspicion of ADHD were ultimately diagnosed with ADHD. The most commonly recognized symptoms of ADHD are shared with multiple psychiatric illnesses and therefore objective assessment was of particular importance in identifying ADHD as well as unsuspected mood and anxiety disorders. The pharmacists have been valuable additions to the established primary care practice in the objective evaluation of ADHD and in the development of guideline-driven treatment plans.

**8. Survey of pharmacist management of subtherapeutic INRs and parenteral anticoagulant bridging practices during vitamin K antagonist therapy.** *Whitney D. Maxwell, Pharm.D., BCPS<sup>1</sup>, Sarah P. Shrader, Pharm.D., BCPS<sup>2</sup>, Sarah F. White, Pharm.D., BCPS<sup>3</sup>, Katherine G. Moore, Pharm.D., BCPS, BCACP<sup>4</sup>;* (1) South Carolina College of Pharmacy-USC Campus, Columbia, SC (2) University of Kansas School of Pharmacy, Lawrence, KS (3) Sullivan University College of Pharmacy, Lexington, KY (4) Presbyterian College School of Pharmacy, Clinton, SC

**PURPOSE:** Despite extensive warfarin use, guidelines provide little direction for significantly subtherapeutic INR management. This study describes usual subtherapeutic INR management strategies of a sample of pharmacists. We hypothesize that the standard of care is not well-defined and significant variation exists in management.

**METHODS:** A web-based survey was distributed to the ACCP Ambulatory Care PRN and Veterans Administration anticoagulation e-mail list-serves. Respondents indicated if they would utilize parenteral anticoagulation bridging in 16 clinical scenarios. The scenarios described three major patient groups: AFib with CHADS<sub>2</sub> score of 3–4, AFib with CHADS<sub>2</sub> score of 5–6, and newly diagnosed venous thromboembolism (VTE). The scenarios also described three major therapeutic time points. For AFib, time points included: initiation, early phase (<1 month), and maintenance phase (>1 month). VTE time points included: early phase (<1 month), months 2–3 of therapy, and maintenance phase (>3 months). Demographic data were also collected.

**RESULTS:** The study was approved by the appropriate Institutional Review Boards, was distributed to approximately 1500 e-mail recipients, and 9.6% (144) recipients responded. Bridging was utilized for AFib with CHADS<sub>2</sub> score of 3–4 at therapy initiation (25%), and during early (20%) and maintenance (15%) phases for INRs < 1.5. Bridging was utilized for AFib with CHADS<sub>2</sub> score of 5–6 at initiation (56%) and during early (45%) and maintenance (31%) phases for INRs < 1.5. Bridging was utilized for VTE with INRs < 1.5 during early (86%), months 2–3 (49%), and maintenance phases with two subsequent INRs < 1.5 (22%).

**CONCLUSIONS:** Bridge therapy was only utilized in >50% of respondents in two clinical scenarios: patients with AFib and CHADS<sub>2</sub> score of 5–6, at therapy initiation, and patients with VTE experiencing INRs < 1.5 during the first month of therapy. Based on our study findings, standards of care for significantly subtherapeutic INRs warrant further definition.

**9. Association between prescription drug benefit and hospital readmission rates.** *Laura Challen, Pharm.D., BCPS, MBA<sup>1</sup>, Christine Kelso, Pharm.D., BCPS AE-C<sup>2</sup>, Bhumi Gandhi, Pharm.D.*

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**PURPOSE:** To determine whether primary care medicine clinic (PCMC) patients with prescription drug benefits had lower rates of hospital readmissions.

**METHODS:** This study was a retrospective, single centered, cohort study of PCMC patients who had at least one hospital readmission in 2011. Data collected included date of birth, race, sex, hospital admission dates, hospital discharge dates, medical and prescription insurance benefits. Eligible patients were divided into two groups: patients without prescription drug benefits and patients with prescription drug benefits.

**RESULTS:** Of the 2362 patients assessed, 352 patients met our inclusion criteria. The number of hospital readmissions for patients with a prescription drug benefit was higher in comparison to those with no prescription drug benefit ( $2.453 \pm 2.49$  versus  $1.88 \pm 1.91$ ,  $p=0.052$ , respectively). The length of index admission and the length of hospital readmission in days were higher in those with no prescription drug benefits ( $5.29 \pm 6.38$  versus  $4.59 \pm 4.50$ ,  $p=0.428$ ) ( $5.31 \pm 5.90$  versus  $4.48 \pm 4.33$ ,  $p=0.166$ ). The number of days to readmission was higher in those with prescription drug benefits ( $58.12 \pm 63.54$  versus  $53.39 \pm 53.47$ ,  $p=0.316$ ). Medicare patients were further divided into those with or without Medicare Part D. Patients with Medicare Part D had a higher number of hospital readmissions than those without Medicare Part D ( $2.48 \pm 2.23$  versus  $2.2 \pm 1.32$ ,  $p=0.555$ ). Patients without Medicare Part D had longer lengths of index admission and hospital readmissions ( $5.02 \pm 7.03$  versus  $4.28 \pm 3.52$ ,  $p=0.751$ ) ( $6.89 \pm 6.74$  versus  $4.32 \pm 4.25$ ,  $p=0.092$ ).

**CONCLUSION:** Although not statistically significant, patients with prescription drug benefits had more hospital readmissions, but shorter hospital lengths of stay. It may be beneficial for healthcare systems to provide additional resources for assisting patients to sign up for Medicare Part D programs.

**10. Retrospective case-control study comparing twice daily insulin glargine and insulin detemir in veteran patients with type 2 diabetes.** *Timothy Harmon, Pharm.D.<sup>1</sup>, Thomas J. Worrall, BS Pharm., Pharm.D.<sup>2</sup>;* (1) Ralph H. Johnson VAMC, Charleston, SC (2) Ralph H. Johnson VA Medical Center, Charleston, SC

**PURPOSE:** Determine the efficacy and tolerability of insulin glargine and detemir administered twice daily over a 12 month period in veterans with type 2 diabetes and an A1c  $\leq 9\%$ .

**METHODS:** A retrospective case-control study of patients prescribed either twice daily insulin detemir or glargine was conducted. The insulin detemir and glargine groups were matched on age, baseline A1c, and daily basal insulin dose. The primary aim was to determine if there was a difference in A1c between the groups at time 0 and 12 months. The secondary aim was to determine if there was a difference in the daily dose of basal insulin between the groups at time 0 and at 12 months. A descriptive analysis of the patients requiring a change in basal insulin was completed. The mean difference in treatment cost was evaluated at 12 months.

**RESULTS:** Baseline characteristics were similar. The median A1c at 12 months was 8.3 and 8.7 in the insulin detemir and glargine groups, respectively ( $p$  value 0.73), with no difference in the insulin detemir group and a 0.3% increase in the insulin glargine group. The median daily basal insulin use was 0.93 and 0.95 units/kg in the insulin detemir and glargine groups, respectively ( $p$  value 0.8), with a difference of +0.3 and +0.5 units/kg in the insulin detemir and glargine groups. There was an estimated cost savings of \$266.3 per patient in the insulin detemir group.

**CONCLUSION:** Glycemic control in this study didn't differ from previously published studies that compared insulin detemir and glargine. Of note, this study did show a daily dose of insulin detemir that was less than insulin glargine but the results were not statistically significant. In conclusion there was no difference in efficacy or tolerability between the insulin detemir and glargine groups when administered twice daily.



### 11. Evaluation of safety and effectiveness of 12 week monitoring of patients stable on warfarin at UC Davis Anticoagulation Clinic.

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**PURPOSE:** The purpose of this study is to investigate whether assessment of warfarin dosing every 12 weeks according to the 9th edition CHEST guideline recommendations is as safe and effective as assessment every 4 weeks in warfarin patients monitored by the UC Davis Anticoagulation Clinic.

**METHODS:** UC Davis Anticoagulation clinic patients receiving long-term warfarin therapy who were therapeutically stable on warfarin, defined as patients with at least six previous months of consistent results within therapeutic range were contacted to change their INR follow-up to 12 weeks. A retrospective chart review was completed after 12 weeks to determine the number of patients who's INR remained within therapeutic range, the number of thrombotic and bleeding events, and the number of medication changes that went undetected during extended follow-up.

**RESULTS:** Fifty-two patients who met inclusion criteria were included in the study. These patients were on warfarin for a variety of indications including: atrial fibrillation/atrial flutter: 33 (average CHADS2 score = 2.06), venous thromboembolism (DVT or PE): 10, heart valve replacement: 1, genetic hypercoagulable conditions: 3, and other: 5. After the completion of the extended 12 week follow-up 50% of patients stayed within strict therapeutic INR range of 2-3. However, 71.2% stayed within "extended" therapeutic range of 1.8-3.2. No major or minor bleeding events related to warfarin occurred during the extended follow-up period. There were also no venous thromboembolic events that occurred. There were 19 new medication changes that were made during the extended follow-up period, with four changes reported to the clinic by patients, and 15 undetected medication changes.

**CONCLUSION:** Extended 12 week follow-up is safe and effective for select low risk patients who have been stable on warfarin for >6 months. Patients require ongoing education regarding informing the clinic of medication changes to detect for potential for drug interactions.

### 12. Impact of a Medicaid prescription limitation policy on health care utilization.

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**PURPOSE:** Pennsylvania State Medicaid implemented a policy in 2012 that limits prescription coverage to six prescriptions per month. This study was designed to determine if Pennsylvania's prescription limitation negatively impacts beneficiaries' health condition management.

**METHODS:** A retrospective, chart review was conducted for all participants between September 1, 2011 and December 31, 2012; data were recorded monthly to allow for within-person analysis. Data were gathered from electronic medical charts and prescription fill profiles of a single large institution. Investigators compared mean number of health care encounters and medication possession ratio (MPR) pre-policy to post-policy for Medicaid beneficiaries covered by a single insurance plan (intervention). Changes in means were then compared to a nonequivalent group of beneficiaries covered by an insurance plan that did not implement a limitation policy (control). Mixed model trajectory analysis tested outcomes by time, policy implementation, insurance plan, an interaction of time and policy implementation, and an interaction of policy implementation and insurance plan.

**RESULTS:** The mean MPR and number of encounters for the intervention group (n=166) were similar before and after the policy was implemented ( $0.893 \pm 0.208$  versus  $0.888 \pm 0.21$  and  $1.7 \pm 1.27$  encounters versus  $1.68 \pm 1.18$  encounters, respectively;  $p > 0.05$  for both). The changes in mean MPR ( $0.006 \pm 0.012$  and  $-0.005 \pm 0.038$ , respectively;  $p > 0.05$ ) and mean number of encounters ( $0.02 \pm 0.08$  and  $-0.06 \pm 0.11$ , respectively;  $p > 0.05$ ) were not significantly different for the intervention group relative to the control group (n=100).

**CONCLUSIONS:** Results demonstrate no significant impact of the policy on outcomes related to health condition management for this subpopulation of Medicaid beneficiaries. Nonetheless, this study demonstrates practice application for mixed model trajectory analysis, which takes the individual into account when evaluating the outcome as a whole. Further studies are needed to investigate the impact of this policy; specifically, an analysis of cost and analysis of changes in health care professional workload.

### 13. Assessing time to failure of maintain blood pressure goals in patients with diabetes discharged from a Veterans Affairs Medical Center (VAMC) pharmacist-managed primary care clinic.

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**PURPOSE:** This study evaluated the ability of patients with diabetes mellitus type II (T2DM) to maintain goal systolic blood pressure (SBP) of <130 mmHg after being discharged from a pharmacist-managed primary care clinic. The goals of this study were to 1) document length of time to failure of maintaining SBP goal, and 2) characterize risk factors that may be associated with a shorter time to failure.

**METHODS:** Medical records were examined for veterans with T2DM that were discharged from the primary care clinic between July 1, 2007 and June 30, 2009 after meeting goal SBP. The time to SBP goal failure, medical history, laboratory data, medications, demographic information, and clinic appointment attendance, were reviewed.

**RESULTS:** Overall, 42 patients were discharged from clinic for achieving SBP goal and afterwards failed to maintain their goal. During clinic enrollment the mean age of patients was 63.8 years old (SD 10.79), with a mean SBP of 135.6 mmHg (SD 15.48). Mean time to SBP goal failure was 9.4 months (SEM 1.35). Risk factors significantly associated with increasing a patient's rate of failure to maintain their SBP goal includes history of: chronic kidney disease (HR 13.16, SEM 1.1548,  $p = 0.026$ ), coronary artery bypass graft surgery (CABG) (HR 3.869, SEM 0.512,  $p = 0.008$ ), or heart failure (HR 3.839, SEM 0.5753,  $p = 0.019$ ).

**CONCLUSION:** Less durability was displayed in patients with T2DM to maintain their SBP goal after being discharged from a pharmacist-managed primary care clinic. Patients with a history of chronic kidney disease, heart failure or coronary artery bypass graft surgery at discharge should benefit from sustained SBP management within the pharmacist-managed primary care clinic, as opposed to being discharged to receive usual care, due to these patients displaying increased rates of failure to maintain SBP goals.

### 14. Implementation of a clinical pharmacist-directed hospital discharge service to improve transitions in care.

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**PURPOSE:** Establishing a systematic approach for clinical pharmacists to manage hospital discharge patients in the ambulatory care setting. Clinical pharmacy services worked collaboratively with members of the primary care team to identify, prevent, and resolve drug therapy problems in post hospitalized patients.

**METHODS:** All patients discharged from a hospital between January 2013 and May 2013 were offered a clinical pharmacist visit before their follow up visit with their medical provider. The clinic's call center or Care Coordinators would follow a script and process

to sign patients up over the phone. During each visit, a clinical pharmacist reviewed the patient's medications and then identified/resolved drug therapy problems, which were categorized into four groups: indication, effectiveness, safety, and convenience.

**RESULTS:** A total of 50 hospital discharge patients were scheduled and seen by a clinical pharmacist in the 5 months period. Twenty-three patients were scheduled as a follow up from the emergency room, while 27 patients were seen after being discharged from the hospital. A total of 81 drug therapy problems were identified by the clinical pharmacists. Eighty two percent of patients presented with one or more drug therapy problems. There were nine patients who did not have any drug therapy problems, many of which were ED discharges. The leading three drug therapy problems were "untreated condition," "does not understand instructions," and "needs additional monitoring."

**CONCLUSION:** Implementing a systematic clinical pharmacist intervention for post hospital discharge patients resulted in the identification of various drug therapy problems and worked towards improving overall patient care.

**15E. Impact of Ramadan fasting on HbA1c in relation to medication use.** Melanie Siaw, B.Sc. (Pharm)(Hons)<sup>1</sup>, Nur Hidayah Bte Shamsuri, B.Sc. (Pharm)(Hons)<sup>1</sup>, Daniel Chew, MBBS, MRCP, FAMS<sup>2</sup>, Rinkoo Dalan, MBBS, MRCP, FAMS, FRCP<sup>2</sup>, S. A. Abdul Shakoor, MBBS, M.D., MRCP, M.D.<sup>2</sup>, Noorani Othman, CDE<sup>2</sup>, Theresa Choo, M.Sc.<sup>3</sup>, Siti Nurhannah Abdul Karim, BSc. (Pharm.) (Hons)<sup>3</sup>, Olive Lai, Pharm.D.<sup>1</sup>, Joyce Lee, Pharm.D., BCPS, BCACP<sup>1</sup>; (1)Department of Pharmacy, Faculty of Science at National University of Singapore, Singapore (2)Department of Endocrinology, Tan Tock Seng Hospital, Singapore (3)Department of Pharmacy, Tan Tock Seng Hospital, Singapore

**PURPOSE:** Muslims worldwide observe religious fasting of Ramadan from dawn to sunset. While the practice of fasting often affects the blood glucose of patients with diabetes as reported in the literature, little is known about the use of pharmacologic agents in relation to the degree of changes in HbA1c during this period.

**METHODS:** In this prospective study, we aimed to examine the change of HbA1c during Ramadan in relation to pharmacotherapy use by tracking HbA1c values and medication use before, during and after Ramadan for a total of 13 months.

**RESULTS:** A total of 136 Muslim patients were eligible for this study. The mean age was 56.4 ± 8.9 years with 40.4% male and 59.6% female. Of these, 63.2% were on insulin containing therapies, 34.6% were on oral hypoglycemic agents (OHA) only and 2.2% were not on medication. During Ramadan, mean HbA1c improved by 0.66% and 0.27% for patients who were on OHA only and insulin containing regimen, respectively. After adjusting for demographics, health status and baseline HbA1c, patients who were on OHA only were 5.9 times more likely to observe improvement in HbA1c during Ramadan compared to those given insulin containing regimen (p<0.05). Furthermore, there were no significant hypoglycemic events related to fasting during Ramadan.

**CONCLUSION:** Overall, the improvement in HbA1c during Ramadan appeared to be more prominent in Muslim patients who take oral antidiabetic medications without insulin.

Presented at to be presented at American Diabetes Association (ADA) 73rd Scientific Sessions, Chicago, IL, June 21 to 25, 2013.

**16. Evaluation of pharmacist intervention in hepatitis C care management.** Katherine Gazlay, Pharm.D.<sup>1</sup>, Jason Bailly, Pharm.D.<sup>1</sup>, Linda Awdishu, Pharm.D.<sup>2</sup>, Charles James, Pharm.D.<sup>1</sup>, Shirley Tsunoda, Pharm.D.<sup>2</sup>; (1)University of California San Diego Health System, San Diego, CA (2)University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla, CA

**PURPOSE:** To describe the financial and clinical effectiveness of a specialty pharmacy program for patients with hepatitis C virus (HCV).

**METHODS:** Our institution initiated a specialty pharmacy program for patients started on HCV therapy. A staff pharmacist

was dedicated to ensuring HCV patients received drug therapy in a timely and efficient manner, including prior authorizations and patient assistance programs. Patients received follow-up telephone calls and mail order service. Providers were given 24 hours access to pharmacy services. In addition, a clinical pharmacist was integrated into the HCV healthcare team 1 day a week. Patients who started treatment before March 5, 2012 were in the "Pre-C-Care" group and patients starting treatment on or after March 5, 2012 were in the "C-Care" group. Patients were included in the study with the following characteristics: ≥18 years old infected with HCV, started HCV therapy between December 3, 2011 and December 31, 2012. Patients were excluded if they were enrolled in a clinical trial.

**RESULTS:** Overall pharmaceutical retention rate increased from 21% to 53% after C-Care was implemented. Patients seen in the co-infected HIV/HCV clinic increased from 50% (n=5/10) to 100% (n=7/7), while patients seen in the mono-infected HCV clinic increased from 5% (n=1/19) to 40% (n=9/23). The contribution margin from HCV prescriptions after C-Care was approximately \$500,000. Although clinical outcome measures did not reach statistical significance, the clinical pharmacist positively contributed to the overall management of the patient and facilitated the retention of patients within the pharmacy system.

**CONCLUSION:** Instituting a specialty pharmacy program for HCV management increased pharmacy retention and provided a considerable financial benefit. A dedicated clinical pharmacist facilitated the effectiveness of retaining patients and providing clinical management, education, and adherence. More clinical data are necessary to show improvements in clinical outcomes.

**17. Hospitalizations and patient outcomes after referral to a pharmacist-physician diabetes co-management service.** Anita Airee, Pharm.D., BCPS<sup>1</sup>, Andrew W.Dake, M.D.<sup>2</sup>, Juli D. Williams, M.D.<sup>2</sup>, Patrick B. Barlow, B.A.<sup>2</sup>, R. Eric Heidel, Ph.D.<sup>2</sup>, Matthew A. Rubertus, Pharm.D. Candidate<sup>3</sup>, Abel M. Yehdego, Pharm.D. Candidate<sup>3</sup>, Michelle Z. Farland, Pharm.D., BCPS, CDE<sup>4</sup>; (1)Department of Clinical Pharmacy, The University of Tennessee College of Pharmacy, Knoxville Campus, Knoxville, TN (2)Graduate School of Medicine, The University of Tennessee Medical Center, Knoxville, Knoxville, TN (3)The University of Tennessee College of Pharmacy, Knoxville Campus, Knoxville, TN (4)University of Tennessee Health Science Center College of Pharmacy, Knoxville, TN

**PURPOSE:** This study assessed the impact of a pharmacist-physician co-management service for patients with type 2 diabetes mellitus on hospitalizations and disease-oriented endpoints in an academic practice.

**METHODS:** This was a retrospective cohort before and after study that enrolled patients ≥18 years of age who had been referred to the pharmacists-physician co-management service over a 32 months time-period. Patients were followed for the duration of enrollment in the service. Patient care was provided in a collaborative manner with involvement from both clinical pharmacists and primary care physicians. Primary outcomes evaluated included change in A1c and change in total number of hospitalizations before and after referral to the service. A dependent t-test and Wilcoxon Signed Ranks test were used to evaluate the changes in A1c and hospitalizations, respectively. Other disease-state endpoints were evaluated as secondary outcomes.

**RESULTS:** A total of 99 patients were enrolled in the study. At baseline, the mean A1c was 9.31 ± 2.14%. A significant difference was observed post-intervention (mean 8.04 ± 1.94%; p<0.001). There was a significant decrease in hospitalizations from the 12 months prior to referral (Median = 1.00, IQR = 1.00) to after the last pharmacist - physician co-management visit (Median = 0.00, IQR = -0.00), p<0.001.

**CONCLUSIONS:** Implementation of a pharmacist-physician co-management service in an academic medical center significantly decreased A1c values and hospitalizations. This study adds to the literature supporting pharmacist involvement in diabetes care taking into account the impact on hospitalizations as well as disease-oriented endpoints.

## Cardiovascular

**18. Defining the dose-response of oral sildenafil in patients with advanced heart failure.** Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV)<sup>1</sup>, Andrew Arter, Pharm.D.<sup>2</sup>, Jeffrey Morgan, M.D., David Lanfear, M.D.<sup>4</sup>; (1)Henry Ford Hospital, Detroit, MI (2)Detroit Medical Center (3)Henry Ford Hospital

**PURPOSE:** Secondary pulmonary hypertension (PH) is a contraindication to cardiac transplantation. The purpose of this project is to determine the optimal dose response and titration for sildenafil in patients with heart failure and PH.

**METHODS:** This prospective observational analysis included advanced heart failure patients admitted to the ICU with a pulmonary artery (PA) catheter. Included patients must have a mean pulmonary arterial (PAPm) pressure > 25 mmHg despite adequate diuresis to a pulmonary capillary wedge pressure < 18 mmHg. Patients were excluded if they had primary pulmonary hypertension, long-term nitrate therapy, any significant changes in diuretic or inotropic therapy during sildenafil initiation. The primary efficacy endpoint was the change in PAPm after the third sildenafil dose as compared to the change after the first dose.

**RESULTS:** Eight male patients (four inotrope dependent) with a mean age of 58 ± 11 years were included. With the first dose of sildenafil 25 mg, PAPm decreased from 38.9 ± 8.3 to 31 ± 6.8 mmHg at 2 hours after the first dose (p=0.004). For the primary efficacy endpoint, the PAPm actually slightly increased after the third dose of sildenafil from 33.5 ± 9.8 to 37.3 ± 10.6 mmHg (p=0.32). However, for the patients who demonstrated ≥20% reduction in PAPm after the first dose, there was a decrease in PAPm 11.4% with the third dose (p=0.006). These four responders demonstrated a reduction in PAPm of 29.4% with the first dose, whereas the four non-responders only demonstrated a reduction in PAPm of 10.3%. There were no significant reduction in mean arterial pressure no patients discontinued the study drug secondary to adverse effects.

**CONCLUSION:** In this cohort responders were separated from non-responders after the first dose of sildenafil. Further study is needed to determine whether higher doses can overcome an initial inadequate response.

**19. The use of antiplatelet agents in secondary prevention of stroke: a network meta-analysis.** Rhynn J. Malloy, Pharm.D.<sup>1</sup>, Abir O. Kanaan, Pharm.D.<sup>2</sup>, Matthew A. Silva, Pharm.D.<sup>2</sup>, Jennifer L. Donovan, Pharm.D.<sup>2</sup>; (1)School of Pharmacy, MCPHS University, Worcester, MA (2)MCPHS University, Worcester, MA

**PURPOSE:** Current guidelines recommend various antiplatelet agents used alone or in combination for secondary prevention of noncardioembolic stroke. The plethora of options is due to the lack of direct comparisons therefore, we conducted a mixed-treatment comparison (MTC) analysis to determine the preferred therapy.

**METHODS:** A comprehensive literature search was conducted to identify randomized trials evaluating the role of various antiplatelet agents and combinations for secondary stroke prevention. Key articles were cross-referenced for additional studies. Data were screened, evaluated and entered into ADDIS (version 1.16.3) to generate direct and indirect comparisons for recurrent stroke and overall hemorrhagic events.

**RESULTS:** A total of 24 articles were included in the analysis. Eleven antiplatelet regimens were compared in over 88,000 patients. The combination of ASA plus dipyridamole was more protective against recurrent stroke than ASA (0.78 [0.64, 0.93]) and there was no difference in all other comparisons with active treatment. ASA plus dipyridamole was associated with more overall hemorrhagic events than dipyridamole (1.83 [1.17, 2.81]), cilostazol (2.12 [1.21, 3.48]), and triflusal (1.67 [1.05, 2.78]), but less events than the combination of ASA plus clopidogrel (0.38 [0.25, 0.56]). The combination of ASA plus clopidogrel was associated with more overall hemorrhagic events compared to clopidogrel (2.81 [1.96, 4.10]), cilostazol (5.56 [3.03, 9.66]), dipyridamole (4.78 [2.80, 8.21]), sarpogrelate (3.59 [1.96, 6.45]), terutroban (2.13 [1.21, 3.61]), ticlopidine (2.80 [1.69, 5.00]), and triflusal (4.36 [2.62, 7.81]).

**CONCLUSION:** We found that ASA plus dipyridamole was more protective than ASA alone for preventing recurrent stroke; however, there was no difference between most comparisons of antiplatelet agents and combinations. The combination of ASA plus clopidogrel seemed to have more overall hemorrhagic events than other treatments. Selection of antiplatelet therapy for the secondary prevention of stroke must be individualized according to patient comorbidities including risk of stroke recurrence and bleeding.

**20E. Participation in a multi-disciplinary heart failure disease management program minimizes risk of aldosterone antagonist-induced hyperkalemia.** Shawn Anderson, Pharm.D., BCACP, Kristyn Mulqueen, Pharm.D., BCACP; Department of Veterans Affairs, Gainesville, FL

**PURPOSE:** Aldosterone antagonists (AA) have been shown to reduce mortality and morbidity in HFREF, but are often underutilized. Concern for hyperkalemia may limit use. We hypothesize that evidence-based prescribing of AAs with appropriate monitoring results in rates of hyperkalemia similar to those seen with standard heart failure (HF) therapy without an AA.

**METHODS:** A retrospective review of HF patients followed in a multi-disciplinary Heart Failure Disease Management Program (HFDMP) was performed to compare the incidence of hyperkalemia in patients managed with HF pharmacotherapy with AA (AA therapy group) or without AA (standard therapy group). Inpatient and outpatient medical records were reviewed to identify episodes of hyperkalemia occurring while patients were enrolled in the HFDMP. Hyperkalemia was classified as clinical (K ≥ 6 mmol/L) or subclinical (6 mmol/L > K ≥ 5.5 mmol/L). Hyperkalemic events were excluded if the blood sample was hemolyzed. One hundred fifty patients were needed in each group to have 80% power to detect a difference in the rate of hyperkalemia, using expected rates of 15% in the AA therapy group and 2% in the standard therapy group.

**RESULTS:** A total of 300 patients were included in the study. Clinical hyperkalemia occurred in 5 (3.3%) patients in the AA therapy group and 6 (4%) patients in the standard therapy group (p=0.76). Subclinical hyperkalemia occurred in 15 (10%) patients in the AA therapy group and 22 (15%) patients in the standard therapy group (p=0.22). The observed rate of any hyperkalemia for patients on AA therapy and standard therapy was 13.3% and 18.7%, respectively (p=0.21).

**CONCLUSIONS:** We found no statistically significant difference in the rate of hyperkalemia between groups of HFDMP patients treated with AA compared with those receiving standard HF therapy. Appropriate patient selection, close laboratory monitoring and follow-up allow for the safe use of AA therapy in patients with HFREF. Presented at Will be presented at the HFSA Annual Meeting, Orlando, FL; September 22–25, 2013.

**21E. Effects of an amlodipine- and olmesartan medoxomil-based titration regimen in patients with hypertension, type 2 diabetes and metabolic syndrome.** C. Venkata S. Ram, M.D., MACP, FACC, FASH<sup>1</sup>, Richard A. Sachson, M.D., FACP, FACE<sup>2</sup>, Chunlin Qian, Ph.D.<sup>3</sup>, Kathy A. Stoakes, RN, BSN<sup>3</sup>, Kathleen J. Chavani, Pharm.D.<sup>3</sup>; (1)Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX (2)Endocrine Associates of Dallas, Dallas, TX (3)Daiichi Sankyo, Inc., Parsippany, NJ

**PURPOSE:** To report the results for a prespecified analysis of patients with metabolic syndrome (MetS; WHO criteria) from a study that evaluated the safety and efficacy of an amlodipine/olmesartan medoxomil (AML/OM)-based titration regimen in patients with hypertension and type 2 diabetes.

**METHODS:** The study comprised 2–3 weeks placebo, 18 weeks active treatment and 2 weeks follow-up. Patients received AML 5 mg and were uptitrated at 3-week intervals to AML/OM 5/20, 5/40, and 10/40 mg, AML/OM+hydrochlorothiazide (HCTZ) 10/40 + 12.5 and 10/40 + 25 mg (if seated [Se] BP ≥ 120/70 mmHg). Endpoints were change from baseline in mean 24-hour ambulatory SBP (primary) and DBP at Week 12 as assessed by ambulatory



BP monitoring (ABPM), mean SeBP changes, 24-hour ambulatory BP target and SeBP goal achievement.

**RESULTS:** Individuals with MetS comprised 167/207 (80.7%) of patients. For MetS patients, baseline mean ( $\pm$ SD) age was  $57.9 \pm 9.3$  years, mean weight was  $98.3 \pm 19.5$  kg, mean SeBP was  $158.8 \pm 12.9/90.2 \pm 10.1$  mmHg and 58.1% were male. ABPM results at Week 12 were available for 131/167 MetS patients. Ambulatory BP was  $144.0/81.8$  mmHg at baseline and was reduced by  $19.7 \pm 0.9/11.2 \pm 0.6$  mmHg at Week 12 ( $\pm$ SEM). Ambulatory BP targets of  $<130/80$ ,  $<125/75$ ,  $<120/80$  mmHg were achieved by 71.8%, 46.6%, and 35.9% of patients, respectively. Treatment emergent adverse events occurred in 58.1% (97/167) of MetS patients; 20.4% were drug-related.

SeBP Endpoints	Baseline SeBP mmHg ( $\pm$ SD)	SeBP Reduction mmHg ( $\pm$ SEM) <sup>a,b</sup>	Patients achieving SeBP goal <sup>c</sup> < 130/80 mmHg (%)
AML 5 mg (n=160)	158.7 $\pm$ 12.5/ 90.1 $\pm$ 10.1	9.5 $\pm$ 1.0/ 3.9 $\pm$ 0.6	2.5
AML/OM 5/20 mg (n=150)	158.6 $\pm$ 12.6/ 90.1 $\pm$ 10.3	17.8 $\pm$ 1.0/ 8.3 $\pm$ 0.7	18.1
AML/OM 5/40 mg (n=143)	158.8 $\pm$ 12.3/ 90.7 $\pm$ 9.9	18.8 $\pm$ 1.2/ 9.2 $\pm$ 0.8	28.6
AML/OM 10/40 mg (n=133)	158.8 $\pm$ 12.3/ 90.5 $\pm$ 10.0	23.0 $\pm$ 1.1/ 10.6 $\pm$ 0.7	39.1
AML/OM+HCTZ 10/40 + 12.5 mg (n=119)	159.2 $\pm$ 12.7/ 90.8 $\pm$ 10.4	27.3 $\pm$ 1.4/ 13.9 $\pm$ 0.8	52.8
AML/OM+HCTZ 10/40 + 25 mg (n=82)	160.0 $\pm$ 12.7/ 91.4 $\pm$ 10.5	28.5 $\pm$ 1.7/ 14.0 $\pm$ 1.1	59.6

<sup>a</sup> $P < 0.0001$  versus baseline. <sup>b</sup>Last observation carried forward. <sup>c</sup>Cumulative percentages.

**CONCLUSIONS:** AML/OM $\pm$ HCTZ enabled significant BP reductions and BP target/goal achievement and was well-tolerated in MetS patients with hypertension.

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## 22. The high dose rosuvastatin once weekly study (HDROWS) – the effects on advanced lipid, glycemic, and inflammatory panels.

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**PURPOSE:** Statins produce significant improvements in lipid and inflammatory markers, but may worsen glycemia. We compared changes in these parameters between a high-dose once weekly (Qwk) statin and usual daily dosing.

**METHODS:** Blood samples of subjects randomized to rosuvastatin 80 mg Qwk (n=10) or atorvastatin 10 mg/day (n=10) from an 8-week double-blind pilot study were analyzed. Advanced lipoproteins (apolipoprotein [Apo] B, ApoA, ApoB/ApoA ratio, small dense low-density lipoprotein cholesterol [sdLDL]), inflammatory markers (myeloperoxidase [MPO], fibrinogen, lipoprotein-associated phospholipase A2 [Lp-PLA2]) and glycemic indices (insulin, C-peptide, fructosamine) were measured at baseline, and 2 and 6 days after last dose.

**RESULTS:** Baseline characteristics were similar between groups. Significant changes from baseline included reductions in ApoB, ApoB/ApoA ratio and sdLDL for both regimens, while atorvastatin increased insulin and C-peptide, and rosuvastatin reduced LpPLA2 (table). For between group comparisons only sdLDL was significantly lower with rosuvastatin. No serious adverse events were reported.

**CONCLUSIONS:** Rosuvastatin 80 mg Qwk produced comparable changes in advanced lipid and inflammatory markers to atorvastatin 10 mg daily. No significant differences were observed between groups in glycemic indices; although atorvastatin increased acute glycemic markers from baseline. These data provide novel findings and additional support for Qwk statin dosing.

**23E. Efficacy of an amlodipine/olmesartan medoxomil regimen in patients uncontrolled on prior diuretic monotherapy.** Joel M. Neutel, M.D.<sup>1</sup>, Alan Graff, M.D.<sup>2</sup>, Jen-Fue Maa, Ph.D.<sup>3</sup>, Ali Shojajee, Pharm.D.<sup>3</sup>, Kathleen J. Chavanu, Pharm.D.<sup>3</sup>; (1) Orange County Research Center, Tustin, CA (2) Private Practice, Fort Lauderdale, FL (3) Daiichi Sankyo, Inc., Parsippany, NJ

**PURPOSE:** A prospective, open-label, dose-titration study assessed the efficacy of an amlodipine/olmesartan medoxomil (AML/OM) treatment regimen in patients with uncontrolled blood pressure (BP) on monotherapy for  $\geq 1$  month (SBP $\geq 140$  mmHg [ $\geq 130$  mmHg in diabetics] and  $\leq 180$  mmHg, and DBP $\leq 110$  mmHg).

**METHODS:** Patients were switched to AML/OM 5/20 mg and uptitrated every 4 weeks to AML/OM 5/40 mg, AML/OM 10/40 mg (to achieve seated [Se] BP $< 120/70$  mmHg), AML/OM 10/40 + hydrochlorothiazide 12.5 mg, then AML/OM 10/40 + hydrochlorothiazide 25 mg (to achieve SeBP $< 125/75$  mmHg). We analyzed a subgroup of patients (n=167) on prior diuretic monotherapy to determine the proportion achieving a cumulative (at any timepoint) SeSBP goal  $< 140$  mmHg ( $< 130$  mmHg in diabetics) by Week 12.

**RESULTS:** Patients were: 62.3% female; mean age $\pm$ SD,  $55.7 \pm 11.2$  years; mean BP,  $151.3 \pm 8.56/91.9 \pm 8.30$  mmHg; 22.8% had type 2 diabetes; mean BMI  $30.8 \pm 6.80$  kg/m<sup>2</sup>. By Week 12, 75.9% of patients achieved cumulative SeSBP target  $< 140$  mmHg ( $< 130$  mmHg in diabetics). At Week 20, 83.1% of patients achieved cumulative SeBP goal  $< 140/90$  mmHg ( $< 130/80$  mmHg in diabetics). Mean changes $\pm$ SE in baseline SeBP during the titration periods (LOCF) ranged from  $-14.3 \pm 1.00/-8.5 \pm 0.59$  mmHg for AML/OM 5/20 mg to  $-25.0 \pm 1.68/-13.3 \pm 1.03$  mmHg for AML/OM 10/40 + hydrochlorothiazide 25 mg. Ambulatory BP monitoring of a patient subset showed mean BP reductions were maintained throughout the

Select Variables	Rosuvastatin 80 mg Qwk Pre Post%Change			Atorvastatin 10 mg Daily Pre Post%Change			Group p-value
Lipids (mg/dL)							
Apo B	106 $\pm$ 18	81 $\pm$ 18	24 $\pm$ 7*	114 $\pm$ 29	86 $\pm$ 23	24 $\pm$ 6*	NS
sdLDL	40 $\pm$ 13	32 $\pm$ 12	19 $\pm$ 4*	40 $\pm$ 11	36 $\pm$ 13	10 $\pm$ 10**	p<0.05
Inflammatory markers							
Lp-PLA2 ng/mL	175 $\pm$ 45	157 $\pm$ 35	19 $\pm$ 34**	165 $\pm$ 24	155 $\pm$ 29	4 $\pm$ 25	NS
Fibrinogen mg/dL	329 $\pm$ 77	317 $\pm$ 61	1 $\pm$ 23	322 $\pm$ 92	343 $\pm$ 120	6 $\pm$ 13	NS
MPO pmol/L	334 $\pm$ 152	313 $\pm$ 115	4 $\pm$ 12	260 $\pm$ 112	281 $\pm$ 97	17 $\pm$ 37	NS
Glycemic indices							
Insulin $\mu$ U/mL	9.9 $\pm$ 6	11.7 $\pm$ 11	13 $\pm$ 48	10.0 $\pm$ 6	13.0 $\pm$ 7	38 $\pm$ 48**	NS
C-peptide ng/mL	2.3 $\pm$ 0.6	2.5 $\pm$ 1.3	5 $\pm$ 24	2.8 $\pm$ 0.7	3.0 $\pm$ 0.9	9 $\pm$ 12**	NS
Fructosamine $\mu$ mol/L	223 $\pm$ 19	218 $\pm$ 18	2 $\pm$ 4	225 $\pm$ 13	219 $\pm$ 14	2 $\pm$ 6	NS

From baseline: \*p<0.001; \*\*p<0.05; otherwise = NS; Post values = mean of days 2 and 6 after last dose.

24-hour dosing interval. Treatment-emergent adverse events (TE-AEs) and drug-related TEAEs occurred in 56.9% and 26.9% of patients, respectively.

	Baseline Mean SeSBP/ SeDBP	End of Titration <sup>a</sup> Mean SeSBP/SeDBP	Mean Change SeSBP/SeDBP from Baseline <sup>b</sup>
AML/OM 5/20 mg (n=161)	151.0/92.0	136.8/83.5	-14.3/-8.5
AML/OM 5/40 mg (n=142)	151.4/92.2	137.3/84.4	-14.1/-7.9
AML/OM 10/40 mg (n=131)	151.7/92.2	133.9/82.1	-17.7/-10.1
AML/OM 10/40 + HCTZ 12.5 mg (n=113)	152.1/92.5	130.0/80.4	-22.1/-12.2
AML/OM 10/40 + HCTZ 25 mg (n=77)	153.2/94.0	128.2/80.7	-25.0/-13.3

<sup>a</sup>LOCF, last observation carried forward<sup>b</sup> $P<0.0001$  versus baseline.

**CONCLUSIONS:** An AML/OM-based treatment regimen effectively controlled BP in a significant proportion of patients previously uncontrolled on diuretic monotherapy.

Published in Neutel, Joel, Graff, Alan, Maa, Jen-Fue, Shojae, Ali; Efficacy of an amlodipine/olmesartan medoxomil regimen in patients uncontrolled on prior diuretic monotherapy (abstract). *Journal of Clinical Hypertension* 2012;14 (Suppl 1):104.

**24E. Outcomes with ticagrelor versus clopidogrel in relation to high sensitivity troponin-T in non-ST-elevation acute coronary syndrome patients managed with early invasive or non-invasive treatment – a substudy from the prospective randomized PLATelet inhibit.** Lars Wallentin, M.D., Ph.D.<sup>1</sup>, Stefan James, M.D., Ph.D.<sup>1</sup>, Evangelos Giannitsis, M.D.<sup>2</sup>, Hugo Katus, M.D., Ph.D.<sup>2</sup>, Richard C. Becker, M.D., M.Ed.<sup>3</sup>, Christopher P. Cannon, M.D.<sup>4</sup>, Jay Horrow, M.D., M.S., FAHA<sup>5</sup>, Steen Husted, M.D., DSc<sup>6</sup>, Agneta Siegbahn, M.D., Ph.D., FESC<sup>7</sup>, Gabriel P. Steg, M.D.<sup>8</sup>, Robert F. Storey, M.D., Ph.D.<sup>9</sup>, Lisa Wernroth, M.Sc.<sup>7</sup>, Robert Harrington, M.D.<sup>10</sup>; (1)Department of Medical Sciences and Uppsala Clinical Research Center, Uppsala University (2)Department of Cardiology, University of Heidelberg (3)Department of Cardiology, Duke Clinical Research Institute, Duke University Medical Center (4)Cardiovascular Division, Brigham and Women's Hospital (5)Global Medicines Development, AstraZeneca, LP (6)Department of Medicine, Hospital Unit West (7)Uppsala Clinical Research Center, Uppsala University (8)Département de Cardiologie, Université Paris Diderot (9)Department of Cardiovascular Science, University of Sheffield (10)Department of Medicine, Stanford University

**PURPOSE:** In the PLATO trial, ticagrelor versus clopidogrel reduced cardiovascular (CV) death, myocardial infarction (MI) and stroke in acute coronary syndrome (ACS) patients. We investigated outcomes in non-ST-elevation (NSTEMI)-ACS patients with or without in-hospital revascularization in relation to high-sensitivity troponin-T (hs-TnT).

**METHODS:** NSTEMI-ACS (two required): (i) ST-segment depression; (ii) positive biomarker; (iii) one additional clinical risk indicator. Physician discretion determined in-hospital invasive procedures. Follow-up was 6–12 months. Frozen samples (randomization) provided hs-TnT. Cox proportional hazards model adjusted for baseline characteristics evaluated treatment effects.

**RESULTS:** Five-thousand-three-hundred-and-fifty-seven patients with hs-TnT underwent revascularization during index hospitalization (invasive); 4589 did not. In 5011 invasive patients with elevated hs-TnT (>14 ng/L), ticagrelor reduced the composite of CV-death, MI and stroke from 11.2% to 8.5% by reducing CV-death, spontaneous MI, and procedure-related MI. The corresponding reduction in 3576 non-invasive patients with elevated hs-TnT was 14.9–12.4%, driven by reduced mortality. One-thousand-and-thirteen non-invasive patients with normal hs-TnT had very low event rates. Neither invasive nor non-invasive cohorts had significant interactions between treatment and hs-TnT status.

Event	Ticagrelor	Clopidogrel	Adjusted HR
<b>Invasive</b>			
hsTnT > 14 ng/L			
CV-death+MI+stroke	215/2516	280/2495	0.76 (0.63–0.91)
CV-death+MI	199/2516	263/2495	0.75 (0.62–0.90)
Total-death	59/2516	88/2495	0.67 (0.48–0.94)
CV-death	51/2516	73/2495	0.70 (0.49–1.01)
Total-MI	161/2516	210/2495	0.76 (0.62–0.93)
Procedure-MI	67/2516	93/2495	0.71 (0.52–0.97)
Spontaneous-MI	98/2516	124/2495	0.79 (0.61–1.04)
CV-death+Spont-MI	137/2516	182/2495	0.76 (0.61–0.95)
<b>Non-Invasive</b>			
hsTnT > 14 ng/L			
CV-death+MI+stroke	222/1785	267/1791	0.81 (0.68–0.97)
CV-death+MI	206/1785	245/1791	0.82 (0.68–0.99)
Total-death	119/1785	156/1791	0.74 (0.58–0.94)
CV-death	105/1785	136/1791	0.74 (0.57–0.96)
MI	133/1785	136/1791	0.97 (0.76–1.23)

**CONCLUSIONS:** Ticagrelor reduces total death and the composite of CV-death and spontaneous and procedure-related MI in invasively managed NSTEMI-ACS patients with elevated hs-TnT. Results emphasize that ticagrelor has its clinically most important effect in ACS patients with elevated troponin regardless of invasive or non-invasive management.

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**25. Impact of new oral anticoagulants on proportion of oral anticoagulant prescribing in patients with non-valvular atrial fibrillation for prevention of stroke and systemic embolism.** Yvonne Phan, Pharm.D., BCPS<sup>1</sup>, Toni Ripley, Pharm.D., FCCP, BCPS (AQ-Card)<sup>1</sup>, Holly Herring, Pharm.D., BCPS<sup>1</sup>, Donald Harrison, Ph.D., FAPhA<sup>2</sup>, R. Chris Rathbun, Pharm.D., BCPS<sup>3</sup>; (1)The University of Oklahoma College of Pharmacy, Oklahoma City, OK (2)College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City, OK (3)Department of Clinical and Administrative Sciences, College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City, OK

**PURPOSE:** Approximately 60% of patients with atrial fibrillation (AF) who are eligible for anticoagulation receive warfarin, which leaves a substantial number of patients without adequate stroke prevention therapy. Challenges of warfarin therapy are frequently cited as reasons for not anticoagulating patients (e.g., drug and food interactions). With approval of new oral anticoagulants for non-valvular AF (NVAFA), we hypothesized that the proportion of patients receiving anticoagulant therapy would increase when options other than warfarin were available. The primary objective was to compare the proportion of NVAFA patients discharged on an anticoagulant during the periods prior to approval versus after approval of new anticoagulants.

**METHODS:** Non-pregnant, adult patients with an International Classification of Diseases, Ninth Revision diagnosis code for AF with CHADS2 > 1 during two timeframes were included: 7-1-2009 to 6-30-2010 and 7-1-2011 to 6-30-2012. Patients' demographics, comorbidities, oral anticoagulant agent and dosage, concomitant medications at discharge, laboratory data, and contraindications to anticoagulation regimen were documented.

**RESULTS:** The first timeframe included 1629 charts (2009–2010) and the second timeframe included 1957 charts (2011–2012). Five hundred twenty-nine charts were screened; 362 were excluded (incomplete charts, duplicate patients, or CHADS2 = 0), leaving 83 and 84 patients eligible for analysis in 2009–2010 and 2011–2012, respectively. No difference was found between the proportion of patients discharged on an oral anticoagulant in the two timeframes (63% for 2009–2010 versus 65% for 2011–2012,  $p=0.704$ ). Relative contraindications for anticoagulation (e.g., past history of bleeding, fall risk) were documented in 45% and 40% of the patients who were discharged without anticoagulation prescriptions (2009–2010 and 2011–2012, respectively).

**CONCLUSION:** Our results show additional anticoagulant options did not improve anticoagulation rates for stroke prevention in AF, suggesting the challenges related to warfarin use do



not impact prescribing substantially. Further exploration of barriers to anticoagulation for stroke prevention in AF is needed.

**26. Evaluation of therapeutic anticoagulation with enoxaparin in hemodialysis.** *Tiffany Pon, Pharm.D., BCPS<sup>1</sup>, William Dager, Pharm.D., BCPS (AQ-Cardiology), FCCP, FCCM, FCSHP<sup>1</sup>, A. Josh Roberts, Pharm.D., BCPS<sup>1</sup>, Richard White, M.D.<sup>2</sup>*; (1)Department of Pharmacy, Davis Medical Center, University of California, Sacramento, CA (2)Department of Internal Medicine, Davis Medical Center, University of California, Sacramento, CA

**PURPOSE:** Currently there is no evidence in medical literature to support the use of low molecular weight heparins (LMWH) for therapeutic anticoagulation in hemodialysis patients. The aim of this study was to determine the safety and efficacy of therapeutic anticoagulation with subcutaneous enoxaparin compared to unfractionated heparin (UFH) intravenous continuous infusions in patients requiring hemodialysis.

**METHODS:** In this retrospective chart review, the Electronic Medical Record was screened for patients admitted from 2004 to 2013 who met the following inclusion criteria: age  $\geq$  18 years, hemodialysis, and at least one dose of enoxaparin  $\leq$  1 mg/kg/day or therapeutic UFH. Primary endpoint measures were 30-day rate of thromboembolic event and/or dialysis catheter clotting and 30-day rate of major bleeding using International Society of Thrombosis and Haemostasis (ISTH) criteria. Secondary endpoints included 30-day re-hospitalization, hospital length of stay, and 30-day mortality.

**RESULTS:** A total of 164 patients met inclusion criteria. The average dose of enoxaparin used was  $0.7 \pm 0.2$  mg/kg/day (range 0.4–1 mg/kg/day). There were no statistically significant differences in either major bleeding (6.1% versus 11%,  $p=0.4$ ) or thromboembolic event (0% versus 2.44%,  $p=0.5$ ). Hospital length of stay was longer in the UFH group ( $20 \pm 58.3$  versus  $28.9 \pm 44.5$  days,  $p=0.02$ ); there were no differences in mortality or readmission rates. Multivariate analysis of ISTH major bleeding showed a trend toward reduced risk in the enoxaparin group but did not reach statistical significance (OR 0.765, 95% CI 0.17–3.5,  $p=0.73$ ).

**CONCLUSION:** This is the first study to evaluate the safety and efficacy of enoxaparin for therapeutic anticoagulation in patients requiring hemodialysis. Subcutaneous doses of enoxaparin ranging between 0.4 and 1 mg/kg/day appear to be as safe and effective as intravenous continuous infusion UFH with respect to rates of thromboembolic and major bleeding events.

**27. The effect of GLP-1 receptor agonists on targets for cardiovascular risk reduction.** *Christopher Westrick, Pharm.D., Melissa Snider, Pharm.D., BCPS, CLS, Nicole Arradaza, M.S., Kavita Sharma, M.D., ABCL Diplomate*; The Ohio State University Wexner Medical Center, Columbus, OH

**PURPOSE:** To evaluate the effect of the glucagon-like peptide-1 (GLP-1) receptor agonists on biomarkers of cardiovascular risk in patients with type 2 diabetes mellitus (T2DM) referred to a specialty lipid clinic and to determine if these affect the proportion of patients who have achieved targets at follow-up compared to baseline.

**METHODS:** This retrospective chart review was conducted at a cardiovascular risk reduction and lipid clinic on patients prescribed a GLP-1 receptor agonist between April 2006 and September 2012. Data was collected regarding baseline characteristics and safety and efficacy of the use of GLP-1 receptor agonists.

**RESULTS:** Twelve patients met inclusion criteria (baseline and follow-up lipid values). After treatment with a GLP-1 receptor agonist for 3 months, the median low-density lipoprotein cholesterol (LDL-C) and non-high-density lipoprotein cholesterol (non-HDL-C) decreased by 21.3% and 17.5% respectively. The proportion of patients achieving LDL-C and non-HDL-C goals improved from 33% ( $n=3$ ) to 66% ( $n=6$ ) and 25% ( $n=3$ ) to 50% ( $n=6$ ) respectively. Targeted hemoglobin A1c (HbA1c) improved from 10% ( $n=1$ ) to 50% ( $n=5$ ). Blood pressure targets of systolic and diastolic blood pressure increased from 40% ( $n=4$ ) to 90% ( $n=9$ ) and 30% ( $n=3$ ) to 50% ( $n=5$ ) respectively.

**CONCLUSION:** This retrospective chart review suggests that the use of GLP-1 receptor agonists in patients with T2DM has the potential to improve lipid parameters and targets for cardiovascular risk reduction.

**28. Comparative accuracy of pharmacogenetic warfarin dosing algorithms and the warfarin dosing label plus clinical judgment.**

*Yana Labinov, Pharm.D., Robert DiDomenico, Pharm.D., Edith A. Nutescu, Pharm.D., Larisa H. Cavallari, Pharm.D.*; University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** The primary objective of this study was to compare the accuracy of the genotype dosing table in the FDA-approved warfarin labeling alone (dose table) versus in the context of clinical factors evaluated by a pharmacist (pharmacist dosing). The secondary objective was to compare the accuracy of published pharmacogenetic dosing algorithms to pharmacist dosing for patients with known CYP2C9 and VKORC1 genotypes.

**METHODS:** Pharmacists were provided with 12 patient cases developed using data from the International Warfarin Pharmacogenetics Consortium (IWPC) database plus a copy of the FDA-approved warfarin dose table by genotype. For each patient case, pharmacists were asked to use the table, in combination with assessment of clinical factors, to estimate the therapeutic warfarin dose for the patient. Pharmacists were blinded to the actual therapeutic warfarin dose the patient required. Absolute dose prediction error, defined as the absolute difference between the predicted and actual stable dose, was compared by dosing method.

**RESULTS:** A total of 45 pharmacists participated in the study; 44% and 31% practice in inpatient and outpatient settings, respectively, 11% are faculty members and 13% are staff pharmacists. Pharmacist dosing was associated with a lower mean absolute dose prediction error versus the dose table alone (1.74 versus 2.08 mg,  $p=0.001$ ). However, mean absolute prediction error was similar between pharmacist dosing and the warfarindosing.org (1.61 mg) and IWPC (1.66 mg) algorithms. Pharmacist dosing, the warfarindosing.org, IWPC, and the dose table predicted doses within 20% of the actual therapeutic doses 42%, 33%, 33%, and 25% of the time, respectively.

**CONCLUSION:** When pharmacists are managing genotype-guided warfarin therapy, they do as well as the recommended algorithms when using the FDA-approved dosing table as a guide to interpret genotype effects on dose requirements. However, pharmacist outperform the FDA-approved dosing table when utilized alone to predict therapeutic warfarin dose.

**29. Anti-factor Xa assay versus aPTT for the monitoring of unfractionated heparin infusions in patients treated for cardiac indications.** *Matthew Marston, Jr, Pharm.D., Emily Heath, B.S., Pharm.D., Renee Ford, Pharm.D., BCPS, Lukas Griffin, B.S., Marybeth Boudreau, Pharm.D., BCPS*; Eastern Maine Medical Center, Bangor, ME

**PURPOSE:** To determine if a difference exists in the time to reach therapeutic anticoagulation when using either activated partial thromboplastin time (aPTT) or anti-factor Xa assay for the monitoring of patients receiving intravenous unfractionated heparin (UFH) for the treatment of cardiac indications.

**METHODS:** A single-center, retrospective cohort analysis of 400 patients treated with UFH for cardiac indications for a period of 2 months before and after the implementation of an anti-factor Xa assay based monitoring protocol in place of an aPTT based protocol. Patients transferring from an outside hospital, that received  $<24$  hours of UFH, or that had treatment interrupted for  $>10$  hours were excluded. A Cox-Proportional Hazards model was used to evaluate the primary endpoint of time to therapeutic anticoagulation as well as secondary efficacy endpoints that may have been influenced by whether patients did or did not receive an initial heparin bolus dose. Other categorical and continuous variables were analyzed using chi-squared and t-tests respectively.

**RESULTS:** A total of 219 patients were included in the study. The Median time to therapeutic range was decreased by 12.5 hours in patients monitored by anti-factor Xa assay compared to aPTT

(24.5 versus 37 hours,  $p=0.323$ ), which did not meet statistical significance. The mean percentage of tests within therapeutic range was increased in anti-factor Xa patients (40% versus 55%,  $p=0.043$ ). The median number of tests to achieve therapeutic anticoagulation was significantly decreased among anti-factor Xa patients (3 versus 4,  $p=0.026$ ). Rates of major bleeding and venous thromboembolism did not differ significantly between groups.

**CONCLUSION:** We found no significant difference in time to achieve therapeutic anticoagulation between using anti-factor Xa assay or aPTT for the monitoring of UFH. Larger studies should be performed to validate these findings.

### 30. Influence of clinical and genetic characteristics on P2Y12 inhibitor selection in high-risk patients with coronary artery disease.

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**PURPOSE:** Guidelines recommend aspirin and a P2Y12 inhibitor in patients receiving percutaneous coronary intervention (PCI) but leave agent selection (clopidogrel, prasugrel, or ticagrelor) to clinician discretion. A genotype-based algorithm was developed at our institution to help guide decisions among high-risk patients. The purpose of this investigation was to evaluate implementation of this algorithm and identify which factors influenced P2Y12 inhibitor selection.

**METHODS:** This retrospective review included 192 patients receiving PCI from July 1 to October 31, 2012. Data collection included demographics, clinical characteristics, and *CYP2C19* genotype (\*2, \*3, \*17). Factors were compared across initial and final P2Y12 inhibitor selection, including whether a change in therapy was made, by chi-square or ANOVA as appropriate.

**RESULTS:** A *CYP2C19* genotype was obtained in 167 patients (87%); of these, 45 (27%) were carriers of \*2 or \*3 alleles (clopidogrel intermediate or poor metabolizer phenotypes). Multiple factors differed across initial P2Y12 inhibitor selection, including risk factors for bleeding, indication for PCI, and admission P2Y12 inhibitor use. Both genetic and clinical factors differed across final P2Y12 inhibitor selection (see table). Maintenance therapy was changed in 27 patients (14%) and mostly involved a change to prasugrel or ticagrelor (74%); this was influenced only by *CYP2C19* phenotype ( $p<0.001$ ).

Characteristic (% yes)	Clopidogrel (n=122) (%)	Prasugrel or Ticagrelor* (n=70) (%)	p-value
<i>CYP2C19</i> intermediate or poor metabolizer	5	54	<0.001
Clopidogrel use at admission	95	54	0.001
Received clopidogrel loading dose	91	32	<0.001
Weight < 60 kg	11	3	0.039
Myocardial infarction at admission	28	48	0.039

\*Ticagrelor (n=8).

**CONCLUSION:** Initial P2Y12 inhibitor use was influenced by clinical factors, whereas maintenance therapy was influenced by both clinical factors and *CYP2C19* genotype. Consistent with the algorithm, changes in therapy were driven primarily by genotype results, suggesting the potential utility of genotype-guided selection of P2Y12 inhibitor therapy in a clinical setting.

**31E. Patient outcomes with anticoagulation therapy after hip and knee replacement: comparison of two models of care.** Sacheeta Bathija, M.S.<sup>1</sup>, Surrey Walton, Ph.D.<sup>1</sup>, Denys Lau, Ph.D.<sup>1</sup>, William Galanter, M.D.<sup>2</sup>, Glen Schumock, Pharm.D., Ph.D.<sup>1</sup>, Edith

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**PURPOSE:** To compare quality of anticoagulation control between specialized care (pharmacist-managed antithrombosis clinic (ATC) and RMC (orthopedic clinic) in an inception cohort receiving short-term post-surgery VTE prophylaxis with warfarin.

**METHODS:** We conducted a retrospective, observational cohort study of patients who underwent total hip or total knee replacement surgery between 2000 and 2009, and were referred to either the ATC or RMC for post-surgical anticoagulation prophylaxis. Means for continuous variables were compared by using t-tests and frequencies for categorical variables were compared by using chi-squared tests. Propensity scores were used to adjust for potential confounding on observable risk factors. Propensity score was defined as the predicted probability of being managed by ATC compared to RMC. The average treatment effect (ATE) and average treatment effect for treated (ATT) for ATC compared to RMC was expressed as the % change in anticoagulation control (expressed as the time in therapeutic international normalized ratio range (TTR) using inverse probability weighting and regression adjustment.

**RESULTS:** A total of 873 patients were included in the study cohort, of which 294 were referred to ATC and 579 to RMC. The average age of the study cohort was  $60 \pm 12.3$  years, and 68% were female. The majority of patients was African Americans (53.8%), followed by Caucasians (19.7%), Hispanics (19.6%) and other race (6.9%). After balancing the groups using inverse probability weighting and performing regression adjustment, TTR remained significantly higher in ATC compared to RMC via both ATE (7.1% higher in ATC versus RMC,  $p<0.001$ ) and ATT (9.08% higher in ATC versus RMC,  $p<0.001$ ).

**CONCLUSION:** Patients managed in the specialized pharmacist-led ATC had better anticoagulation control compared to routine medical care. Our study is among the first to evaluate and show benefit of a specialized systematic anticoagulation management model on quality of anticoagulation in an inception cohort receiving short-term post-surgery thromboprophylaxis. Presented at Presented at the XXIV Congress of the International Society of Thrombosis and Haemostasis, Amsterdam, Netherlands, June 29–July 4, 2013.

### 32. Predictors of medication adherence: results from the Atherosclerosis Risk in Communities Study.

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**PURPOSE:** Studies assessing predictors of medication adherence are often limited in size and scope and are focused on a single disease. This study investigates predictors of medication adherence among members of the ARIC Study cohort, a large population-based study.

**METHODS:** Medication adherence was assessed by the Morisky Medication Adherence Scale obtained during ARIC Visit 5 (preli-

mary data from 2011 to 2012), and categorized as low, intermediate, or high. Detailed reasons for nonadherence (e.g., affordability, transportation, side effects), number of medications, and medication coverage were obtained. Medication adherence, which was modeled as a dichotomous variable (high versus intermediate/low), was examined using logistic regression with adjustment for socioeconomic status (SES) (education, income, and the MacArthur Scales of Subjective Social Status); health literacy (Wide Range Achievement Test-Reading); and health status (SF-12 questionnaire).

**RESULTS:** Among 5735 ARIC cohort participants (mean age 75.6 + 5.2 years, 60% female), the mean number of medications reported was 9.3 + 4.8. Cardiovascular diseases were common, including hypertension (65%), hyperlipidemia (65%), and diabetes (30%). Forty percent of participants reported low or intermediate medication adherence. Memory was the primary reason for nonadherence (70%) while 20% of participants did not identify a specific reason. Medication adherence improved with age, up to 80 years and was stable thereafter. Adherence was low for persons from a predominantly African American study community, those with low SES, high health literacy, and low physical and mental health scores. Despite over 90% having medication coverage (e.g., private insurance, Medicaid, Part D), coverage was not associated with adherence.

**CONCLUSION:** Only 60% of participants reported high medication adherence in this large community population. Despite a high number of medications used, demographics and SES, rather than medication coverage, were associated with medication adherence. Memory was the most common reported cause of nonadherence. Future adherence interventions should focus on these identified predictors.

**33E. The effect of cardiovascular credentialed pharmacists on process measures and outcomes in myocardial infarction and heart failure.** Michael P. Dorsch, Pharm.D., M.S., BCPS, (AQ, CV)<sup>1</sup>, Jennifer M. Lose, Pharm.D., BCPS<sup>2</sup>, Robert DiDomenico, Pharm.D.<sup>3</sup>; (1) University of Michigan Hospitals and Health Centers, Ann Arbor, MI (2) Mayo Clinic, Rochester, MN (3) University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** Although cardiology pharmacist credentialing is strongly advocated, there is little to no evidence suggesting board certification improves patient outcomes. The purpose of this study is to determine if institutions with inpatient cardiology credentialed pharmacists exhibit improved quality measures for acute myocardial infarction (AMI) and heart failure (HF) compared to institutions without inpatient cardiology credentialed pharmacists.

**METHODS:** This is a multicenter, retrospective, cross-sectional, matched case-control study. The cardiology credentialing studied was the Board of Pharmaceutical Specialties (BPS) Added Qualification in Cardiology (AQCVC). A list of AQCVC pharmacists was derived from publically available data on the BPS website in July 2011 for inclusion in the study. Each case AQCVC pharmacist hospital was matched to a hospital without an AQCVC pharmacist in a 1–3 manner. Control hospitals were matched by geographical region, number of cardiovascular discharges, and the type of hospital. The proportion of patients meeting HF and AMI process of care measures, 30-day readmission, and 30-day mortality for each hospital were determined from the Hospital Compare website.

**RESULTS:** Thirty four AQCVC hospitals were matched to 102 non-AQCVC hospitals. Hospitals that employed inpatient AQCVC pharmacists performed better on process of care measures compared to hospitals that do not employ inpatient AQCVC pharmacists (OR 1.41, 95% CI 1.25–1.58,  $p < 0.0001$ ,  $p < 0.001$  for heterogeneity). The individual measures improved were aspirin on discharge for AMI and ACEi/ARB on discharge for HF. Thirty-day readmission and mortality rates for HF and AMI were not different between hospitals that employed inpatient AQCVC pharmacists compared to those that do not.

**CONCLUSION:** Hospitals that employ inpatient AQCVC credentialed pharmacists have improved performance on process of care

measures compared to those that do not employ AQCVC credentialed pharmacists. This analysis did not demonstrate that inpatient AQCVC credentialed pharmacists improved 30-day readmission or mortality rates for AMI and HF patients. Presented at the American Heart Association Quality of Care and Outcomes Meeting in Baltimore, MD, May 15–17, 2013.

## Community Pharmacy Practice

**34. Availability and needs of herbal medicinal information resources at community pharmacy, Riyadh region, Saudi Arabia.** Mohamed Alarifi, Ph.D.; Department of Clinical Pharmacy, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia

**PURPOSE:** To assess availability of current and perceived resources that would be helpful in answering inquiries about herbal medicines at community pharmacy.

**METHODS:** A cross-sectional survey of community pharmacists in Riyadh region, Saudi Arabia was conducted over a period of 6 months from July through December 2011. Data collection was carried out using a structured self-administered questionnaire. The questions consisted of close ended, multiple-choice, and fill-in short answers. Stratified random samples of 1700 registered pharmacy practitioners all over Saudi Arabia were randomly chosen. SPSS version 19 software was used for statistical analysis. Response rate was 82.4%.

**RESULTS:** Study results show that 59.7% of the participants sometimes discuss herbal medicine use with their patients, while only 4.25% never discuss it. The study shows 48.5% of participated pharmacist's record herbal medicine uses sometimes where only 9.4% of them never did so. Initiation of discussion, 44.3% of the respondents reported that patients initiate herbal issue discussion while 20.8% pharmacists initiate the discussion. Discussion was to be a one time or an ongoing by 14.3% or 9.9% of the respondents respectively. Most common barriers that limit discussing herbal medicines' use with their patients were lack of time due to other obligations assigned to the community pharmacist (46%), lack of reliable resources (30.3%), lack of scientific evidence that support herbal medicine use (15.2%), or lack of knowledge of herbal medicines (13.4%). Yet, a small number of respondents were concerned about interest in herbal medicines (9.1%) and other reasons (2.4%).

**CONCLUSION:** It is urgent to ensure that pharmacists are appropriately educated and trained. Extra efforts are needed to increase the awareness of pharmacists to adverse drug reactions reporting system at Saudi Food and Drug Authority. Finally, more consideration to herbal issues should be addressed in both pharmacy colleges' curricula and continuous education program.

**35. Implications of medicare part D on community pharmacy: a nationwide study.** Shamima Khan, MBA, Ph.D.<sup>1</sup>, Joshua Spooner, Pharm.D., M.S.<sup>1</sup>, Christopher Hakala, Ph.D.<sup>2</sup>, Evan Robinson, R.Ph., Ph.D.<sup>1</sup>; (1) College of Pharmacy, Western New England University, Springfield, MA (2) College of Arts & Sciences, Western New England University, Springfield, MA

**PURPOSE:** A nationwide study was initiated to determine the implications of Part D on community pharmacies.

**METHODS:** A cross-sectional online survey of pharmacists practicing nationwide was initiated in April 2013. Questions were asked in multiple categories: demographics, implications of Part D on community pharmacy and patients, beliefs about ideal pharmacy practice and Part D plans, and questions about Medicare Part D 2010 Updates. Pharmacists received three email requests; participation was voluntary and anonymous.

**RESULTS:** Data collection is still ongoing. The current adjusted response rate (unique opens) is 26% (329 responses after the completion of the 2nd email request). More than half (54.7%) of the respondents were practicing in independent pharmacies, and 32.1% were either an owner or part-owner. Half of the respondents were between 41 and 60 years old, 60.9% were male, and 72.3% had 15+ years of work experience. A vast majority (77.7%) stated that reimbursement was the most important con-



cern in reference to Part D and 83.7% thought that various pharmacies received different reimbursement rates. Further, 82% of respondents reported that the 2010 updates (which require plans to report actual price paid to the pharmacy to Center for Medicare and Medicaid Services) would not have a positive financial impact on community pharmacies. However, two-thirds of respondents reported that the opt-out enrollment provisions (part of the 2010 updates) would make it easier to promote Medication Therapy Management (MTM) services. More than half of the respondents reported providing MTM services at their primary practice site were reimbursed by at least one Part D plan.

**CONCLUSION:** Reimbursement remains the number one concern of community pharmacists in reference to Part D, and the 2010 Medicare Part D updates did not mitigate this concern. The updated MTM opt-out enrollment provides pharmacists an additional opportunity to promote MTM services.

## Critical Care

**36. Association of venous thromboembolism with missed doses of prophylactic anti-thrombotic medications in high risk patients.** Stacy A. Voils, Pharm.D., M.S.<sup>1</sup>, Alexa Carlson, Pharm.D.<sup>2</sup>; (1) Virginia Commonwealth University Health System, Richmond, VA (2) Northeastern University School of Pharmacy, Boston, MA

**PURPOSE:** To identify any association between missed doses of venous thromboembolism (VTE) prophylaxis medications and development of acute, in-hospital VTE events.

**METHODS:** This study is a case-control study in hospitalized adult patients at high risk for developing VTE, defined as an intensive care unit (ICU) length of stay (LOS) >24 hours. A random sample of patients admitted between January 2009 and October 2011 was extracted from a database of 7680 patients who met the inclusion criteria. Cases were defined as patients who experienced an acute VTE event during hospitalization and controls were patients from the same population who did not experience a VTE. Multivariate logistic regression modeling was used to assess the odds ratio of acute VTE in patients with any missed dose of prophylactic VTE.

**RESULTS:** Of the 920 patients with complete demographic information sampled from the total population, 59 (6.4%) experienced an acute, in-hospital VTE. In the univariate logistic regression analysis, there was no significant association between any missed dose of VTE prophylaxis medication and acute VTE (OR 0.96 [0.56–1.7]). A “dose-response” relationship was observed between hospital LOS and odds of acute VTE (LOS 4–6 days, OR 0.7 [0.2–2.4]; LOS 7–13 days, OR 2.2 [0.9–5.5]; and LOS 14 days or greater, OR 5.5 [2.4–12.8]). We found no relationship between acute VTE and age, gender, BMI, history of malignancy, or use of mechanical compression devices. In the multivariate logistic regression analysis, no association was observed between any missed dose of VTE prophylaxis medication and acute VTE (OR 0.7 [0.4–1.2]) when controlling for hospital LOS.

**CONCLUSION:** We found no evidence of a relationship between any missed dose of prophylactic anti-thrombotic medication and development of acute, in-hospital VTE. Hospital LOS was strongly associated with acute VTE in a “dose-response” manner.

**37. Influence of dexmedetomidine therapy on the management of severe alcohol withdrawal syndrome in critically ill patients.** Erin N. Frazee, Pharm.D., Heather A. Personett, Pharm.D., Jonathan Leung, Pharm.D., Sarah Nelson, Pharm.D., Ross Dierkhising, M.S., Philippe Bauer, M.D., Ph.D.; Mayo Clinic, Rochester, MN

**PURPOSE:** Although benzodiazepines are the first-line treatment for alcohol withdrawal syndrome (AWS), rapidly escalating doses may offer little additional benefit with increased complications. The purpose of this study was to evaluate the impact of dexmedetomidine therapy on benzodiazepine requirements and hemodynamics in AWS. Severity comparisons were also made between individuals with early use of the agent (BZD/Early DEX) and those with benzodiazepines alone (BZD). We hypothesized that early introduction of dexmedetomidine would improve AWS

symptom control with fewer side effects than traditional benzodiazepine-based treatment.

**METHODS:** This retrospective cohort study evaluated critically ill adults with a primary diagnosis of AWS from 2006 to 2012 at a tertiary academic medical center. Data were abstracted from each patient’s record for 7 days or until intensive care unit (ICU) discharge.

**RESULTS:** Of the 87 included patients, 31 (36%) received dexmedetomidine during the study time frame. In the 12 hours after dexmedetomidine was initiated, these patients experienced a 21 mg reduction in cumulative benzodiazepine dose ( $p<0.001$ ), a 14 mmHg lower mean arterial pressure ( $p=0.03$ ), and a 19 bpm reduction in heart rate ( $p<0.001$ ). Despite higher baseline AWS severity in BZD/Early DEX patients, these individuals exhibited greater improvement in day 2 and day 3 severity scores than BZD patients ( $p<0.001$ ,  $p=0.01$ , respectively).

**CONCLUSION:** Dexmedetomidine decreased benzodiazepine requirements, withdrawal severity, and improved the hemodynamic profile of patients with severe AWS. These results provide promising evidence about the potential benefit of dexmedetomidine in reducing AWS severity.

**38. Midodrine for weaning of vasopressor infusions.** Elizabeth Michalets, Pharm.D., BCPS, FCCP<sup>1</sup>, Laura Poveromo, Pharm.D.<sup>2</sup>, Susan Sutherland, Ph.D.<sup>3</sup>; (1) Mission Health System and UNC Eshelman School of Pharmacy, Asheville, NC (2) Department of Pharmacy, Mission Health System, Asheville, NC (3) Mission Health System, Mission Health System Research Institute, Asheville, NC

**PURPOSE:** Vasopressor infusions (VI) may lead to complications and extend hemodynamic monitoring. Midodrine may allow earlier weaning of VI and reductions in ICU length of stay (LOS). This IRB-approved study evaluated outcomes in patients who received midodrine (MG) for VI weaning compared to control (CG).

**METHODS:** Patients  $\geq 18$  years, admitted to an ICU January 2007–March 2012, received VI, had an ICD-9 relating to cardiovascular, trauma, or sepsis diagnoses and received midodrine (MG only) for weaning were reviewed. Primary outcome comparison: duration of VI. Secondary comparisons: mean arterial pressure (MAP) upon discontinuation, ICU LOS, VI dose reduction and time to discontinuation, adverse events.

**RESULTS:** A total of 111 patients were included in each group with no significant differences at baseline: 58 (52.3%) cardiovascular, 29 (26.1%) trauma and 24 (21.6%) sepsis. Baseline demographics for MG ( $n=111$ ) and CG ( $n=111$ ): Age (yrs) mean  $\pm$  SD  $64.1 \pm 14.7$ ,  $66.2 \pm 14.9$ ,  $p=0.277$ , males 68.5% and 63.1%,  $p=0.396$ , MAP (mm) at VI initiation mean  $\pm$  SD  $68 \pm 12$ ,  $66 \pm 14$ ,  $p=0.211$ . The median (IQR) duration (days) of VI: 2.6 (1.6–5.4) for MG compared to 1.6 (0.7–2.8) for CG,  $p<0.0001$ . Mean  $\pm$  SD MAP (mm) upon VI discontinuation:  $76 \pm 11$  MG and  $75 \pm 13$  CG,  $p=0.767$ . Median (IQR) ICU LOS (days): 5 (2–12) for MG and 5 (2.5–9.5) for CG,  $p=0.936$ . Median (IQR) percentage vasopressor reduction 24 hours after midodrine: 100 (25–100). Median (IQR) time to VI discontinuation after midodrine (days): 1.1 (0.3–2.3). Adverse events on and off midodrine: hypertension: 9% versus 26.1%,  $p=0.004$ , bradycardia: 13% versus 29%,  $p=0.002$ , tachyarrhythmias: 8% versus 18%,  $p=0.087$ .

**CONCLUSION:** Patients were able to discontinue VI within 1 day of midodrine initiation, and midodrine was associated with a low rate of adverse events.

**39. Outcomes associated with prothrombin complex concentrate for international normalized ratio reversal in patients on oral anticoagulants with acute bleeding.** Elizabeth Michalets, Pharm.D., BCPS, FCCP<sup>1</sup>, Ryan Tilton, Pharm.D.<sup>2</sup>, Bethany S. Delk, Pharm.D., BCPS<sup>2</sup>; (1) Mission Health System and UNC Eshelman School of Pharmacy, Asheville, NC (2) Department of Pharmacy, Mission Health System, Asheville, NC

**PURPOSE:** Published studies evaluating three-factor prothrombin complex concentrates (PCCs) for management of major

bleeding and international normalized ratio (INR) reversal have had small sample sizes. This IRB-approved study evaluated outcomes in patients who received three-factor PCC.

**METHODS:** Patients admitted between October 2007 and October 2012, received PCC, and with active bleeding secondary to oral anticoagulant therapy were reviewed. Primary objective: evaluate time to INR  $\leq$  1.4. Secondary objectives: evaluate degree of INR reduction based on baseline INR, impact from utilization of institutional protocol, and assess bleeding cessation, thromboembolic complications and cost.

**RESULTS:** A total of 403 patients were evaluated with a mean  $\pm$  SD age of  $76 \pm 12.2$  years, 56.8% male, weight  $83.1 \pm 24.6$  kg, median (IQR) baseline INR 2.9 (2.3–4.1). The location of bleeding was 60% intracranial, 20% gastrointestinal, 12% abdomen or chest, 6% other and 2% cervical spine. The mean PCC dose was  $1780 \pm 711$  units, and 400 (99%) patients were receiving prior warfarin, two dabigatran and one rivaroxaban. Concomitant vitamin K was administered to 330 (81.9%) patients and FFP to 116 (28.8%). INR target  $\pm$  1.4 was achieved in 358 (88.8%) patients with a median (IQR) time of 9.3 (2.9–13.3) hours. Bleeding cessation occurred in 333 (82.6%) patients, thromboembolic events in 15 (3.7%) and mean hospital cost/patient was  $\$2852 \pm 1739$ . Baseline INR influenced degree of INR reduction ( $R^2 = 0.614$ ). Utilization of the protocol was more likely to result in target INR: 301 (91.8%) versus 36 (70.6%),  $p < 0.0001$ , concomitant vitamin K: 85.1% versus 56.9%,  $p < 0.0001$ , bleeding cessation: 281 (85.7%) versus 35 (68.6%),  $p = 0.01$ .

**CONCLUSION:** The majority of patients achieved target INR. The time required was comparable to previous studies. Protocol utilization resulted in superior achievement of target INR, concomitant vitamin K and cessation of bleeding. Factors contributing to achievement of target INR will be evaluated.

**40E. High dose dexmedetomidine is not associated with increased risk of hypotension.** Anthony Gerlach, Pharm.D., BCPS, FCCM<sup>1</sup>, Danielle Blais, Pharm.D., BCPS<sup>2</sup>, G. Morgan Jones, Pharm.D., BCPS<sup>3</sup>, Pamela Burcham, Pharm.D., BCPS<sup>4</sup>, Stansilaw Stawicki, M.D.<sup>5</sup>, Charles Cook, M.D., FACS, FCCM<sup>5</sup>, Claire Murphy, Pharm.D., BCPS<sup>4</sup>; (1)Department of Pharmacy, The Ohio State University Wexner Medical Center, Columbus, OH (2)The Ohio State University Wexner Medical Center (3)Department of Pharmacy, Methodist University Hospital, Memphis, TN (4)The Ohio State University Wexner Medical Center, Columbus, OH (5)Department of Surgery, The Ohio State University Wexner Medical Center, Columbus, OH

**PURPOSE:** Dexmedetomidine (Dex) has been increasingly used for sedation in critically ill patients. The rate of hypotension in recent trials has ranged from 20% to 98%, raising concerns for increased hypotension with high-dose Dex (HDD;  $>0.7$  mcg/kg/hour). While studies have validated methods to reduce adverse effects, predictors of Dex-associated hypotension remain to be fully defined. To determine predictors of Dex-associated hypotension in critically ill patients.

**METHODS:** We conducted a retrospective review of all ICU patients receiving Dex for sedation from 7/16/09 to 7/15/10. Hypotension was defined as a single episode of mean arterial pressure (MAP)  $<60$  mmHg. Univariate analyses were performed to determine clinical factors associated with hypotension. Multivariate analysis was performed on univariate parameters with significance  $p < 0.20$  to identify independent predictors of hypotension.

**RESULTS:** A total of 283 patients were analyzed. Hypotension occurred in 121 (42.8%) patients with a median nadir of 54 mmHg. Half received HDD, of whom 48.1% developed hypotension and 54.5% did not ( $p=0.45$ ). Univariate analyses showed patients with hypotension had increased age (55.1 versus 50.9 years;  $p=0.027$ ), higher median APACHE II score (22 versus 20;  $p=0.024$ ), lower median body mass index (26.8 versus 29.9 kg/m<sup>2</sup>;  $p=0.031$ ), and higher incidences of surgical or cardiac ICU admission (63 versus 48.8%;  $p=0.03$ ), ejection fraction  $<40\%$  (11 versus 3.7%;  $p=0.017$ ), post-cardiac surgery (18.2 versus 4.2%,

$p=0.0009$ ), history of coronary heart disease (32.2 versus 16%;  $p=0.02$ ) concurrent use of vasopressor (14.0 versus 2.5%;  $p < 0.001$ ) and MAP  $<70$  mmHg prior to Dex initiation (25.6 versus 7.4%;  $p < 0.001$ ). Only MAP  $<70$  mmHg prior to initiation (OR 4.4, 95% CI 2.1–9.1;  $p < 0.001$ ) and APACHE II scores (OR 1.08, 95% CI 1.03–1.14;  $p=0.002$ ) were independently predictive of hypotension by multivariate analysis.

**CONCLUSION:** HDD was not associated with increased risk of hypotension. Pre-existing hypotension and higher APACHE II scores are independent risk factors for hypotension during Dex treatment.

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## Education/Training

**41. Implementing and assessing an elective learning experience in medical missions for PGY1 pharmacy residents.** Elias Chahine, Pharm.D., BCPS, (AQ-ID), Mara Poulakos, Pharm.D., Jamie Fairclough, MPH, Ph.D., M.S. Pharm., Angela Skaff, Student Pharmacist, Riley Williams, II, Pharm.D.; Palm Beach Atlantic University, Lloyd L. Gregory School of Pharmacy, West Palm Beach, FL

**PURPOSE:** According to ASHP accreditation standards, PGY1 residency programs must create a structure that permits residents to exercise leadership and gain experience in diverse patient populations. At Palm Beach Atlantic University, a center of excellence in medical missions was established to develop servant leaders who are indigent care advocates. The goal of this study was to implement and assess an elective learning experience in medical missions for PGY1 residents.

**METHODS:** A medical mission elective learning experience was developed and has been offered to PGY1 residents since program inception. The residents who elected this experience had the opportunity to assist faculty in leading an international medical mission trip. A survey was administered to assess the perception of the residents regarding the services provided during the mission trip and the impact of this learning experience on their professional development. The Fisher's Exact Test was used to test for significant associations between factors of interest.

**RESULTS:** Six out of eight residents pursued an elective in medical missions. Five out of those six residents completed the survey. Eighty percent of the participants were Caucasian and were between 26 and 30 years of age; only one resident was a male. Although all participants reported high levels of satisfaction with their mission experiences, the Fisher's Exact Test yielded no significant associations, suggesting that residents' perceptions were not dependent upon any particular factor. When evaluating the impact of missions experiences, the most common themes that emerged from qualitative analyses were increased faith and spiritual development and improved clinical, precepting, and leadership skills.

**CONCLUSION:** Residents were very satisfied with the services provided during medical missions and found that these experiences had a great impact on their professional and spiritual development. We encourage residency directors and preceptors to incorporate an elective in medical missions into their programs.

**42. Development of criteria for clinical activities for pharmacy practice faculty at annual evaluations.** April N. Smith, Pharm.D., BCPS, Pamela A. Foral, Pharm.D., BCPS, Jon T. Knezevich, Pharm.D., BCPS, Michael S. Monaghan, Pharm.D., BCPS; Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** Standardized criteria for evaluation of clinical services performed by pharmacy practice faculty are not readily available. A substantial percentage of daily activities performed by pharmacy practice faculty revolve around clinical practice. A more objective approach to guide and document clinical impact is necessary. The goal was to design an assessment tool to be

utilized for both self-assessment and by the department chair to evaluate faculty members' performance in clinical practice.

**METHODS:** A literature search was performed via PubMed and International Pharmaceutical Abstracts for clinical activity evaluation forms for pharmacy practice faculty. There were no publications found. Using our School's Rank and Tenure Guidelines for clinical educator faculty as a guide, we developed a rubric and peer evaluation form for faculty performance of various clinical service activities.

**RESULTS:** Clinical service activities were divided into five categories: (i) patient care and intervention, (ii) program development and assessment, (iii) program management, quality assurance, administrative functions, (iv) education, interaction, supervision of other health care professionals, and (v) service as a content expert. A list of example activities was provided within each category. Additionally, an evaluation form to support the faculty member's clinical service performance was developed. The faculty member, in collaboration with the department chair, selected clinical activities for evaluation during the annual performance review (APR). In 2012–2013, the department chair utilized the tools in the APR process to facilitate a more objective assessment of the practice faculty's clinical activities for all faculty with clinical components.

**CONCLUSION:** We developed a rubric and supporting documents to define goals and objectives for faculty in clinical practice to evaluate their clinical service activities performed. The rubric and supporting peer evaluation forms may be incorporated into the faculty member's dossier for consideration of rank and/or tenure. Future research is needed on the impact of these assessment tools.

**43. Improvement in pharmacy students' attitudes toward mental illness as the result of participation in an elective course based on mental illness and treatment in the movies.** *Marshall E. Cates, Pharm.D., BCPP, FASHP<sup>1</sup>, Kristina Mullins, Pharm.D. Candidate<sup>1</sup>, Thomas Woolley, Ph.D.<sup>2</sup>; (1)Samford University McWhorter School of Pharmacy, Birmingham, AL (2)Samford University, Birmingham, AL*

**PURPOSE:** Although some pharmacy schools offer an elective course that is entirely or primarily centered on watching and discussing mental illness-themed movies as the instructional delivery method, the effects of such courses on pharmacy students' mental illness attitudes are unknown. This study examined the effects of a new elective course – Mental Illness and Treatment in the Movies – on the mental illness attitudes of 2nd-year pharmacy students.

**METHODS:** During the course, students watched 10 mental illness-themed movies, and then group presentations and faculty-led discussions centered on the fundamental aspects of the mental illnesses and their treatments as well as the attitudes of main characters/others toward the mental illnesses and their treatments. Various standard mental illness attitude scales concerning dangerousness, social distance, stigmatization, and provision of care were administered to students at the beginning and end of the course. Two-independent samples t-test results were corroborated by Wilcoxon-Mann-Whitney tests.

**RESULTS:** Twenty-seven (100%) students completed both pre- and post-course surveys. Statistically significant improvements in mean scores from pre- to post-course were seen for the following scales: Perceived Dangerousness of Mental Patients Scale (16.42–12.70;  $p=0.002$ ); Social Distance Scale (18.78–16.07;  $p=0.003$ ); Attitudes Toward Provision of Pharmaceutical Services to Consumers With a Mental Illness Scale – Schizophrenia (33.59–37.96;  $p<0.001$ ) and Depression (36.07–39.93;  $p=0.001$ ); and Stigmatization Scale – Schizophrenia (27.63–29.67;  $p=0.01$ ) and Depression (29.44–31.70;  $p=0.008$ ). Pre- to post-course scores on the Index of Attitudes Toward the Mentally Ill Scale improved numerically, but not statistically (39.89–40.96;  $p=0.280$ ).

**CONCLUSION:** An elective course that taught pharmacy students about mental illness and treatment via watching and discussing movies was effective at improving the students' attitudes toward the mentally ill and providing pharmaceutical care to the mentally ill.

**44. Does participation in actual drug testing influence the attitudes of first-year pharmacy students toward mandatory drug testing?.** *Marshall E. Cates, Pharm.D., BCPP, FASHP<sup>1</sup>, Michael Hogue, Pharm.D., FAPhA, FNAP<sup>1</sup>, Thomas Woolley, Ph.D.<sup>2</sup>; (1)Samford University McWhorter School of Pharmacy, Birmingham, AL (2)Samford University, Birmingham, AL*

**PURPOSE:** This study examined the changes in attitudes of first-year pharmacy students toward a mandatory, random urine drug screening program as the result of participation in actual drug testing.

**METHODS:** The study was an anonymous, voluntary survey that was composed of 30 pretested Likert-type questions relating to knowledge, concerns, and beliefs about drug testing. The survey was administered during orientation week (pre-testing) and then again at the end of the academic year after all students had participated in drug testing at least once (post-testing). Two-independent samples t-test results were corroborated by Wilcoxon-Mann-Whitney tests.

**RESULTS:** The survey was completed by 129 (100%) students in the pre-testing phase and 91 (71%) students in the post-testing phase. Of the 30-items, only nine items showed statistically significant changes from pre- to post-testing. Students' responses revealed greater agreement that they had an extensive knowledge about random urine drug screening ( $p=0.03$ ), but greater disagreement that they understood the reasons behind the school's random drug screening program ( $p=0.005$ ). There was greater agreement with various concerns about drug testing, including cost of testing ( $p<0.05$ ), being called for testing when busy with other matters ( $p<0.001$ ), accidentally missing drug testing ( $p<0.001$ ), consequences of missing drug testing ( $p<0.001$ ), and being in situations in which showing up for drug testing would be difficult to impossible ( $p<0.001$ ). Students' responses revealed greater disagreement that drug screening had the potential to decrease illegal substance use among students ( $p=0.05$ ) and that it was important to detect a substance use problem in a pharmacist ( $p=0.03$ ).

**CONCLUSION:** Pharmacy students' attitudes toward drug testing were relatively unaffected by their participation in actual drug testing. Some concerns about drug testing were heightened, probably as the result of how busy the students' lives had become during pharmacy school. However, changes in two of the belief questions were rather disconcerting.

**45. Doctor of Pharmacy students' perception of telemedicine prior to and following completion of a telemedicine course.** *Juliana Chan, Pharm.D., Phuong Dao, Pharm.D. Candidate, Zahra Kassamali, Pharm.D., Melissa E. Badowski, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL*

**PURPOSE:** Telemedicine uses communication technologies to provide clinical services and improve health outcomes by overcoming geographical barriers. While health professional students are familiar with using technology as a means of communication, they may be unfamiliar with the concept of telemedicine. This study surveyed pharmacy students enrolled in a pilot telemedicine course to evaluate students' perspectives regarding telemedicine.

**METHODS:** First, second and third-year pharmacy students in the "Exploration of Telemedicine" course completed an anonymous, 25-question, IRB-approved survey on the first day of instruction to assess their baseline knowledge of telemedicine. At the end of the 15-week course, a similar anonymous survey was completed to determine whether the course influenced the students' perception of telemedicine.

**RESULTS:** Twenty-three students were surveyed on the first day of instruction. No student had prior exposure to a telemedicine environment. Six students withdrew from the course. In the pre-survey, 76% rated their knowledge of telemedicine as weak and 24% rated fair, compared to 71% good and 29% very good in the post-survey. Students' concerns with telemedicine in the pre- and post-survey included privacy (39% versus 30%), security (43% versus 17%), reliability (43% versus 17%), effectiveness (57% versus 4%) and provider accessibility (39% versus 9%). In the pre-survey, 61% felt the quality of medical care via telemedi-



cine was not as good as in-person and 39% reported it was the same as in-person, compared to 13% and 81% in the post-survey, respectively.

**CONCLUSION:** The students transitioned from minimal understanding of telemedicine at the beginning of the course to a greater understanding at course conclusion. The addition of a telemedicine course into the pharmacy curriculum proves beneficial to students. As the use of advanced technology in healthcare becomes more commonplace, early exposure to telemedicine would provide pharmacy students with the skill set necessary to utilize it in practice.

**46. Pharmacy students' competency with medication delivery devices.** *Shandrika Williams, Pharm.D., BCACP, CDE<sup>1</sup>*, Margarita Echeverri, M.Sc., Ph.D.<sup>2</sup>; (1) College of Pharmacy – DCAS, Xavier University of Louisiana College of Pharmacy, New Orleans, LA (2) Xavier University of Louisiana, College of Pharmacy, New Orleans, LA

**PURPOSE:** To assess pharmacy students' knowledge of proper use, and confidence in their ability to counsel patients on the use of five commonly used medication delivery devices (MDDs): metered-dose inhalers (MDIs), dry-powder Diskus<sup>®</sup> inhalers, insulin pen devices, insulin vials with syringes, and nasal sprays.

**METHODS:** Third year pharmacy students enrolled in a pharmacy practice laboratory completed a 15-items pre-post questionnaire to assess the change in their knowledge of the proper use of the MDDs and their confidence in counseling patients on the proper use of these devices. Students received didactic and hands-on training on the proper use of these devices throughout the course. Knowledge was accessed through multiple-choice and case study questions and confidence through self-assessment questions.

**RESULTS:** A total of 124 students completed the pre-post assessments and the training during class. More than 50% of participants had not received previous training on any of the devices. Knowledge scores improved for all devices except MDIs (pre-80% versus post-65.3%) and were higher for insulin pens and insulin vials with syringes (88.7% and 94.4%) and lower for metered-dose and dry-powder Diskus<sup>®</sup> inhalers (65.3% and 62.9%, respectively) at post assessment. Although, confidence levels increased more than 40% for all devices, more than half of students desired to receive additional training.

**CONCLUSION:** Reasons for the discrepancy between knowledge and confidence seen with inhaler devices need to be evaluated as well as strategies for training students on the proper use of these devices. Although overall knowledge and confidence levels were high at post survey, results suggest that training should be introduced early in the program and reinforced throughout the curriculum to increase student knowledge and confidence at graduation.

**47. Decision making style preference among third year pharmacy students.** *Greene Shepherd, Pharm.D., Wendy Cox, Pharm.D., Charlene Williams, Pharm.D., Jacqueline McLaughlin, Ph.D.*; Division of Practice Advancement and Clinical Education, UNC Eshelman School of Pharmacy

**PURPOSE:** Clinical decision making is necessary for success in the practice of pharmacy. While cognitive psychology has extensively explored issues underlying the decision making process, the extent to which pharmacists rely on intuitive and analytical modes of information processing is not known. The purpose of this study was to determine student pharmacists' preferences towards experiential (intuitive) and rational (analytic) thinking.

**METHODS:** The Rational Experiential Inventory (REI), a validated survey tool, was administered electronically to all third year student pharmacists in a public pharmacy school in the southeast. The REI is a 40 question survey with 20 questions assessing engagement and ability on each decision making style. Participants rate their agreement with statements using a 5 point scale (1-definitely false to 5-definitely true). Differences in decision making style based on gender, ethnicity, previous degree, age, PCAT, and undergraduate grade point average (GPA) were examined using t-test or one way ANOVA.

**RESULTS:** The survey response rate was 76% (n=114). Mean (SD) rational scores were higher than experiential scores (3.85 [0.33] versus 3.29 [0.30]). No significant differences in decision making styles were found among students based on gender, ethnicity, or prior degree. Students > 30 years had significantly lower rational scores than younger students (3.62 [0.46] versus 3.91 [0.45]). All correlations between PCAT or GPA and REI scales were weak ( $r_p < 0.30$ ). When compared to mean REI scores from other populations, results were similar to physicians and paramedics but were significantly higher on rational and significantly lower on experiential scores than undergraduates.

**CONCLUSION:** Although the student pharmacists studied use both decision making styles, they typically favor rational over experiential decision making styles, which is similar to other health professions studied. This could have implications for pharmacy education, particularly for assessing clinical decision making.

**48. Pilot of interprofessional education using high-fidelity simulation.** *Frank M. Szczerba, Pharm.D.<sup>1</sup>, Michael J. Peeters, Pharm.D., MEd., BCPS<sup>2</sup>*, Paul Rega, M.D., FACEP<sup>3</sup>; (1) University of Toledo Medical Center, Toledo, OH (2) University of Toledo College of Pharmacy, Toledo, OH (3) University of Toledo College of Medicine, Toledo, OH

**PURPOSE:** Our objectives were to (i) examine if multiple high-fidelity simulation scenarios affect development of students' perceptions of interprofessional education, and (ii) evaluate development of interprofessional students' teamwork skills.

**METHODS:** Students from multiple health profession programs (medicine, pharmacy, nursing, physician assistants and public health) participated in sequential weekly educational simulation sessions while on their emergency medicine rotations. Prior to each session, students' perceptions of interprofessional education were assessed with the Readiness for Interprofessional Learning Scale (RIPLS). Students' teamwork within interprofessional teams was scored for all scenarios in every session using the Team-STEPPS' Team Performance Observation Tool (TPOT). Multiple linear regression of change scores from first to last RIPLS was used. During our limited data collection period of 5 months, we could only use descriptive statistics for our TPOT data. Cronbach's alpha was used for internal consistency of both instruments.

**RESULTS:** Twenty-five students were included. The mean change for RIPLS was  $0.2 \pm 1.9$  ( $p=0.275$ , Wilcoxon-signed-rank). After controlling for confounding from among professional programs, a multiple linear regression showed that both student ( $p=0.031$ ) and program ( $p=0.015$ ) affected students' change in perception of interprofessional readiness. Over 5 months, the median change in TPOT between initial and final sessions was  $0.7 \pm 2.1$ . Sound internal consistency was found using both instruments in our sample; Cronbach's alpha for RIPLS was 0.865 and for TPOT it was 0.898.

**CONCLUSION:** Based on our results, students perceived benefit with interprofessional education using these high-fidelity simulations. However, controlling for confounding from professional programs was needed to show this positive result. Faculty within our healthcare professional programs may need more encouragement to continue highlighting the importance of interprofessional teamwork. We had difficulty using the TPOT in our simulation education context, and an alternative instrument maybe better suit our needs. Continued study of students' behaviors with interprofessional simulation in healthcare education seems warranted.

**49. Evaluation of the ambulatory care practice and research network mentoring program.** *Kelly A. Lempicki, Pharm.D., BCPS<sup>1</sup>*, Melody L. Hartzler, Pharm.D., AE-C<sup>2</sup>, Marissa C. Salvo, Pharm.D.<sup>3</sup>; (1) Department of Pharmacy Practice, Midwestern University Chicago College of Pharmacy, Downers Grove, IL (2) Cedarville University School of Pharmacy, Cedarville, OH (3) University of Connecticut – School of Pharmacy, Storrs, CT

**PURPOSE:** For several years, the American College of Clinical Pharmacy (ACCP) Ambulatory Care Practice and Research

Network (PRN) has sought to increase pharmacy student and resident/fellow involvement in the organization. A mentoring program within the PRN was established in Fall 2012 to help achieve this goal.

**METHODS:** Twenty-five mentor groups were established, consisting of a student/resident/fellow, a new practitioner ( $\leq 5$  years in practice), and an experienced practitioner. In October 2012, an electronic pre-survey was distributed to participants to assess anticipated benefits from the program. Throughout the year, participants were encouraged to engage with their mentor groups and e-mails were sent with topic discussion prompts. Participants completed a post-survey in May 2013 to assess the program's benefits.

**RESULTS:** Forty-seven individuals (28 mentors, 19 mentees) completed the initial survey and 35 individuals (20 mentors, 15 mentees) completed the post-survey. The top benefits anticipated by mentors from participating in the program (in order) were: sharing knowledge and experience ( $n=25$ ), satisfaction of helping a trainee reach his/her professional goals ( $n=23$ ), and expanded network of professional colleagues ( $n=19$ ). After participation in the program, the same areas remained as the top-ranked benefits received by mentors. The top benefits mentees anticipated from participating in the program (in order) were: networking opportunities ( $n=19$ ), exposure to diverse perspectives and experiences ( $n=15$ ), and career development/advancement ( $n=13$ ). Again, the same areas remained the top-ranked benefits received by mentees after participation in the program. Respondents also felt that ACCP benefitted from the mentoring program through an improved environment that fosters personal and professional growth and an enriched learning culture.

**CONCLUSION:** After a successful inaugural year, the PRN will utilize participant feedback to enhance the program as it continues to expand student and resident/fellow involvement.

**50. Evaluation of the impact of instruction and feedback on reflective responses completed by 4th year pharmacy students on their ambulatory care advanced pharmacy practice experience.** *Robyn Teply, Pharm.D., Mikayla Spangler, Pharm.D., Laura Klug, Pharm.D., Jennifer Tilleman, Pharm.D., Kelli Coover, Pharm.D.;* Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** A key element in developing as a healthcare professional is the ability to be a reflective practitioner. One area of study that still needs investigation is whether instruction and feedback on how to be a more reflective practitioner are beneficial in increasing the level of pharmacy students' reflection on their clinical rotations.

**METHODS:** Students on three separate ambulatory care rotations were randomly assigned to either an intervention or control group. Both groups answered weekly reflection questions during the rotation. The intervention group received an orientation on methods to become more reflective and weekly feedback from faculty preceptors on their reflections while the control group received neither. Answers to the final week reflection question were de-identified and two faculty members independently categorized the level of reflection from 1 to 6 as defined in previous literature (1-3 = non-reflective and 4-6 = reflective). The primary outcome measure was comparing the number of reflective responses in each group. Possible confounding variables were also collected and analyzed.

**RESULTS:** A total of 34 students were included in the study, 16 in the control group and 18 in the intervention group. A Chi-square test was completed and 83.3% of students in the intervention group had reflection responses deemed reflective by blinded faculty members as compared to only 37.5% of the control group ( $p=0.006$ ). A logistic regression analysis showed the odds that the fourth week answer would be categorized as reflective are 8.3 times higher in the intervention group than that in control group ( $p=0.009$ ). Other demographic information collected did not show any significant differences between groups.

**CONCLUSION:** In this pilot study, providing instruction and feedback to students during their clinical rotations improved the

likelihood that their work was determined to be reflective. These instructional practices should be considered when looking to develop students into reflective practitioners.

**51. Describing pharmacy residents' cognitive abilities.** *Michael J. Peeters, Pharm.D., MEd., BCPS, Julie A. Murphy, Pharm.D., BCPS, FASHP, FCCP;* University of Toledo College of Pharmacy, Toledo, OH

**PURPOSE:** Professionalism and critical thinking are integral to clinical pharmacy practice. The Defining Issues Test-2 (DIT-2) assesses professionalism and moral-reasoning skills, while the Health Sciences Reasoning Test (HSRT) assesses critical thinking. Use of these assessments among pharmacy practice residents has not yet been described, though both assessments have been used broadly among students from various health professions including medicine, pharmacy, nursing, and dentistry. The objective of this pilot investigation was to describe cognitive abilities of pharmacy residents.

**METHODS:** This IRB-approved pilot project was a descriptive study. Both PGY-1 and PGY-2 pharmacy residents at the University of Toledo Medical Center completed the DIT-2 and the HSRT; each assessment administered at a different time, and both during the 11th month of the program year. Demographic data including age, gender, and prior education history, were also collected.

**RESULTS:** Seven residents participated in this pilot. The median age of participants was 25 years (range: 24-27). Among residents, five (71%) were female and two (29%) were male; five (71%) obtained their PharmD from a private institution and two (29%) from a public institution. On the DIT-2, the median p-score was 44 (interquartile range [IQR]: 33) and n2-score of 45 (IQR: 28). Cronbach's alpha was 0.677 (p-score) and 0.776 (n2-score). On the HSRT, the median was 24 (IQR: 5.8) with corresponding median percentile of 82 (IQR: 34) from all HSRT participants in the testing company's current database.

**CONCLUSION:** While a small cohort, this pilot study is a start to research at describing residents' cognitive abilities. In many residency programs, residents engage in various activities over the course of a residency year (clinical rotations, staffing responsibilities, research project completion, teaching certificate program, etc.); but do these activities help develop residents' cognitive abilities? Future research could delve into this, though description, as here, is a first step.

**52E. Pediatric education diagnosis survey (PEDS): analyzing pediatric education within PharmD programs in the United States.** *Phillip Weddle, Pharm.D., Terri Warholak, Ph.D., Hanna Phan, Pharm.D.;* Department of Pharmacy Practice and Science, College of Pharmacy, University of Arizona, Tucson, AZ

**PURPOSE:** Pediatric-specific education within Doctorate of Pharmacy (PharmD) programs in the United States (US) has previously been described as limited with need for additional consideration in curriculum development. The purpose of this study was to describe current trends in pediatric pharmacy education provided in ACPE-accredited PharmD programs throughout the US.

**METHODS:** This study involved a cross-sectional, descriptive survey of pediatric faculty (adjunct and appointed). The questionnaire was sent electronically to members of the American College of Clinical Pharmacy (ACCP) Pediatric Practice and Research Network (PRN). Data collection included topics and time spent on pediatric didactic and experiential education as well as demographics. Responses were limited to one per institution to prevent duplication of data and grouped based institution type (state-funded versus private) and geographic location for analyses. Chi-square tests were used to compare rotation types and the percentage of students participating in pediatric Advance Pharmacy Practice Experiences (APPEs). Student t-tests and analysis of variance were performed to analyze the number of hours spent on pediatric education.

**RESULTS:** Questionnaires were completed by 36 of 124 schools or colleges of pharmacy. Time spent on pediatric didactic educa-

tion was  $16.3 \pm 19.2$  hours. Extent of pediatric didactic education was similar based on institution type ( $p=0.24$ ) as well as geographic location ( $p=0.74$ ). The percentages of students participating in pediatric APPEs were similar based on institution type ( $p=0.64$ ). There was a significant difference in percentage of students participating in pediatric APPEs ( $p<0.001$ ) geographically, with the majority in the Northeast and Midwest regions.

**CONCLUSION:** Pediatric didactic and experiential education appears to be consistent between state and privately-funded institutions as well as between geographic regions with the exception of a higher percentage of students participating in pediatric APPE. Additional assessment of a larger sample of schools should be considered for future study with findings applied to future curriculum development. Presented at Pediatric Pharmacy Advocacy Group Annual Meeting, Indianapolis, IN, May 1–5, 2013.

**53. Evaluation of focused teaching during advanced pharmacy practice experiences.** Andrew J. Crannage, Pharm.D., BCPS<sup>1</sup>, Jamie M. Pitlick, Pharm.D., BCPS<sup>1</sup>, Amy M. Drew, Pharm.D., BCPS<sup>1</sup>, Lindsay M. Rippelmeyer, Pharm.D.<sup>1</sup>, Julie A. Murphy, Pharm.D., BCPS, FASHP, FCCP<sup>2</sup>; (1) St. Louis College of Pharmacy, St. Louis, MO (2) University of Toledo College of Pharmacy, Toledo, OH

**PURPOSE:** A method of estimating student knowledge, learning, and experience gained during an Advanced Pharmacy Practice Experience (APPE) is to administer a rotation assessment before and after the completion of the rotation. Performance on the pre-rotation assessment could be reviewed at the start of the rotation with areas for improvement identified and addressed using various focused teaching (FT) sessions during the rotation. The objective of this study was to determine the impact of FT sessions during a 5-week APPE on student knowledge.

**METHODS:** Students completing a 5-week ambulatory care or acute care APPE with one of the study investigators from January 2011 to December 2012 were included. Students were randomized to receive either usual teaching (UT) or FT. All students completed a pre-rotation and post-rotation assessment. The absolute difference between mean change in pre- and post-rotation assessment scores between the groups was evaluated. The t-test and ANOVA were used for statistical analyses.

**RESULTS:** Thirty-four students were included in the UT arm and 44 students were included in the FT arm. Overall, the mean pre-rotation assessment score was 42/75 (56%) and mean post-rotation assessment score was 46/75 (61%) ( $p \leq 0.001$ ). The absolute mean change in assessment score was  $4.03 + 6.30$  and  $4.84 + 6.65$  ( $p=0.586$ ) for the UT and FT groups, respectively. In subgroup analyses, there was no difference in student performance across different academic years ( $p=0.259$ ) or when comparing different semesters of the academic year ( $p=0.074$ ).

**CONCLUSION:** During a 5-week APPE, FT had a similar influence on student knowledge as UT. Placing additional focus on certain areas may distract from the general experience of an ambulatory care or acute care rotation, resulting in no difference between the methods. Evaluating scores on pre- and post-rotation assessments may not be able to capture all student factors of learning or account for external influences on student performance.

**54. American college of clinical pharmacy student Chapters survey 2013 update.** Andrew Smith, Pharm.D., BCPS (AQ-CV)<sup>1</sup>, Sandra Benavides, Pharm.D.<sup>2</sup>, Laura Tsu, Pharm.D., BCPS<sup>3</sup>, Nancy Yunker, Pharm.D., BCPS<sup>4</sup>; (1) UMKC School of Pharmacy, Kansas City, MO (2) Nova Southeastern University, College of Pharmacy, Davie, FL (3) Midwestern University – College of Pharmacy Glendale, Glendale, AZ (4) Virginia Commonwealth University School of Pharmacy, Richmond, VA

**PURPOSE:** Student chapters of ACCP have formed at schools or colleges of pharmacy to allow students increased opportunities to work towards the mission of ACCP on their campus. A previous survey demonstrated that approximately one-third of institu-

tions had an ‘informal’ chapter. The executive board recently voted to formally recognize student chapters. This survey study was performed to describe the current state of ‘informal’ ACCP chapters at schools or colleges of pharmacy, assess barriers and identify desired support from the national organization.

**METHODS:** A 40 question survey was designed to assess demographic information about the respondents’ college of pharmacy and to describe the presence, structure, and function of ‘informal’ chapters of ACCP. The survey was distributed electronically to College of Pharmacy Liaisons. The primary outcome is to determine the prevalence of ‘informal’ student chapters. Secondary outcomes include description of the structure and function of ‘informal’ chapters, barriers to formation, and support desired from ACCP.

**RESULTS:** Preliminary results revealed 50% of the respondents have an informal student chapter, of which most (78%) are independent of other student organizations. Stated barriers to the formation of such chapters included too many student organizations on campus (88%), no direct connection to national organization (63%), or lack of funding (25%) and time (25%) for starting an organization. Membership dues vary from none (40%), to more than \$20 (6%) to required membership in national organization (39%). Chapters are active in educational programming, service projects, research projects, and various lunch and learn activities. Respondents stated that ACCP resources helping in establishing a student chapter would include information and resources for chapter initiation (87%), ACCP activities (77%), and financial support (74%).

**CONCLUSION:** Formal recognition of student chapters by ACCP will likely assist current and future student chapters in establishing consistent membership dues, bylaws, and activities.

**55E. Incorporating multiple mini interviews in a post-graduate year one pharmacy residency program selection process.** Douglas Oyler, Pharm.D.; Department of Pharmacy, University of Kentucky, Lexington

**PURPOSE:** The use of multiple mini interviews (MMI) is emerging as a tool to assess affective domain skills and emotional intelligence of applicants to health professional degree and postgraduate training programs. MMI use has not been evaluated in the pharmacy residency setting, but has the potential to be a valuable mechanism to assess applicant suitability. This study was designed to assess the feasibility and acceptance of MMI as part of a PGY1 pharmacy residency interview. Secondly this study aimed to assess the contribution of MMI to the traditional interview process.

**METHODS:** Four MMI stations evaluating the highest-rated nonacademic attributes of prospective residents were incorporated into the traditional post-graduate year one (PGY1) residency interview process at an academic medical center. Upon completion of the interview, candidates and interviewers were each surveyed regarding their perceptions of the refined interview process. Data regarding scores on various components of the applicant profile were also compared for correlations.

**RESULTS:** Thirty-seven of the 38 candidates who participated in MMI responded to the follow-up survey. Overall candidates felt the MMI was effective (median response = 3, IQR 2–3 on a 4-point scale) and its use would not deter them from applying to a program (median response = 1, IQR 1–2). All of the 15 interviewers responded and felt the MMI provided valuable information (median response = 3, IQR 2.5–3) and was not subject to rehearsed responses to standard interview questions (median response = 2, IQR 1–2). These responses did not differ between residents and preceptors. MMI appeared to assess different attributes than other components of the candidate profile.

**CONCLUSION:** The use of MMI in a PGY1 pharmacy practice residency was well-received based on candidate and interviewer survey response. MMI likely assesses different attributes than traditional PGY1 interviews.

Presented at Presented at the Great Lakes Pharmacy Residency Conference, West Lafayette, IN, May 24–26, 2013.



**56. Simulation training improves pharmacists' competency in advanced cardiac life support response.** Elizabeth VanWert, Pharm.D., Rose Sohraby, Pharm.D., Julie A. McIndoo, Pharm.D., Stephanie Younts, Pharm.D., BCPS, Conrado Gamboa, BS, Darrel W. Hughes, Pharm.D., BCPS; Department of Pharmacy Services, University Health System, San Antonio, TX

**PURPOSE:** Sudden cardiovascular death is a significant cause of mortality for patients in acute care hospitals. Participation of a pharmacist during cardio-pulmonary arrest events has been associated with an increased likelihood of survival and compliance with Advanced Cardiac Life Support (ACLS) guidelines. Despite the purported benefit, many hospitals do not routinely involve pharmacists in cardio-pulmonary arrest response due to concerns for inadequate preparation. We sought to demonstrate an improvement in pharmacists' ability to achieve ACLS-related objectives through use of simulation with didactic training.

**METHODS:** Pharmacists completed a 2 hours ACLS training program. Hour one included a didactic review of ACLS goals, ACLS medication pharmacology, the ACLS algorithms, and cardio-pulmonary arrest event policies and procedures. Hour 2 consisted of hands-on, case-based simulation using a manikin-based patient simulator. Competency was assessed using a 4-point Likert scale self-survey to assess pharmacists' ability to achieve objectives related to pharmacists' involvement in ACLS. Anonymous, self-assessment ratings were completed before and after didactic and simulation based training. Pre- and post-training scores were compared.

**RESULTS:** Thirty three hospital pharmacists participated in the simulation training. Pharmacists had been in practice for an average of 15 years. Pharmacists were Doctor of Pharmacy, ACLS-certified, residency trained, and board certified in pharmacotherapy 66%, 49%, 42%, and 27%, respectively. Pre- and post-course self assessment scores are presented in Table 1.

Table 1. Pre- and post-course self assessment scores

Learning objective	Pre-course Score	Post-course Score	p-value
Define pharmacologic goals of ACLS	2.3	3.6	p<0.001
Identify the role of pharmacist on code blue resuscitation teams	2.6	3.8	p<0.001
Recommend medications used in cardiopulmonary arrest events	2.2	3.6	p<0.001
Utilize critical thinking skills to apply knowledge in simulated code blue scenarios	2.2	3.6	p<0.001

**CONCLUSION:** ACLS simulation training improved hospital pharmacists' anonymous, self-assessment ratings regarding their ability to achieve objectives related to pharmacist involvement in ACLS.

**57. Implementation and measurement of an activity to foster a sense of community among pharmacy students at distance locations.**

Kelly Cochran, Pharm.D., BCPS<sup>1</sup>, Erica Ottis, Pharm.D., BCPS<sup>1</sup>, Daniel Aistrope, Pharm.D.<sup>1</sup>, Linda Garavalia, Ph.D.<sup>2</sup>, Maqual Graham, Pharm.D.<sup>2</sup>; (1) Division of Pharmacy Practice & Administration, University of Missouri-Kansas City School of Pharmacy at MU, Columbia, MO (2) Division of Pharmacy Practice & Administration, University of Missouri-Kansas City School of Pharmacy, Kansas City, MO

**PURPOSE:** ACPE standards encourage the implementation of activities which foster a sense of community among pharmacy students at various campus locations. No literature exists identifying or measuring activities to foster a sense of community across locations. This research seeks to determine factors which contribute to the development of a sense of community among learners from distance locations and identify appropriate measurement of these factors.

**METHODS:** The Classroom and School Community Inventory (CSCI) was adapted to a 26 item Likert scale tool and administered to 128 P-3 students prior to and following the sense of com-

munity activities which included: fun fact team finder exercise, team-based scavenger hunt, group luncheon, reflective writing exercise, and a didactic session from a distance location, all occurring in concert with an Objective Structured Clinical Exam at the distance location. A paired t-test was performed to analyze change in sense of community.

**RESULTS:** CSCI pre and post-surveys were completed by 90.6% of students. Responses to "feeling connected to other students in this course" resulted in a significant increase in mean score from 2.89 pre to 3.02 post, SD 0.65, p=0.035 and "I regularly talk to faculty/staff in this program about personal matters" increased mean score from 1.2 pre to 1.65 post, SD 0.99, p=0.0001. Most other items resulted in increased mean sense of community scores from pre to post-activity, although they were not statistically significant.

**CONCLUSION:** Significant improvement in a sense of community occurred in the areas of connectedness among students and perceived approachability of faculty/staff to discuss personal matters. The sense of community activities employed resulted in modest improvement in feelings of mattering, trust, shared values, reliance and support. Future activities should be focused on enhancing these factors which foster a sense of community and should continue to be measured throughout pharmacy curricula.

**58. On-line versus live lecture in an evidence-based medicine course: effectiveness and student perception.** Jennifer Phillips, Pharm.D., BCPS, Sean Mirk, Pharm.D., Huzefa Master, Pharm.D., BCPS;

Department of Pharmacy Practice, Midwestern University Chicago College of Pharmacy, Downers Grove, IL

**PURPOSE:** To compare the effectiveness of an interactive on-line lecture (OL) to a live lecture (LL) on short- and long-term learning and to evaluate student perceptions towards OL in a required first-year, evidence-based medicine course.

**METHODS:** All students (n=208) enrolled in the course were eligible to participate. Students who provided informed consent in this IRB-approved study were randomized to either the OL or the LL group. The lecture topic was the same. The OL was created using Storyline (Articulate Global, Inc; New York, NY). Effectiveness was determined by analyzing scores on a post-lecture quiz and final exam questions. Student perceptions were assessed via survey.

**RESULTS:** A total of 177 students (85%) agreed to participate in the study and completed the assessments; 164 (79%) completed the survey. Students in the OL group scored higher than students in the LL group on the post-lecture quiz (55% versus 48%, p=0.039); scores on the final exam questions were similar (87% versus 84%, p=0.40). Regardless of the lecture format, there was no difference in the students' perceptions of how each format stimulated their interest, enhanced their understanding of the material, provided opportunities for feedback, or matched their learning style. More students in the OL group felt there were advantages to an OL format (90% v. 66%, respectively, p=0.02). There was no difference in preference for how an OL should be utilized - 94% versus 86% of students felt an OL should be used to supplement a LL and 58% versus 56% felt an OL should not replace a LL (OL versus LL format, respectively).

**CONCLUSION:** An OL appears to be more effective than a LL in facilitating short-term learning and has similar effects on long-term learning. Overall, students have positive perceptions toward an OL, but students who viewed the OL were more likely to feel that this format offers advantages.

**59. Clinical pharmacotherapy notes: assessment of students' perceptions and performance.** 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 assess students' perceptions of confidence and performance on clinical pharmacotherapy notes in a therapeutics course when utilizing a structured approach to documentation, specifically the Subjective Objective Assessment Plan Education (SOAPE) note format.

**METHODS:** Five weekly patient-case discussion sessions were incorporated into a cardiovascular therapeutics course for second-year pharmacy students, for three consecutive years. Students came prepared each week for small-group discussions on a patient case they completed ahead of time, utilizing the SOAPE note format. Students then worked-up a second in-class patient case and submitted a SOAPE note for a grade. A pre-test and post-test assessing students' perceptions 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. The Institutional Review Board approved data collection for this study and students voluntarily signed informed consent prior to participation. Scores on the pre-test and post-test were compared utilizing descriptive statistics and student's t-tests.

**RESULTS:** A total of 373 (88.4%) students completed both the pre-test and post-test. There was significant improvement in students' perception of confidence in writing SOAPE notes by the end of the course, with a mean (SD) score of 2.62 (0.49) on the pre-test and 3.58 (0.36) on the post-test ( $p < 0.001$ ). Students' mean (SD) performance on the knowledge section of the pre- and post-tests were 85.2% (19.3) and 99.0% (4.6), respectively ( $p < 0.001$ ). Students with prior experience writing SOAPE notes had higher confidence scores on the pre-test compared to those without experience, however on the post-test, there was no significant difference between both groups in either confidence or knowledge scores.

**CONCLUSION:** A structured approach to clinical pharmacotherapy notes may improve students' knowledge and confidence to perform this vital documentation skill on experiential patient care rotations and in clinical practice.

**60. Student pharmacists' self-assessment of their communication skills with healthcare providers.** Lisa M. Lundquist, Pharm.D., BCPS, Angela O. Shogbon, Pharm.D., BCPS, Kathryn M. Momy, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

**PURPOSE:** To evaluate student pharmacists' self-assessment of communication skills with healthcare providers (HCP) during therapeutics oral examinations.

**METHODS:** For four 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 with HCP using an 8-item rubric assessing rapport (confidence, non-verbal) and presentation of therapeutic recommendations. 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 544 (97%) 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 3.46 (0.44), respectively. For the group oral examination, mean (SD) student self-assessment and faculty's evaluation of communication were 3.36 (0.47) and 3.54 (0.34). Student pharmacists' self-assessment of their communication skills with HCP were statistically significantly lower than the faculty evaluations in both the individual and group oral examinations ( $p < 0.001$ ). Students' self-assessment of communication skills however increased from the individual to the group examination ( $p < 0.001$ ).

**CONCLUSION:** Student pharmacists' self-assessment of communication skills with HCP was consistently lower than the faculty's

evaluation scores. Students' lower self-assessment may be due to a lack of practice in verbal communication with HCP. Increased utilization of oral examinations may help to prepare students for communication with HCP to facilitate the effective delivery of patient care and improve self-assessment of communication skills.

**61. Pharmacy student participation in an interprofessional medical relief trip as members of a joint student organization.** Jordan Masse, Pharm.D. Candidate<sup>1</sup>, Sabrina Grandi, Pharm.D. Candidate<sup>1</sup>, Chih Chuang, M.D.<sup>2</sup>, Helen Berlie, Pharm.D., CDE<sup>1</sup>; (1) Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI (2) School of Medicine, Wayne State University, Detroit, MI

**PURPOSE:** Analyze learning activities and pharmacy student perspectives of participation in an interprofessional medical relief student organization during separate week-long medical relief trips to Haiti and Nicaragua.

**METHODS:** A medical school relief organization was expanded to include a sister organization at the pharmacy school. Pharmacy student activities included pre-trip preparation and patient care while in country. The number of patients seen and medications dispensed were recorded daily. Student perceptions were assessed using an anonymous and voluntary, post-trip 40-question survey (29 likert-scale and 11 open-ended questions).

**RESULTS:** Nine pharmacy students, one pharmacist, 33 medical students and four physicians participated in these trips. For the 1089 patients seen, 3128 prescriptions were dispensed. Pharmacy students assisted in triage, made recommendations, and participated in dispensing and patient counseling. Seven of nine (78%) pharmacy students completed the survey. All agreed that pharmacy services were beneficial and reported positive overall satisfaction with team and pharmacy services. All students agreed that their individual involvement was helpful and that the organization of the medications by the pharmacy team enhanced the workflow process. The reported level of confidence with regards to making recommendations varied among the students. Four students reported feeling confident with dosing, three with therapeutic, and two with substitution recommendations. Students with more years of education generally expressed more confidence. Results from open-ended questions revealed that students felt they would have benefited from pharmacy focused education prior to the trips. Additionally, they felt that participating in teamwork was their greatest contribution. Students all agreed that interprofessional care is needed to maximize patient care and that they see themselves practicing within an interprofessional team in the future.

**CONCLUSION:** Pharmacy students participated in many interprofessional activities and perceived a significant benefit from their involvement. Ongoing program evaluation will lead to continued improvements in the interprofessional student organization.

**62. Pharmacy student perceptions and performance after using a reverse classroom instructional strategy in an ambulatory care elective.** Stacey Thacker, Pharm.D., BCPS, Jennifer L. Rosselli, Pharm.D.; Southern Illinois University Edwardsville School of Pharmacy, Edwardsville, IL

**PURPOSE:** To assess pharmacy student performance and perceptions in an ambulatory care elective course after implementation of a reverse classroom instructional method.

**METHODS:** A 2 hours elective course offered to pharmacy students in their third professional year was redesigned using the reverse classroom model, also known as "flipped classroom". Students were provided focused study objectives, supplemental readings, and voice-narrated or note-supplemented PowerPoint slides to review prior to each class. Class time was devoted to case-based learning, application, presentation, and discussion. A 25-question no-stakes multiple choice exam encompassing topics covered throughout the semester was administered the first and last day of the course. Student opinions of the course strengths and limitations were collected using group instructional feedback

technique (GIFT). Student feedback and scores from exams and case presentations were compared to the previous year of traditional classroom teaching. A survey was completed by students to assess their perceptions of the reverse classroom method.

**RESULTS:** Student performance on the exam remained unchanged. Mean case presentation scores in the “flipped classroom” were 6% higher compared to scores in the traditional classroom. Students in the traditional classroom struggled with the time limits of completing in-class activities and strongly suggested expanding to a 3 hours course. To make up for the time constraints, revisions to in-class activities were allowed for grade improvement. In the “flipped classroom”, students felt comfortable with how class time was utilized, did not require assignment revisions, and 100% indicated they would recommend the course to future students. Students suggested utilizing the reverse classroom teaching style in small classes that build upon previously taught concepts.

**CONCLUSION:** Reverse classroom was an effective teaching method in an ambulatory care elective course. This type of instructional strategy allows for the delivery of higher order learning activities, such as case-based application and discussion, during class.

### 63. Evaluation of scholarship and research among full-time pharmacy practice faculty members serving as pharmacy residency preceptors.

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**PURPOSE:** Determine and compare scholarship of non-tenure track full-time faculty who serve as residency preceptors. Scholarship was defined as any peer-reviewed publication including journal articles, poster presentations, and/or platform presentations.

**METHODS:** A survey was developed and emailed to full-time practice faculty at all schools/colleges of pharmacy in the United States. The survey consisted of 14 items for participants who identified themselves as having no involvement in pharmacy resident training, and 18 items for residency preceptors.

**RESULTS:** A total of 348 responses from non-tenure track faculty were analyzed (preceptors n=241; non-preceptors n=107). More preceptors were employed at public schools/colleges (62%, n=149) than non-preceptors (43.5%, n=47). Ninety one percent of respondents were ranked as assistant (n=224) or associate (n=93) professors. Approximately 77.8% (n=271) of respondents indicated that 1–2 publications per year were required according to school/college promotion and tenure guidelines. The median number of publications for preceptors and non-preceptors, respectively, was as follows: posters per year were 1 (IQR 0.5–2) and 1.16 (IQR 0.33–2) (p=0.816); presentations per year were 0.33 (IQR 0–1.5) and 0.5 (IQR 0–1) (p=0.844); journal articles per year were 0.82 (IQR 0–1.66) and 0.67 (IQR 0.13–1.58) (p=0.696). When preceptors were asked to indicate whether involvement in residency projects increased scholarly activity, 64.3% (n=155) ‘agreed’ or ‘strongly agreed’.

**CONCLUSION:** There was no statistical difference between number of posters, presentations, or journal articles published when non-tenure track preceptors were compared to non-preceptors. Especially with regard to posters, this was an unexpected finding since a common role of preceptors is to serve as project mentors for residency projects, which are often presented as posters. Although there was no statistical difference in number of publications, most preceptors indicated that involvement in residency projects increased scholarly activity.

### 64. Student pharmacists' reflections on the challenges of communicating medication therapy recommendations to physicians.

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Pharmacy Practice, Albany College of Pharmacy and Health Sciences, Albany, NY

**PURPOSE:** Many student pharmacists find it challenging to effectively communicate their medication therapy recommendations to physicians. This paper seeks to examine the professional socialization and role delineation of student pharmacists on advanced pharmacy practice experiences (APPEs).

**METHODS:** This paper applies theoretical and conceptual tools from the social scientific discipline of Communication. In-depth ethnographic interviews are conducted with 14 pharmacy preceptors and 26 pharmacy students completing APPEs. All participants are associated with a single, fully accredited, college of pharmacy in the northeastern United States. The mean length of interviews is 93 minutes, yielding approximately 1400 pages of transcribed text. These data are analyzed inductively, using qualitative methodology. This includes repeated exposure to recordings and transcripts, software-assisted topical analysis, thematic analysis of topical collections, and close attention to participants' language choices, narratives, opinions, premises, and reasoning.

**RESULTS:** When pharmacists interact with physicians, they balance a dialectic tension between assertiveness (proactively demonstrating the value of a pharmacist to the team) and deference (respecting the physician's role as the team leader and final decision maker). Student pharmacists experience two types of role ambiguity (“student versus professional” and “drug information resource versus clinical collaborator”). There are important differences between medication therapy recommendations that are initiated by the physician and those that are initiated by the pharmacist. Specific communication challenges, as well as strategies for addressing them, are described for each type.

**CONCLUSIONS:** Pharmacy preceptors can enhance the experiential education of student pharmacists by encouraging them to reflect on the proper balance between assertiveness and deference, by clarifying role ambiguities, and by explicitly teaching communication strategies to navigate both physician-initiated and pharmacist-initiated recommendations.

## Emergency Medicine

### 65E. Propofol versus benzodiazepine infusion for alcohol withdrawal requiring mechanical ventilation: a retrospective chart review.

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**PURPOSE:** When chronic, excessive alcohol intake is abruptly halted, patients are at risk for developing life-threatening alcohol withdrawal syndrome (AWS). Benzodiazepines have established efficacy, yet some patients' symptoms persist despite treatment with high doses of benzodiazepines. The study objective was to compare time to resolution of AWS symptoms in mechanically-ventilated patients receiving propofol versus benzodiazepine infusion. We predict that propofol-treated patients will experience significantly less time to resolution of AWS symptoms compared to patients receiving benzodiazepine monotherapy.

**METHODS:** This retrospective cohort study was performed at one tertiary-care academic medical institution. Data were analyzed from patients admitted between January 1, 2006 and December 31, 2011 meeting criteria for AWS and requiring mechanical ventilation due to symptoms of AWS.

**RESULTS:** Sixteen-hundred and thirty-seven records were reviewed and 64 were included. Patients were predominately male (97%) with a mean age of 45 years. Lorazepam-equivalent benzodiazepine doses given prior to intubation were greater in patients receiving propofol infusion (56 versus 15 mg, p=0.03). Propofol-containing regimens were used in 46 cases (72%), while benzodiazepine infusion monotherapy accounted for 18 cases (28%). Time to resolution of AWS symptoms for propofol- and benzodiazepine-treated patients was 8 and 7 days, respectively (p=0.34). Median hospital and ICU lengths of stay were similar (9 versus 10 days and 4 versus 4 days, respectively; p>0.05 for both com-



parisons), as were days of mechanical ventilation (4 versus 3 days,  $p=0.98$ ). Patients in the benzodiazepine infusion monotherapy group required increased amounts of benzodiazepine bolus doses while on continuous sedation, compared to patients receiving propofol infusion (36 versus 10 mg,  $p=0.06$ ).

**CONCLUSION:** Propofol-treated patients with AWS requiring mechanical ventilation experienced similar days of AWS symptoms, length of stay, and mechanical ventilation. Patients in the benzodiazepine monotherapy group required increased amounts of benzodiazepine bolus doses while on continuous sedation.

Presented at 42nd Critical Care Congress, Society of Critical Care Medicine, San Juan, Puerto Rico, January 2013.

**66. Is low dose 3-factor PCC effective for warfarin reversal?** Jennifer Mai, Pharm.D., BCPS, Harminder Sikand, Pharm.D., FCSHP, FASHP, Scripps Mercy Hospital, San Diego, CA

**PURPOSE:** Four factor Prothrombin Complex Concentrate (PCC) is currently recommended by the American College of Chest Physicians for emergent reversal of warfarin-induced life-threatening bleeding. This study evaluated if 3-factor PCC was effective for warfarin reversal at lower doses (30 units/kg instead of 50 units/kg) when given together with vitamin K with or without fresh frozen plasma (FFP).

**METHODS:** In July 2011, a treatment protocol for reversal of warfarin anticoagulation was implemented for life-threatening bleeding using Profilnine<sup>®</sup>, a 3-factor PCC. All patients were given PCC 30 units/kg intravenously, with a repeat dose of 12.5 units/kg if patients were inadequately reversed (international normalized ratio (INR) < 1.5). Demographic data, baseline and post INR, time to initial INR, time to INR < 1.5, concomitant use of FFP and vitamin K, and adverse event rate was evaluated.

**RESULTS:** Thirty-two study patients were included for analysis and the indications included: major emergent bleeding ( $n=9$ ), intracranial hemorrhage ( $n=14$ ), and emergent surgery ( $n=9$ ). The median age was 78. The mean initial INR was 5.0 (+ 4.6, Range 1.6–20) and post-treatment INR was 1.69 (+ 0.57, Range 1.1–3.6). The median time from administration of PCC to post-treatment INR was 1.23 hours. The median time to INR < 1.5 was 4.5 hours. 70.9 percent of patients received FFP and 94% received Vitamin K. The median number of units of FFP was 2. Seven patients (22.5%) received a repeat PCC dose. Three patients developed a thromboembolic event (9%).

**CONCLUSIONS:** Treatment with low-dose 3-factor PCC with vitamin K and FFP was effective in reversing warfarin in our study population. However, even at lower doses, potential thrombotic complications can occur. More randomized, prospective studies are needed to determine the minimum effective PCC dose for warfarin reversal.

**67. Comparison of activated factor VII and prothrombin complex concentrates on emergent reversal of coagulopathy.** Elizabeth VanWert, Pharm.D., Darrel W. Hughes, Pharm.D., BCPS, Department of Pharmacy Services, University Health System, San Antonio, TX

**PURPOSE:** The annual incidence of major bleeding associated with warfarin therapy ranges from 1% to 10%. Rapid reversal of warfarin-induced anticoagulation is necessary to limit hemorrhagic complications. Options include activated recombinant factor VII (rFVIIa) and prothrombin complex concentrates (PCC). We sought to compare the percentage of patients achieving an international normalized ratio (INR)  $\leq 1.5$  after the administration of rFVIIa or PCC in traumatically injured patients receiving warfarin therapy.

**METHODS:** A single-center, retrospective chart review was performed for 211 patients between January 2007 – November 2012 who received rFVIIa or PCC. Patients were identified through a database query and included if they were traumatically injured, receiving warfarin at time of injury with baseline INR  $\geq 2$ , and were at least 18 years of age. Data collected included INR measurements, medication interventions, hospital mortality, and medication cost.

**RESULTS:** Twenty-six patients were included in the final analysis. Twenty-three patients received PCC and three patients received rFVIIa. Glasgow coma score was lower in the rFVIIa group versus PCC (11 versus 15,  $p=0.48$ ). Baseline INR was higher for patients who received rFVIIa versus PCC (6.3 versus 4.2,  $p=0.14$ ). Mean dose was 24.5 units/kg and 89.4 mcg/kg for PCC and rFVIIa respectively. 100% of rFVIIa patient and 47.8% of PCC patients achieved INR  $\leq 1.5$  ( $p=0.22$ ). Time to INR  $\leq 1.5$  was 87 minutes with PCC versus 168 minutes with rFVIIa ( $p=0.51$ ). 17.4% of patients who received PCC died in-hospital compared to 66.7% of patients who received rFVIIa ( $p=0.2$ ). Cost of therapy was significantly higher with rFVIIa versus PCC (\$8979 versus \$1720,  $p=0.007$ ).

**CONCLUSION:** Neither the rate of INR reversal nor time to INR  $\leq 1.5$  appears to differ between PCC and rFVIIa. Cost of therapy was significantly higher with rFVIIa compared to PCC.

## Endocrinology

**68. Weekly-exenatide therapy: a real-world comparison of incretin therapies.** Sara Micale, Pharm.D.<sup>1</sup>, Shahabodin Khatounabadi, BHSc<sup>1</sup>, Michael Kane, Pharm.D., FCCP, BCPS, BCACP<sup>1</sup>, Robert Busch, M.D., FACE<sup>2</sup>, Gary Bakst, M.D.<sup>2</sup>, Jill Abelseth, M.D., FACE<sup>2</sup>, Robert Hamilton, Pharm.D., MPH<sup>3</sup>; (1) Albany College of Pharmacy and Health Sciences, Albany, NY (2) The Endocrine Group, L.L.P., Albany, NY (3) Albany College of Pharmacy and Health Sciences, Vermont Campus, Colchester, VT

**PURPOSE:** To evaluate the real-world clinical utility of once weekly exenatide in type 2 diabetes mellitus (T2DM) patients from a private endocrinology practice who previously received once or twice daily GLP-1 therapy.

**METHODS:** In this pre-post observational study, electronic medical records (EMRs) were reviewed to identify patients meeting all study criteria. Data collected included baseline patient demographic information, duration of diabetes, medical history, medications, pertinent laboratory data, blood pressure, height, weight, and reported adverse drug events. Primary (changes in A1C and percentage of patients reporting adverse effects of therapy) and secondary (percentage of patients with A1C of <7%, and changes in weight, blood pressure, and lipids) outcomes were evaluated using appropriate statistical analysis.

**RESULTS:** EMRs of 81 patients met all study criteria. Baseline patient demographic information included an average age of  $60.5 \pm 11.9$  years, an average duration of T2DM of  $12.5 \pm 6.3$  years, 56.8% of patients were male, and 93.8% were Caucasian. Mean body weight at baseline was  $243.7 \pm 65.5$  pounds, mean BMI was  $38.6 \pm 9.1$ , and average A1C was  $7.51 \pm 1.48\%$ . After a minimum of 3 months, there were significant decreases in A1C ( $-0.35\%$ ;  $p=0.0067$ ) and weight ( $-3.5$  pounds;  $p=0.0151$ ). Two patients (2.5%) discontinued once weekly exenatide due to documented adverse reactions.

**CONCLUSION:** Once weekly exenatide was generally well tolerated and significantly reduced A1C levels and body weight in patients with T2DM when switched from a shorter-acting GLP-1 analog.

**69. Change in levothyroxine dose requirements after bariatric surgery.** Christopher M. Bland, Pharm.D., BCPS, Lori B. Sweeney, M.D., Adam M. Tritsch, M.D., David A. Bookstaver, Pharm.D., Yong U. Choi, M.D.; Eisenhower Army Medical Center, Fort Gordon, GA

**PURPOSE:** It is well established that thyroid hormone requirements are influenced by body weight and composition. It is unclear how levothyroxine dosage requirements change after bariatric surgery. This study sought to evaluate change in thyroid dose requirements in patients after bariatric surgery.

**METHODS:** A retrospective chart review was conducted at a single center to evaluate for change in levothyroxine dose up to 1 year postoperatively in patients who had undergone bariatric surgery from January 2006 to January 2012. Dose changes were analyzed by type of bariatric surgery and percent BMI reduction achieved at 1 year after surgery.

**RESULTS:** Fifty-five patients receiving levothyroxine therapy were evaluated. Roux-en-Y gastric bypass and sleeve gastrectomy were performed in 22 and 33 patients respectively. Dose reductions were observed in 26% of bariatric patients within 12 months of surgery including one discontinuation of levothyroxine therapy. Five patients had TSH levels of <1 with no subsequent decrease in levothyroxine dosage. The average dose reduction was 26.7 mcg/day with a range of 12–75 mcg/day. Dose increases were observed in 13% of bariatric patients within 12 months of surgery. The average dose increase was 29 mcg/day with a range of 12–50 mcg/day. No clear association existed between levothyroxine dose change and type of surgery performed or percent BMI reduction achieved, including those with a >30% BMI reduction. Monitoring of thyroid function was inconsistent both preoperatively and postoperatively.

**CONCLUSION:** Weight loss after bariatric surgery does not appear to independently predict change in levothyroxine dose requirement, nor does type of bariatric surgery performed. Levothyroxine dosage reductions were common with several additional patients having low TSH levels that should have resulted in dose reduction. Further studies should delineate appropriate timing of thyroid function testing and levothyroxine dosage adjustments.

**70E. Colesevelam HCl: glycemic and lipid parameter effects in patients with type 2 diabetes mellitus treated with metformin-based therapy and a statin.** Michael R. Jones, Ph.D.<sup>1</sup>, Harold E. Bays, M.D., FACP<sup>2</sup>, Soamnauth Misir, RPh., Pharm.D., MBA<sup>1</sup>; (1) Daiichi Sankyo, Inc., Parsippany, NJ (2) Louisville Metabolic and Atherosclerosis Research Center, Louisville, KY

**PURPOSE:** The two most common medications used by patients with type 2 diabetes mellitus (T2DM) are metformin and a statin. This post-hoc analysis evaluated the effect on glycemic and lipid parameters of adding colesevelam HCl (COL) to subjects with T2DM on metformin-based therapy and a statin.

**METHODS:** In a previously-reported 26-week study, adults with T2DM (A1C values: 7.5%–9.5% on metformin-based therapy) were randomly administered COL 3.75 g/day (N=159) or matching placebo (PBO; N=157) in addition to pre-study background therapies. In the total study population, COL had a mean treatment difference (MTD) in A1C of -0.54% (p<0.001) and LDL-C of -15.9% (p<0.001). Sixty-two COL recipients (39%) and 75 PBO recipients (42%) were treated with pre-study statin therapy, which continued throughout the trial. This post-hoc analysis evaluated the changes from baseline in glycemic and lipid parameters in the subgroup of T2DM patients on metformin-based therapy and statin therapy.

**RESULTS:** T2DM patients on metformin-based therapy and statin therapy receiving COL or PBO had similar demographic characteristics and baseline A1C similar to the overall study population (8.1%). COL reduced A1C more than PBO in metformin-based statin users (MTD -0.63%; p=0.0003) and the overall population (-0.49%; p=0.001), and LDL-C (-16.4%; p=0.0024 and -15.8%; p<0.0001), respectively. Among metformin-based statin users, COL reduced non-HDL-C (-11.7%, p=0.021), total cholesterol (-8.5%, p=0.025), and apolipoprotein B/apolipoprotein A1 (-0.1%, p=0.014), with no change in HDL-C and apolipoprotein A1 versus PBO. COL did not significantly alter triglyceride levels versus PBO in metformin-based statin users (-1.6%; p=0.885).

**CONCLUSION:** In this post-hoc analysis with T2DM patients on metformin-based therapy and statin therapy, COL significantly reduced A1C and LDL-C. The reduction in A1C with COL was numerically greater in patients on metformin-based statin therapy versus overall study population. This post-hoc analysis did not support any attenuation of COL efficacy depending upon statin use/nonuse.

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**71E. Saxagliptin as add-on to metformin+ sulfonyleurea in patients with type 2 diabetes: outcomes stratified by baseline glycated hemoglobin and patient characteristics.** Robert Moses, M.D.<sup>1</sup>,

Sanjay Kalra, M.D., DM<sup>2</sup>, John Monyak, Ph.D.<sup>3</sup>, Genevieve Wertzman-Show, Ph.D.<sup>3</sup>, Vicky Osborn, Pharm.D., MS<sup>4</sup>, Helen Yeh, Ph.D.<sup>3</sup>; (1)Illawarra Diabetes Service, South East Sydney & Illawarra Area Health Service (2)Bharti Research Institute of Diabetes and Endocrinology (BRIDE) (3) AstraZeneca (4) Bristol-Myers Squibb

**PURPOSE:** To assess saxagliptin (SAXA) efficacy based on age, race, baseline glycated hemoglobin (A1C), or body mass index (BMI) in patients with type 2 diabetes inadequately controlled with metformin (MET)+sulfonyurea (SU).

**METHODS:** A post hoc analysis was performed with A1C data stratified by patient age (<65 years, ≥65 years), race (white versus Asian), baseline A1C (<8%, 8% to <9%, ≥9%), and BMI; (<30 kg/m<sup>2</sup>, ≥30 kg/m<sup>2</sup>) from a placebo (PBO)-controlled 24-week, phase 3b trial in patients receiving MET+SU and randomized to SAXA 5 mg/day or PBO (NCT01128153).

**RESULTS:** Across categories of age (interaction p value=0.40), race (p=0.36), baseline A1C (p=0.12), and BMI (p=0.99), A1C (baseline A1C, 7.45% to 9.53%) was reduced more with SAXA versus PBO (Table). Adverse events were comparable across treatment groups and categories and were reported by 58%–85% of patients. Symptomatic confirmed hypoglycemia (fingerstick glucose ≤ 50 mg/dL) was reported by two Asian patients receiving SAXA, with baseline A1C <8% and BMI < 30 kg/m<sup>2</sup>.

Category	A1C,%		Difference versus PBO (95% CI)
	Adjusted Mean Change (SE) From Baseline at Week 24		
Age			
<65 years n=196	-0.78 (0.08)	-0.08 (0.09)	-0.71 (-1.00, -0.41)
≥65 years n=61	-0.60 (0.16)	-0.09 (0.14)	-0.51 (-1.04, 0.03)
Race White n=116	-0.48 (0.21)	0.08 (0.21)	-0.56 (-0.95, -0.18)
Asian n=141	-0.99 (0.20)	-0.24 (0.19)	-0.75 (-1.09, -0.40)
Baseline A1C			
<8% n=106	-0.58 (0.12)	0.02 (0.11)	-0.60 (-1.04, -0.15)
8% to <9% n=92	-0.70 (0.12)	-0.15 (0.12)	-0.55 (-1.03, -0.08)
≥9% n=56	-1.13 (0.15)	-0.10 (0.16)	-1.03 (-1.64, -0.42)
BMI < 30 kg/m <sup>2</sup> n=144	-0.73 (0.10)	-0.06 (0.10)	-0.67 (-1.01, -0.33)
≥30 kg/m <sup>2</sup> n=110	-0.77 (0.12)	-0.10 (0.11)	-0.66 (-1.05, -0.27)

**CONCLUSIONS:** When added to MET+SU, SAXA improves A1C across categories of age, race, baseline A1C, and BMI and is generally well tolerated.

Presented at Presented at the 73rd scientific sessions of the American Diabetes Association, Chicago, IL, June 21–25, 2013.

**72. Effect of a protocol driven interdisciplinary team on inpatient glycemic control.** Jennifer Marquart, Pharm.D., BCPS<sup>1</sup>, Jonathan Schulz, Pharm.D., BCPS<sup>1</sup>, Megan Matak, Pharm.D., BCPS<sup>1</sup>, Shelley Weier, M.D.<sup>2</sup>; (1)Department of Pharmacy, North Memorial Medical Center, Robbinsdale, MN (2)North Memorial Medical Center, Oakdale Ave N, MN

**PURPOSE:** Hyperglycemia in hospitalized patients is associated with prolonged hospital stay, increased incidence of infection and increased morbidity and mortality. We evaluated if a physician-pharmacist interdisciplinary team using an evidence based protocol would improve glycemic control, defined as blood glucose between 80 and 180 mg/dL for at least 80% of measurements during admission.

**METHODS:** A physician-pharmacist team was formed between a pharmacist and four physicians for a 2 weeks prospective interventional arm. The pharmacist, following an evidence based gly-

chemic control protocol developed for this intervention, provided recommendations for each non-ICU patient with a history of diabetes, the development of inpatient hyperglycemia, or requiring any form of hyperglycemia treatment. The pharmacist would obtain any relevant patient treatment history through both patient interview and chart review, provide patient education, and also provide discharge regimen recommendations where applicable. The control arm consisted of a retrospective review of non-ICU patients requiring hyperglycemia management of the same four hospitalists for a 2 weeks period prior to the intervention. The primary outcome was the comparison of the percentage of patients achieving glycemic control starting 24 hours after the start of the intervention.

**RESULTS:** Glycemic control improved from 31.3% (n=64) in the control group to 60% (n=35) in the intervention group (p=0.010; OR 1.29–8.53). Hypoglycemic occurrences were reduced from 32 episodes in 14 patients (21.9%) in the control arm to one episode (2.9%) in the intervention arm (p<0.001).

**CONCLUSION:** A physician-pharmacist interdisciplinary team following an evidence based glycemic control protocol led to clinically and statistically significant improvement of patients achieving optimal glycemic control while reducing the number of hypoglycemia occurrences.

**73. Evaluation of hyperglycemia in noncritically ill patients before and after implementation of a standardized subcutaneous insulin order set.** *Kristina M. Marchese, Pharm.D., BCPS<sup>1</sup>, Gina M. Prescott, Pharm.D., BCPS<sup>2</sup>, (1) Erie County Medical Center Corporation, Buffalo, NY (2) State University of New York at Buffalo, Buffalo, NY*

**PURPOSE:** Hyperglycemia in hospitalized patients has been associated with increased mortality, infection, and hospital length of stay. Nevertheless, compliance with established guidelines for management in noncritically ill patients is believed to be suboptimal. The primary objective was to evaluate the effect of a subcutaneous insulin order set on achieving and maintaining goal blood glucose in noncritically ill patients (70–180 mg/dL).

**METHODS:** Medical records of 158 noncritically ill patients were reviewed between February 1 – February 28, 2011 (pre-order set initiation) and February 1 – February 28, 2012 (post-order set initiation). Patient demographics, blood glucose values, and insulin use were collected. The primary objective was measured as the percentage of blood glucose readings between 70 and 180 mg/dL calculated for each patient and averaged over each study arm. Rates of correctional/sliding scale insulin monotherapy were evaluated as well. The subcutaneous insulin order set was a 1-page document that contained options for ordering basal, nutritional, and/or correctional/sliding scale insulin.

**RESULTS:** The median percentage of blood glucose readings between 70 and 180 mg/dL was 47.4% in the pre-order set group (N=91) and 54.5% in the post-order set group (N=67, p=0.28). Rates of correctional/sliding scale insulin monotherapy were 45.1% (pre-order set) and 51.6% (post-order set, p=0.42).

**CONCLUSION:** The subcutaneous insulin order set did not improve rates of hyperglycemia nor decrease correctional/sliding scale insulin monotherapy. Improved management and compliance with established guidelines require a multidisciplinary approach and could not be achieved with use of an order set alone.

## Family Medicine

**74. Impact of collaborative shared medical appointments on diabetes outcomes in a family medicine clinic.** *Melody L. Hartzler, Pharm.D., AE-C<sup>1</sup>, Julie Williams, Psy.D., CRC, ABPP<sup>2</sup>, James Schoen, D.O.<sup>3</sup>, Kali Hollingsworth, D.O.<sup>4</sup>, Thomas Dunn, D.O.<sup>3</sup>, Douglas Anderson, Pharm.D., CACP<sup>1</sup>; (1) Cedarville University School of Pharmacy, Cedarville, OH (2) Wright State University, School of Professional Psychology, Dayton, OH (3) Grandview Medical Center/Community Health Centers of Greater Dayton, Dayton, OH (4) Kettering Medical Center/Community Health Centers of Greater Dayton, Dayton, OH*

**PURPOSE:** Group visits are a unique opportunity to consolidate resources aimed at achieving better diabetes control. The impact of group visits on Hemoglobin A1c (HbA1c) has not been consistent across the literature. The purpose of this study was to evaluate the impact of a collaborative diabetes group medical appointment on patient outcomes in an urban family medicine clinic. The primary objective was to compare HbA1c from baseline to 6 months; secondary analyses included comparing changes in LDL, systolic blood pressure (SBP), and weight.

**METHODS:** Selected inclusion criteria included: Type II Diabetes diagnosis, receiving at least one medication for diabetes treatment, and HbA1c > 7.5%. Each group visit lasted approximately 2 hours and consisted of up to ten patients. Diet, lifestyle, treatment barriers, and pharmacotherapy were addressed at each visit by the team, which included a resident physician, clinical pharmacist, and psychologist. The clinical pharmacist reviewed the patient charts prior to each visit and was active in management decisions during the appointment. The clinical psychologist utilized behavioral techniques and addressed stress management, barriers to change, and stages of change. Patients generally followed up in the group appointment every 4 weeks if HbA1c > 8%, and every 6–8 weeks if HbA1c < 8% depending on individual circumstances.

**RESULTS:** Forty-three patients of sixty-five (mean age: 53.98 ± 9.45 years) completed the 6 months program. Only three patients (7%) met ten pre-selected ADA criteria for management of type 2 diabetes at baseline. Mean HbA1c at baseline was 9.9% and significantly decreased to 8.5% at 6 months (p<0.001). LDL also significantly decreased from 105.7 to 90.82 mg/dL (p=0.01). There were no statistically significant changes in SBP or weight.

**CONCLUSIONS:** Collaborative group visits significantly improved glycemic control. They are an important model to consider as patient care providers move towards patient-centered medical homes and team-based care.

**75. Diabetes and cardiovascular risk assessment utilizing a personal health profile in an employer-sponsored family medicine clinic.**

*Holly Gurgle, Pharm.D., BCACP, CDE<sup>1</sup>, Carrie McAdam-Marx, RPh., MS, Ph.D.<sup>2</sup>, Eman Biltaji, BPharm., MS<sup>2</sup>, Peter Weir, M.D., MPH<sup>3</sup>; (1) Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City, UT (2) Department of Pharmacotherapy & Pharmacotherapy Outcomes Research Center, University of Utah College of Pharmacy, Salt Lake City, UT (3) Department of Family and Preventative Medicine, University of Utah, Salt Lake City, UT*

**PURPOSE:** Diabetes and cardiovascular disease are prevalent and costly conditions for employers. Primary care clinical pharmacists are competent providers of diabetes and cardiovascular disease management. This research describes a personal health profile (PHP) utilized to assess diabetes and coronary heart disease (CHD) risk amongst employees and spouses.

**METHODS:** The PHP consisted of: high density lipoprotein, low density lipoprotein (LDL), triglycerides, total cholesterol, hemoglobin A1c (A1c), glucose, systolic and diastolic blood pressure (SBP, DBP), body mass index, and survey data. The Framingham Heart Study's Risk Assessment Tool for Estimating 10-year Risk of Developing CHD and the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults were utilized to calculate a CHD risk score and LDL goal. Patients were provided a PHP report card to help understand diabetes and CHD risk, and goals.

**RESULTS:** Over the first 6 months of 2013, 1856 employees and spouses completed a PHP. The median 10-year CHD risk was 1% and 73 (3.9%) patients had a risk >10%. History of myocardial infarction or stroke was reported by 31 patients. LDL was above risk-based goal for 169 (9.1%) patients. Of 289 patients with self-reported hypertension, 26.0% had SBP and 17.0% had DBP ≥ 140/90 mmHg. Of the remaining 1567 patients with no history of hypertension, 95 (6.1%) had SBP and 52 (3.3%) had DBP ≥ 140/90 mmHg. Of 99 patients who reported having diabetes, the following percent had specific risk factors above goal: A1c (≥7.0%) 48.5%, LDL 32.3%, SBP 26.3%, DBP 53.5%.



Additionally, 18 patients who reported no history of diabetes had an A1c  $\geq$  6.5%.

**CONCLUSION:** A PHP is an effective way to identify employees and spouses who have or are at risk for diabetes or cardiovascular disease. Future research will evaluate if the PHP and subsequent interventions improved patient outcomes.

**76. Comparison of prescribing patterns and identification of risks with metoclopramide in a family medicine clinic.** *Justin J. Sherman, M.C.S. Pharm.D.*; The University of Mississippi School of Pharmacy, Jackson, MS

**PURPOSE:** Metoclopramide should be used for no longer than 12 weeks in duration unless the benefit outweighs the potential for tardive dyskinesia (TD). The prescribing patterns and patients at risk for developing TD were described for two groups within a family medicine clinic before and after an educational intervention: patients receiving metoclopramide for longer than approved length of therapy (LTALT) versus those receiving metoclopramide within the approved length of therapy (ALT).

**METHODS:** After institutional review board approval, all patients during a retrospective chart review who had received at least one prescription of metoclopramide over the previous 2 years were included. Demographic data was obtained and prescribing patterns were identified, including patients at risk for TD. Data was captured regarding physician use of the Abnormal Involuntary Movement Scale (AIMS) or other assessment of involuntary movements. Descriptive statistics were used for demographic data. Comparisons were made between the two groups before and 8 months after an educational intervention.

**RESULTS:** Patients in the LTALT group (n=90) versus those in the ALT group (n=34) were more likely have one or more risk factors for TD (p<0.05). The difference in average daily doses for the two groups was not statistically significant, and doses were changed infrequently. Although patients in the LTALT group were more likely to be documented for assessment of involuntary movements, no patients were assessed with a documented AIMS test. Eight months after a brief educational intervention, patients receiving metoclopramide for longer than the approved treatment period decreased significantly; documented assessment increased significantly (p<0.05).

**CONCLUSION:** Patients in the LTALT group were more likely to be at risk for developing TD. An educational intervention was successful in achieving appropriate length of metoclopramide use and assessment.

## Gastroenterology

**77. Proton pump inhibitors and *Clostridium difficile* associated diarrhea: when does risk increase?.** *Jeffrey Barletta, Pharm.D.*, Shareen El-Ibiary, Pharm.D., Lindsay Davis, Pharm.D., Bao Nguyen, Pharm.D., Carrington (Kip) Raney, Pharm.D.; Department of Pharmacy Practice, Midwestern University, College of Pharmacy-Glendale, Glendale, AZ

**PURPOSE:** This study evaluated the relationship between proton pump inhibitors (PPI) and nosocomial *Clostridium difficile*-associated diarrhea (CDAD) and determined the duration of therapy whereby risk became greater.

**METHODS:** This case-control study identified consecutive adult patients with nosocomial CDAD who were admitted to one of two affiliated hospitals for at least 3 days. Patients with CDAD were matched to non-CDAD patients in a 1:2 ratio using age, gender, date of admission and antibiotic usage. Patient-specific variables, including PPI use and duration, were compared between patients with and without CDAD. Classification and regression tree (CART) analysis was used to determine the threshold for PPI duration whereby risk for CDAD increased. A multivariate regression model was used to control for confounding variables and identify risk factors for CDAD.

**RESULTS:** There were 201 patients evaluated (67 CDAD, 134 matched controls) with 51% receiving a PPI and 97% receiving an antibiotic. Patients who developed CDAD were more likely to

receive a PPI (76% versus 39%, p<0.001) and had a longer duration of PPI therapy (5 [0–20] versus 0 [0–11] days, p<0.001). Histamine-2-receptor-antagonist use was similar in patients with and without CDAD (22% versus 22%, p=1.00). After controlling for prior hospital admission, ICU admission, admission from a skilled nursing facility, immunosuppression, number of antibiotics received and PPI duration via multivariate analysis, PPI duration was found to be a risk factor for CDAD (OR [95% CI] = 1.2 [1.1–1.3], p<0.001). CART analysis suggested PPI use for more than 2 days increased the probability of CDAD for patients without a prior hospital admission and for patients with a prior admission, this threshold was 1 day.

**CONCLUSION:** The duration of in-patient PPI therapy is significantly associated with CDAD among patients with and without prior hospitalization. Clinicians should strongly consider restricting PPI use given the short exposure time associated with this increased risk.

**78. Impact of helicobacter pylori treatment on nonsteroidal anti-inflammatory drugs (NSAIDs)-induced ulcer formation in adult patients: a meta-analysis.** *Tantri Budiman, Pharm.D.*<sup>1</sup>, Bingle John Fontanos, MT<sup>2</sup>; (1)Department of Pharmacy, Sage Memorial Hospital, Ganado, AZ (2) Sage Memorial Hospital, Ganado, AZ

**PURPOSE:** This meta-analysis is sought to investigate whether *H. pylori* treatment in patients on NSAIDs therapy prevents ulcer development. Research on this topic reveals conflicting data, therefore, defining the precise relationship between *H. pylori* and NSAIDs would provide crucial evidence for proper patient management.

**METHODS:** A systematic search was conducted for articles published between January 1st, 1992 and December 31st, 2012. The primary outcome evaluated was the appearance of an endoscopically diagnosed peptic ulcer at the end of follow-up period. Subanalyses were performed to evaluate the effect of treatment in naïve NSAIDs versus chronic NSAIDs users and the protective effect of *H. pylori* treatment versus proton pump inhibitor (PPI) maintenance for ulcers development.

**RESULTS:** Overall, *H. pylori* treatment did not reduce peptic ulcer development (7.5% versus 8.1%; OR = 0.94; 95% CI: 0.42–2.13, p=0.64). There was significantly less patients developed ulcers in the treatment group among NSAIDs naïve (3.3% versus 11.3%; OR = 0.23; 95% CI: 0.09–0.56, p=0.003). However, there was no significant difference among patients who were already taking NSAIDs on *H. pylori* presentation (9.3% versus 6.7% OR = 1.56; 95% CI: 0.79–3.06, p=0.13). Five studies comparing *H. pylori* treatment to PPI treatment showed a non-statistically significant reduction for preventing NSAIDs-associated ulcers (9.7% versus 8.9%; OR = 1.28; 95% CI: 0.46–3.55, p=0.67).

**CONCLUSION:** The meta-analysis found that eradicating *H. pylori* did not reduce the development of peptic ulcer in the overall population receiving NSAIDs treatment. However, evidence shows that *H. pylori* treatment significantly reduces the risk of peptic ulcer in NSAIDs naïve patients. This means that risk reduction is more marked in patients starting NSAIDs than in patients who tolerate and were already receiving NSAIDs therapy. Furthermore, PPI therapy may offer a modest, but non-significant clinical benefit over *H. pylori* treatment in preventing ulcers.

**79. Evaluating the incidence and treatment of telaprevir-induced rash.** *Michael A. Smith, Pharm.D.*, BCPS<sup>1</sup>, Heather J. Johnson, Pharm.D., BCPS<sup>1</sup>, Ashley M. Ulrich, BS<sup>2</sup>, Kapil B. Chopra, M.D.<sup>2</sup>, Michael A. Dunn, M.D.<sup>2</sup>, Rima A. Mohammad, Pharm.D., BCPS<sup>1</sup>; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA (2) University of Pittsburgh School of Medicine, Pittsburgh, PA

**PURPOSE:** Direct acting antivirals have significant adverse drug effects (ADEs) and drug interactions (DIs). Telaprevir-induced rash is difficult to treat due to DIs with systemic corticosteroids. The objectives of this study were to determine incidence of telaprevir-induced rash, evaluate its management, and identify any risk factors related to rash development.

**METHODS:** Retrospective study of adult HCV patients who completed or discontinued telaprevir in a hepatology clinic from

7/1/2011 to 8/30/2012. Pertinent demographic, past medical history, medications, lab work, and patient reported outcomes of rash and other ADEs related to HCV treatment or other therapies, and physician grading of rash were collected.

**RESULTS:** One hundred and fifty-nine patients were included. Forty-four percent (70/159) developed rash. Four percent of patients (7/159) discontinued therapy due to rash. Median number of days until rash did not differ between groups (25 versus 45;  $p=0.88$ ). Patients who developed rash were more likely to have lower actual body weight, body mass index, and psychiatric disorders history ( $p\leq 0.01$ ). There was no significant difference in rash development when drug-allergy history was considered. Most patients who continued telaprevir were prescribed topical corticosteroids (90.5%) and cetirizine (41.3%). Patients who discontinued therapy due to rash were more likely seen by dermatology ( $p=0.002$ ), and prescribed oral corticosteroids ( $p=0.02$ ), hydroxyzine ( $p=0.001$ ) and topical triamcinolone ( $p=0.01$ ). Nine percent of patients (6/70) were hospitalized for rash for a median of 3.5 days. Three patients suffered from DRESS. Adding systemic corticosteroids to telaprevir did not affect blood pressure and cortisol levels. SVR rates were not affected by rash development ( $p=1.0$ ).

**CONCLUSION:** Rash and treatment discontinuation rates were similar to trial data (44% versus 35–40%, and 4% versus 4–7%). ABW and BMI were related to rash development, while drug-allergy history was not. Patients who discontinued treatment were more aggressively treated (e.g., oral corticosteroids), although this did not prolong course of therapy or cause ADEs.

**80. The effect of bariatric surgery on hypertension.** *Sheila Wilhelm, Pharm.D., BCPS<sup>1</sup>, Jamie Young, Pharm.D. Candidate<sup>2</sup>, Pramodini Kale-Pradhan, Pharm.D.<sup>3</sup>*; (1)Pharmacy Practice, Wayne State University and Harper University Hospital, Detroit, MI (2)Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences (3)Pharmacy Practice, Wayne State University and St. John Hospital and Medical Center, Detroit, MI

**PURPOSE:** Obesity is a growing epidemic leading to world-wide public health concerns. Bariatric surgery is an option for patients with a body mass index of  $>40$  or BMI of  $>35$  with serious comorbid conditions. There are three types of procedures that are typically employed to address the issue of obesity including restrictive, malabsorptive and restrictive-malabsorptive. This meta-analysis examines the effect of bariatric surgery on the improvement or resolution of hypertension.

**METHODS:** Two independent investigators conducted a literature search of PubMed (1990–2013) and Cochrane databases using terms bariatric surgery and hypertension to identify appropriate human adult studies published in English. Studies were included if they reported the number of patients with hypertension prior to undergoing any bariatric surgery procedure, and whether the hypertension improved or resolved post surgery. The number of patients with hypertension and their response rates were extracted and analyzed using RevMan 5.1.

**RESULTS:** Seven prospective and five retrospective studies met all criteria. The types of bariatric surgery performed included: roux-en-y, gastric banding, laparoscopic adjustable gastric banding, vertical gastric banding, sleeve gastrectomy, duodenal switch and biliopancreatic diversion. Eight of the 12 studies reported the improvement of hypertension in 30,765 of 48,609 patients (OR: 11.81, 95% CI 2.92, 48.14). Nine studies reported the resolution of hypertension in 23,202 of 46,745 patients (OR 1.76, 95% CI 0.49, 6.32). A random effects model was used as the heterogeneity between the studies was high ( $I^2 > 95\%$ ).

**CONCLUSION:** The results of this meta-analysis indicate that patients who undergo bariatric surgery experience improvement of their hypertension.

**81. Project extension for community healthcare outcomes (ECHO) expands access to hepatitis C treatment for underserved populations.** *Paulina Deming, Pharm.D.<sup>1</sup>, Karla Thornton, M.D., MPH<sup>2</sup>, Summers Kalishman, Ph.D.<sup>2</sup>, Glenn Murata, M.D.<sup>2</sup>,*

Sanjeev Arora, M.D.<sup>2</sup>; (1)College of Pharmacy, University of New Mexico, Albuquerque, NM (2)Project ECHO, University of New Mexico, Albuquerque, NM

**PURPOSE:** The Extension for Community Healthcare Outcomes (ECHO) model was developed by the University of New Mexico Health Sciences Center (UNMHSC) to improve access to best practice care for complex health problems such as hepatitis C virus (HCV) infection for populations in rural and underserved areas. Using videoconferencing technology, best practice protocols, and case-based learning, ECHO trains and supports primary care clinicians (PCCs) to deliver appropriate care for patients with HCV. Community clinicians participate in weekly HCV tele-ECHO clinics, called “knowledge networks,” by joining a one-to-many videoconference. Clinicians present their cases by sharing patient medical histories and laboratory results. University specialists in hepatology, infectious diseases, psychiatry and pharmacy provide advice and clinical mentoring to clinicians.

**METHODS:** In a prospective cohort study previously published (Arora S, et al., NEJM, June 9, 2011), we showed that PCCs treat HCV safely and effectively. No difference was found in the rate of sustained virologic response between the dedicated HCV clinic at UNMHSC and PCCs at 21 ECHO partner sites in New Mexico. In 2007, the University of Washington (UW)-Seattle replicated the model and run a successful HCV ECHO clinic. Subsequently, multiple organizations have replicated HCV ECHO including: University of Utah; Beth Israel Deaconess Medical Center, Massachusetts; St. Joseph’s Hospital, Arizona; Community Health Center Inc., Connecticut; Institute of Liver and Biliary Sciences, India.

**RESULTS:** Since 2004,  $>6000$  patients were presented and 585 started on HCV treatment in NM. In addition, 200 patients initiated HCV therapy through ECHO at UW. Among other U.S. sites and India, ECHO has dramatically expanded access to HCV therapy.

**CONCLUSION:** The ECHO model is an effective way to treat HCV in rural and underserved communities and expands access to treatment. By implementing the ECHO model more patients with HCV can be treated, thereby preventing an enormous burden of illness and death.

## Geriatrics

**82. Evaluation of fall risk assessments in community-dwelling veterans.** *Mallory Jones, Pharm.D., Stephen Neu, Pharm.D.*; Pharmacy Department, VA Tennessee Valley Healthcare System, Nashville, TN

**PURPOSE:** Unintentional falls lead to significant morbidity and mortality. Several tools are available to assess fall risk; however, the optimal way to evaluate fall risk is unclear. The purpose of this study is to evaluate the prevalence of falls in community-dwelling Veterans with high-risk fall assessment scores.

**METHODS:** Medical records of a community-dwelling Veteran population were retrospectively evaluated for two common fall risk scores (Morse Fall Scale (MFS) and Timed Up and Go Test (TUG)). A medication fall risk score was also calculated. The primary objective was to evaluate the prevalence of falls in patients with a high-risk combined score compared to a high-risk medication score alone or a high-risk MFS alone. Secondary objectives included the evaluation of the prevalence of falls associated with a high-risk TUG score compared to other scores, as well as correlation between risk score(s) and fall severity and frequency.

**RESULTS:** One hundred and one patients met inclusion criteria. 60.3% of patients had high-risk MFS scores, 61.3% had high-risk medication scores, and 85.1% had high-risk combined scores. Additionally, 59.2% of patients with documented TUG scores were high-risk. Within 12 months, 46.5% of patients fell, 31.7% sustained injuries, and 16.8% experienced multiple falls. The combined risk score identified the highest percentage of patients that fell within 1 year. The percentage of patients classified as high-risk who suffered a fall within 12 months was similar among all risk scores except for the TUG, which showed an increased prevalence of falls in high-risk patients. No differences were shown

between rates of multiple falls and severity of falls among assessments.

**CONCLUSION:** Although several of the fall risk assessments used in this study are not validated in the outpatient setting, it could be beneficial to assess fall risk in multiple ways, including the use of a medication risk score.

**83. Inhaler misuse in an older adult population.** Adam Vanderman, Pharm.D.<sup>1</sup>, Jason Moss, Pharm.D., CGP<sup>2</sup>, Janine Kosmoski, Pharm.D., BCPS<sup>1</sup>, S. Dee Melnyk, Pharm.D., MHS, CLS<sup>3</sup>, *Jamie Brown, Pharm.D., BCPS<sup>1</sup>*; (1)Pharmacy Service, Durham VA Medical Center, Durham, NC (2)Department of Pharmacy Practice, Campbell University College of Pharmacy and Health Sciences, Durham, NC (3)Health Services Research & Development, Durham VA Medical Center, Durham, NC

**PURPOSE:** Inhaler devices are the standard of care for chronic respiratory diseases and if used incorrectly, may lead to inappropriate dose escalation, addition of unnecessary medications, and poorer outcomes. The purpose of this study was to evaluate inhaler misuse exclusively in an older adult population.

**METHODS:** This was an IRB-approved, single-center, prospective observational study from December 2012 to April 2013. We assessed inhaler technique in veterans >65 years of age with an active prescription for a pressurized metered dose inhaler (pMDI) or dry powder inhaler (DPI). Inhaler technique was evaluated in participants using placebo inhaler devices and a standardized technique assessment form. Total and critical errors committed were evaluated in addition to potential risk factors for misuse and the time necessary for technique evaluation.

**RESULTS:** Twenty four patients were enrolled in this study and yielded 44 unique device observations. Patients were male with an average age of 82 years (range 65–94 years). All patients (100%) made at least one error with a mean error rate of 2.5 errors/patient/inhaler, while 83% of patients made at least one critical error with a mean error rate of 1.2 critical errors/patient/inhaler. Assessment of inhaler technique required 2.3 minutes/inhaler. Most patients (63%) used multiple inhalers and the rate of critical errors was 79% and 88% in pMDI users and DPI users, respectively. Patients with multiple inhalers or a history of stroke committed errors more often, although no other risk factors demonstrated meaningful differences in error rates.

**CONCLUSION:** Inhaler misuse in older adults is common, including committing critical errors that considerably reduce drug delivery. The time necessary for inhaler technique evaluation is relatively small. Given the high rate of misuse observed, increased vigilance, individualized technique education, and routine re-assessment is necessary in this highly heterogeneous population.

**84E. The effects of melatonin and trazodone on delirium in hospitalized patients.** *Lacey Shumate, Pharm.D.<sup>1</sup>*, Susan Fosnight, RPh, CGP, BCPS<sup>2</sup>, David DiNuoscio, M.D.<sup>3</sup>, Rex Wilford, D.O., RPh<sup>3</sup>; (1)Department of Pharmacy, Summa Health System, Akron, OH (2)Northeast Ohio Medical University, Rootstown, OH (3)Department of Internal Medicine, Summa Health System, Akron, OH

**PURPOSE:** A recent randomized trial found melatonin was associated with a decreased risk for delirium. Therefore, this study evaluated the conversion to a positive delirium screen in hospitalized elderly patients receiving melatonin or trazodone as compared to control patients to (i) evaluate the relationship between melatonin and trazodone on the incidence of delirium and (ii) compare the length of stay and duration of delirium in patients with a positive delirium screen.

**METHODS:** Patient medical records were reviewed in reverse chronological order starting September 30, 2012. Patients at risk for delirium were determined by a delirium risk screen documented on the initial nursing assessment. A positive delirium screen during admission was determined by the Nursing Delirium Screening Scale (Nu-DESC) scores.

**RESULTS:** The melatonin arm had a statistically significant lower number of patients with a positive delirium screen as com-

pared to the control arm (4.29% versus 18.53%,  $p=0.0079$ ). There was not a statistically significant difference between trazodone and control (11.43% versus 18.53%,  $p=0.2366$ ). Mean length of stay (days) in patients who had a positive delirium screen was as follows for melatonin, trazodone, and control: 4, 6.38, and 5.23, respectively. Mean duration of delirium (days) for the three study arms was as follows for melatonin, trazodone, and control: 1, 1.88, and 2.85, respectively.

**CONCLUSION:** Melatonin was associated with a significant decrease in the number of patients with a positive delirium screen. Trazodone did not show a statistically significant difference. For the patients with a positive delirium screen, the individuals who received melatonin had a shorter mean duration of delirium as well as a shorter mean length of stay. As a result, melatonin may be a favorable option for insomnia in hospitalized elderly patients.

Presented at Presented at the Ohio Pharmacy Residency Conference, Ada, Ohio, May 17, 2013 and Poster Presentation at the OCCP Spring Meeting, Cleveland, Ohio, May 31, 2013.

**85. Impact of updated beer's criteria on percentage of inappropriate medication use in a long-term care facility.** *Amber N. McLendon, Pharm.D.<sup>1</sup>*, Amity Bunkofske, Pharm.D.<sup>2</sup>, C. Brock Woodis, Pharm.D.<sup>3,4</sup>; (1)Department of Pharmacy Practice, Campbell University College of Pharmacy and Health Sciences and Glenaire, Inc. CCRC, Buies Creek, NC (2)Campbell University College of Pharmacy & Health Sciences, Buies Creek, NC (3)Campbell University College of Pharmacy and Health Sciences, Durham, NC (4)Department of Community and Family Medicine, Duke University, Durham, NC

**PURPOSE:** The 2012 update to the Beer's Criteria included the addition of new medications that are potentially harmful to those over the age of 65 years, as well as the removal of drugs no longer on the market or those that have been deemed safe in older adults. The update resulted in a 65% increase in potentially inappropriate medications (PIMs) from the 2003 criteria. This increase has the potential to affect quality measures based on the criteria. The purpose of this study was to compare the 2003 and 2012 Beer's criteria by evaluating the percentage of PIMs in residents of a long-term care facility (LTCF).

**METHODS:** A retrospective review of medication administration records (MARs) was performed to collect medication data from all residents of a LTCF in central NC as of November 30, 2012. The following data was collected: total number of medications, number of PIMs according to the 2003 and 2012 Beer's criteria and organ system or therapeutic category of 2012 Beer's PIMs medications. Percentages of PIMs were calculated for 2003 and 2012 and compared using a t-test.

**RESULTS:** Fifty-four patients met the inclusion criteria and were included in the analysis. Of the medications administered, 2.1% were on the 2003 Beer's criteria and 4.9% were on the 2012 Beer's criteria for an increase of 2.8% ( $p<0.01$ ). Medications from the Beer's criteria prescribed most often were insulin use via sliding scale, antipsychotics and benzodiazepines.

**CONCLUSIONS:** The update of the Beer's criteria in 2012 resulted in a large increase of included drugs. In this long-term care facility, the update resulted in a significant increase of the percentage of PIMs. In-services educating prescribers of the common classes from the new Beer's criteria will hopefully result in an overall decrease in the use of PIMs in older adults.

## Health Services Research

**86. Type 2 diabetes mellitus among medicare beneficiaries in 2011: overall and subgroup prevalence, comorbidities and hypoglycemia.**

*Robert Bailey, M.D.<sup>1</sup>*, Janice Lopez, Pharm.D., MPH<sup>1</sup>, Huai-Che Shih, NA<sup>2</sup>, Sharanya Murty, NA<sup>2</sup>, Rachel Feldman, MPA<sup>2</sup>; (1)Janssen Scientific Affairs, LLC (2)The Moran Company

**PURPOSE:** To describe demographic characteristics, comorbidities, and occurrence of hypoglycemia in Medicare Beneficiaries (MB) with Type 2 Diabetes (T2DM).



**METHODS:** Medicare 2011 5% Standard Analytic Files were used to identify MBs with >2 physician or outpatient/inpatient facility claims for T2DM. Demographic characteristics, comorbidities, and hypoglycemia resulting in a healthcare provider visit were assessed. Prevalence of these endpoints was determined and racial group comparisons were made to Whites using the Chi-squared test.

**RESULTS:** A total of 367,602 MBs with T2DM were identified from 1,193,477 MBs. Mean age was 71.2 (SD = 11.2) years; 53.7% were female. Most were White (77.7%), 13.9% were Black, and 3.1% were Hispanic. Overall T2DM prevalence was 19.2%, 20.2% in those age > 65 years, and 21.4% in those age > 75 years. T2DM was present in 18.0% of Whites versus 26.4% of Blacks ( $p < 0.0001$ ), and 25.5% of Hispanics ( $p < 0.0001$ ). The most common comorbidities included hypertension 87.8%, lipid disorder 76.6%, ischemic heart disease 39.3%, diabetic neuropathy 20.7%, diabetic retinopathy 11.3%, and heart failure 21.5%. Compared to Whites, hypertension was more common in Blacks ( $p < 0.0001$ ). Lipid disorder and atrial fibrillation were more common in Whites than Blacks or Hispanics (all  $p$  values  $< 0.0001$ ). Retinopathy was more common in Blacks ( $p < 0.0001$ ) and Hispanics ( $p < 0.0001$ ). Hypoglycemia requiring >1 healthcare provider visit occurred in 3.2% overall, 2.9% of Whites (reference group), 4.7% of Blacks ( $p < 0.0001$ ), 3.6% of Hispanic ( $p = 0.0002$ ).

**CONCLUSION:** This study describes the burden of T2DM, closely related comorbidities, and hypoglycemia in the overall Medicare population and racial/ethnic subgroups. The overall prevalence of T2DM, closely related comorbidities, and hypoglycemia significantly differ between subgroups. This information may inform healthcare providers, payers, and policy-makers opportunities to improve care of this population.

**87. A multidisciplinary intervention for reducing readmissions among older adults in a patient-centered medical home.** Paul Stranges, Pharm.D., BCPS<sup>1</sup>, Tami Remington, Pharm.D., BCPS<sup>2</sup>, (1) Department of Pharmacy, University of Michigan, Ann Arbor, MI (2) University of Michigan, Ann Arbor, MI

**PURPOSE:** Effective transitions of care activities are needed to improve health care delivery and cost. Patient-centered medical homes allow implementation of multi-disciplinary programs to target various threats to care quality. The objective of this study was to evaluate a multidisciplinary transitional care program to improve transitions to the community from hospital among older patients in a patient-centered medical home.

**METHODS:** A retrospective cohort study was conducted among patients discharged from a large, public, academic medical center over 30 months. The intervention cohort consisted of patients receiving the transitional care program, defined as a post-discharge pharmacist telephone follow-up and medical provider office visit with social work support within 30 days of discharge. The control group consisted of individuals not receiving the transitional care program. All patients were 60 years of age or older, discharged from health system's primary hospital, and discharged to home or assisted living. The primary outcome was rate of all-cause 30 day non-elective hospitalizations. Process measures and economic impact of the service were also assessed. Intervention patients were matched 1:5 to control patient on demographic and clinical characteristics.

**RESULTS:** One hundred and ninety-seven patients in the transitional care program cohort were matched to 985 patients in the control group, which contained 18,336 total unique subjects. Overall, patients receiving the transitional care program experienced a lower 30 day readmission rate compared to both unmatched (11.7% versus 18.1%,  $p = 0.22$ ) and matched (11.7% versus 21.9%,  $p = 0.01$ ) control groups. Among matched patients readmitted within 30 days, patients receiving the intervention experienced a longer time to readmission ( $18 \pm 8$  days with intervention versus  $12 \pm 8$  days with usual care, 95% CI 2–9 days,  $p = 0.003$ ). Hospitalization costs avoided was estimated to be over \$1600 per patient.

**CONCLUSION:** A clinic-based multidisciplinary transitional care program practice model reduced hospital readmissions and accompanying costs.

**88. What are the appropriate clinical pharmacy key performance indicators for hospital pharmacists?.** Olavo Fernandes, Pharm.D.<sup>1</sup>,

Sean Gorman, Pharm.D.<sup>2</sup>, Richard Slavik, Pharm.D.<sup>2</sup>, William Semchuk, Pharm.D.<sup>3</sup>, Douglas Doucette, Pharm.D.<sup>4</sup>, Heather Bannerman, Pharm.D.<sup>5</sup>, Jennifer Lo, Pharm.D.<sup>5</sup>, Simone Shukla, Pharm.D.<sup>5</sup>, Winnie Chan, Pharm.D.<sup>5</sup>, Natalie Benninger, Pharm.D.<sup>5</sup>, Neil MacKinnon, Ph.D.<sup>6</sup>, Chaim Bell, Ph.D.<sup>7</sup>, Jeremy Slobodan, B.Sc. Pharm.<sup>8</sup>, Catherine Lyder, MHA<sup>9</sup>, Peter Zed, Pharm.D.<sup>10</sup>, Kent Toombs, B.Sc. Pharm.<sup>11</sup>; (1) University Health Network, Toronto, ON, Canada (2) Interior Health Authority, Kelowna, BC, Canada (3) Regina Qu'Appelle Health Region, Regina, SK, Canada (4) Horizon Health Network, Moncton, NB, Canada (5) University of Toronto, Toronto, ON, Canada (6) University of Arizona, Tucson, AZ (7) Mount Sinai Hospital, Toronto, ON, Canada (8) Alberta Health Services, Red Deer, AB, Canada (9) Canadian Society of Hospital Pharmacists, Ottawa, ON, Canada (10) University of British Columbia, Vancouver, BC, Canada (11) Capital District Health Authority, Halifax, NS, Canada

**PURPOSE:** Key performance indicators are quantifiable measures of quality. There are currently no published, systematically-derived clinical pharmacy key performance indicators (cpKPI). A working group of Canadian hospital pharmacists aimed to develop national cpKPI to advance clinical pharmacy practice and improve patient care.

**METHODS:** A cpKPI working group systematically and sequentially established a cpKPI consensus definition, eight evidence-derived cpKPI critical activity areas, 26 candidate cpKPI, and 11 cpKPI ideal attributes in addition to one overall consensus criterion. Over a 3-month period, 26 clinical pharmacists and hospital pharmacy leaders participated in a 3-round modified Delphi survey. Using an Internet-based, pre-tested survey instrument, panelists independently rated the 26 candidate cpKPI using the 11 cpKPI ideal attributes and one overall consensus criterion on a 9-point Likert scale. A meeting was facilitated between rounds 2 and 3 to debate the merits of each candidate cpKPI and clarify wording. Consensus was reached if 75% or more of the panelists assigned a score of 7–9 on the consensus criterion during the third Delphi round.

**RESULTS:** All panelists completed the three Delphi rounds and 25/26 (96%) attended the meeting. Eight candidate cpKPI of activities performed by pharmacists met the consensus definition after the third Delphi round: (i) performing admission medication reconciliation (including best possible medication history); (ii) participating in inter-professional patient care rounds; (iii) completing pharmaceutical care plans; (iv) resolving drug therapy problems; (v) providing in-person disease and medication education to patients (vi) providing discharge patient medication education; (vii) performing discharge medication reconciliation; and (viii) providing bundled, proactive direct patient care activities.

**CONCLUSIONS:** A Delphi panel of hospital pharmacists was successful in determining eight consensus cpKPI. Measurement and assessment of these cpKPI, which are believed to be generalizable to other health systems, will serve to advance clinical pharmacy practice and improve patient care.

**89. Care transitions service: an inpatient pharmacy-driven medication reconciliation service.** John Togami, Pharm.D.<sup>1</sup>, Jessica Conklin, Pharm.D.<sup>2</sup>, Gretchen Ray, Pharm.D.<sup>2</sup>, Allison Burnett, Pharm.D.<sup>1</sup>, Melanie Dodd, Pharm.D.<sup>2</sup>; (1) Department of Pharmacy, University of New Mexico Hospitals, Albuquerque, NM

(2) College of Pharmacy, University of New Mexico, Albuquerque, NM

**PURPOSE:** Medication discrepancies often lead to medication errors at critical junctures such as care transitions. This study analyzed an ongoing inpatient pharmacy-driven care transitions service and its impact on the identification and resolution of medication related problems (MRP).

**METHODS:** The care transitions service at The University of New Mexico Hospital provides admission medication reconciliation to patients admitted to the Family Medicine service. Patients who received the service between November 2012 and March 2013 were included in the analyses. The sources of medication

verification, types of medication related problems and the associated medications, interventions and recommendations were documented.

**RESULTS:** Admission medication reconciliation was conducted on 191 patients during the 5-month evaluation period. Three sources, the electronic medical record (EMR), outpatient pharmacy and patient interview, were utilized for reconciliation 73% of the time. A total of 1140 MRP were identified with an average of six MRP per patient. Approximately 70% of MRP were resolved independently of provider review based on pharmacy-driven protocols. The remaining 30% of MRP required provider review or clarification. Patient non-adherence and patient-specific variables were the most common MRP identified. Cardiovascular, GI/GU and CNS agents comprised >50% of the medication classes associated with the MRP. Marital status, type of insurance, age, medications requiring monitoring and number of medications prior to reconciliation were patient-specific predictors of MRP.

**CONCLUSION:** Medication related problems are prevalent among hospitalized patients. Use of information sources beyond the EMR may be beneficial to verify medication lists. Most MRP were patient-related and several predictors were identified. The inpatient care transitions service effectively augmented provider efforts in identifying and resolving MRP. Future plans include exploring the feasibility of hospital-wide expansion of the service.

## Hematology/Anticoagulation

**90. Anticoagulation of thrombocytopenic cancer patients: safety and efficacy of reduced-dose low-molecular weight heparin.** *Larry K. Golightly, Pharm.D., BCPS<sup>1</sup>, Tyree H. Kiser, Pharm.D., FCCP, BCPS<sup>2</sup>, Katrina M. Babilonia, Pharm.D.<sup>3</sup>, Toby C. Trujillo, Pharm.D., BCPS (AQ Cardiology)<sup>4</sup>*; (1) Health Sciences Library/Center for Drug Information, Education, and Evaluation, Aurora, CO (2) University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO (3) University of Colorado Hospital, Aurora, CO (4) Department of Clinical Pharmacy, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO

**PURPOSE:** Cancer patients are at increased risk for thromboembolic complications. Current practice guidelines are discordant regarding preferred anticoagulation strategies for cancer patients with incidental thrombocytopenia. For these reasons, we evaluated outcomes associated with a reduced-dose low-molecular weight heparin protocol for management of venous thromboembolism in thrombocytopenic inpatients with cancer.

**METHODS:** Adult cancer patients hospitalized from September 2009 through March 2012 with abnormally low platelet counts ( $20-50 \times 10^9$  cells/L) who received anticoagulation with reduced-dose subcutaneous dalteparin 100 units/kg once daily were compared with a cohort of mildly or non-thrombocytopenic cancer patients who received standard-dose dalteparin 200 units/kg/day. The primary outcome was resolution or prevention of new extension of venous thromboembolism. The secondary outcome was presence of signs of overt or insidious hemorrhage.

**RESULTS:** A total of 56 patients (mean age  $56 \pm 15$  years) were evaluated; 32 thrombocytopenic patients (mean platelet count  $26 \pm 8.3 \times 10^9$  cells/L) received reduced-dose dalteparin and 24 patients without thrombocytopenia (mean platelet count  $124 \pm 75 \times 10^9$  cells/L) received standard-dose dalteparin. Aside from differences in platelet counts, patient groups were well matched for age, gender, types of cancer, hematological findings, and thromboembolic history. One patient in each group met evidentiary requirements for diagnosis of new-onset thromboembolism and failed anticoagulation ( $p=0.681$ ). The incidence of serious bleeding in thrombocytopenic patients who received reduced-dose dalteparin was statistically indistinguishable from that in patients without thrombocytopenia who received standard-dose dalteparin (6.2% and 4.1%, respectively;  $p=0.615$ ).

**CONCLUSIONS:** In this population of thrombocytopenic cancer patients, anticoagulation with reduced-dose low-molecular weight heparin was generally effective and safe.

**91. Bleeding outcomes in patients given clopidogrel within 5 days of robotic coronary artery bypass graft procedure.** *Sophia Vainrub, Pharm.D.<sup>1</sup>, Asad Patanwala, Pharm.D.<sup>1</sup>, Richard Cosgrove, Pharm.D.<sup>2</sup>, Robert Poston, M.D.<sup>3</sup>, Paul Nolan, Pharm.D.<sup>1</sup>*; (1) Department of Pharmacy Practice and Science, The University of Arizona (2) Department of Pharmacy Services, University of Arizona Medical Center (3) Department of Surgery, The University of Arizona

**PURPOSE:** The American Heart Association recommends that clopidogrel should be held for 5 days prior to coronary artery bypass graft procedure (CABG). However, it is unknown if this recommendation should apply to robotic CABG, which is less invasive because it does not involve sternotomy. The purpose of this study was to compare postoperative bleeding in patients who received clopidogrel within 5 days of robotic CABG, to those who did not.

**METHODS:** This was a retrospective cohort study conducted between January 1st, 2012 and December 31st, 2012. Consecutive patients who received a robotic CABG during this time period were included. Patients were categorized into two groups based on whether or not patients continued to receive clopidogrel within 5 days prior to surgery. The primary outcome measure was the occurrence of the Bleeding Academic Research Consortium (BARC) definition for CABG-related bleeding. The secondary outcome measure was a comparison of chest tube output during the first 24-hour postoperative period.

**RESULTS:** A total of 136 patients were included in the final analyses. Of these, 39 (29%) received clopidogrel within 5 days of surgery. There were no baseline differences in demographics or comorbidities between groups. The only exception being that smoking (26% versus 9%,  $p=0.026$ ) and prior percutaneous coronary intervention (97% versus 39%,  $p<0.001$ ) was more common in the clopidogrel group. CABG-related bleeding using the BARC definition occurred in 26% of patients who received clopidogrel and 8% of patients who did not ( $p=0.011$ ). Median chest tube output during the first 24-hour postoperative period was also greater in patients who received clopidogrel (900 versus 735 mL,  $p=0.002$ ).

**CONCLUSION:** The use of clopidogrel within 5 days of robotic CABG is associated with greater postoperative bleeding and chest tube output. Thus clopidogrel should be held for 5 days even in patients scheduled to receive robotic CABG.

**92. Efficacy of once daily enoxaparin for the prevention of venous thromboembolism in hospitalized obese patients.** *Carmen B. Smith, Pharm.D.<sup>1</sup>, Lena Maynor, Pharm.D.<sup>2</sup>, Jay L. Martello, Pharm.D., BCPS<sup>2</sup>*; (1) West Virginia University Healthcare, Morgantown, WV (2) West Virginia University School of Pharmacy, Morgantown, WV

**PURPOSE:** Enoxaparin is commonly used as thromboprophylaxis at fixed doses in medical patients and has been shown to be both effective and safe at reducing the risk of venous thromboembolism (VTE). However, obese patients are underrepresented in these thromboprophylaxis studies. A weight based regimen of 0.5 mg/kg enoxaparin has been suggested, but is based on pharmacokinetic data in a small population. This study aimed to evaluate clinical outcomes of a fixed dose of enoxaparin 40 mg once daily in obese patients compared to non-obese patients by determining the difference in VTE incidence.

**METHODS:** Medical records of patients who received enoxaparin 40 mg daily between 01/01/2012 and 12/31/2012 were reviewed. Patients were assigned to one of two groups based on body mass index (BMI): obese ( $BMI \geq 30 \text{ kg/m}^2$ ) and non-obese ( $BMI < 30 \text{ kg/m}^2$ ). Inclusion criteria: age  $\geq 18$  and receipt of enoxaparin 40 mg daily. Exclusion criteria: chronic anticoagulation, known VTE or bleeding event on admission.

**RESULTS:** A total of 3797 patients were included ( $n=2247$  for non-obese,  $n=1550$  for obese). The mean BMI was  $24 \text{ kg/m}^2$  in the non-obese group versus  $38 \text{ kg/m}^2$  in the obese group ( $p<0.001$ ). No significant difference in VTE incidence was seen in obese patients compared to non-obese patients (0.9% versus 1.3%,  $p=0.28$ ). When stratified by VTE risk category of high, medium and low the difference in VTE incidence between BMI

groups remained non-significant. The use of sequential depression devices (SCD) in combination with enoxaparin did not differ between groups. No differences in VTE events were seen between BMI groups on enoxaparin alone versus enoxaparin plus SCD ( $p=0.2$  and  $p=0.8$ , respectively).

**CONCLUSION:** Rates of VTE did not differ between obese and non-obese patients suggesting that the use of fixed dose enoxaparin may be sufficient thromboprophylaxis in hospitalized obese patients. Additional prospective studies are needed.

## Herbal/Complementary Medicine

### 93. Evaluating the effects of krill oil, supplemental fish oil, and prescription fish oil on lipoproteins and gastrointestinal symptoms – a randomized controlled trial.

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**PURPOSE:** Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are approved for lowering triglyceride (TG) levels. Commercially available sources include prescription and supplemental fish oil (FO) and krill oil (KO). KO provides less EPA+DHA per capsule compared to FO but may be more bioavailable and better tolerated. We evaluated the effects of KO, prescription FO, and supplemental FO on major lipid/lipoprotein levels (total cholesterol [TC], low-density lipoprotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C], TG, and non-HDL-C), and gastrointestinal (GI) symptoms.

**METHODS:** Thirty subjects (N=10/arm) were randomized to KO (Arctic Pure<sup>®</sup>, Source Naturals; eight capsules, 960 mg EPA+DHA), prescription FO (Lovaza<sup>®</sup>, GSK; four capsules, 3360 mg EPA+DHA), or a supplemental FO (Triple Strength FO<sup>®</sup>, Spring Valley; four capsules, 3340 mg EPA+DHA) in a 6 weeks, open-label, parallel design study. Lipid/lipoproteins and GI symptoms (heartburn, belching, fishy aftertaste) were assessed at baseline and end of study. Due to differing EPA+DHA doses, changes in lipid/lipoproteins were analyzed by per gram of EPA+DHA consumed/day.

**RESULTS:** Baseline characteristics were similar between groups, except TG were significantly higher in the supplemental FO group. Other than LDL-C, no changes were significant per gram of EPA+DHA between groups (Table). GI symptoms were similar between groups, but fishy aftertaste was significantly higher with supplemental FO ( $p=0.005$ ).

	KO (0.96 g EPA +DHA/day)	Prescription FO (3.36 g EPA +DHA/day)	Supplemental FO (3.34 g EPA +DHA/day)
Percent change per gram EPA+DHA (Mean±SD)			
TC	4 ± 13	0 ± 4	1 ± 4
LDL-C	7 ± 12	1 ± 4*	4 ± 8
HDL-C	7.9 ± 9.7	2.2 ± 3.75	1.9 ± 4.3
TG**	3 ± 19	-9 ± 8	-8 ± 6
Non-HDL-C	3 ± 15	0 ± 5	0 ± 5

\*Different than KO ( $p \leq 0.05$ ) \*\*Outlier removed for analysis.

**CONCLUSIONS:** KO was well tolerated but raised LDL-C significantly compared to prescription FO; supplemental FO produced similar lipid/lipoprotein effects as KO and prescription FO but had a fishy aftertaste. Larger trials comparing these agents are needed to confirm the effects seen in this pilot study.

### 94. Hemodynamic and electrocardiographic effects of acai berry in healthy volunteers: a randomized controlled trial.

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University of Connecticut School of Pharmacy, Storrs, CT (2) Hartford Hospital, Hartford, CT

**PURPOSE:** To evaluate the effects of acai berry on electrocardiographic parameters, blood pressure, and heart rate in healthy volunteers.

**METHODS:** This was a randomized, double-blind, placebo-controlled crossover study conducted at a university campus. Individuals at least 18 years of age and in general good health were enrolled. Following a 24-hour abstinence from caffeine intake, subjects were randomized to receive either a single dose of acai berry 1000 mg or a matching placebo. Each subject had a 12-lead electrocardiogram (ECG), blood pressure (BP; both seated and standing), and heart rate (HR) recorded before study drug ingestion (baseline) and at 1, 2, 4, and 6 hours after ingestion. Following at least a 7-day washout period, subjects were given the alternate study drug and had the measurements repeated. Electrocardiographic variables (PR, QRS, QT, and RR intervals) were manually derived by a single blinded study investigator, with the QTc determined using the Fredericia and Bazett's formulas. The maximal post-ingestion values, irrespective of time point, for each variable were compared between groups.

**RESULTS:** Thirteen females and 10 males were enrolled in the study. Mean ± standard deviation (SD) baseline seated standing blood pressures were  $119.8 \pm 10.2/73.3 \pm 9.1$  mmHg for the placebo arm and  $121.1 \pm 11.2/73.6 \pm 9.7$  mmHg for the acai berry arm. No significant differences in BP or HR were seen between the groups. Individuals receiving acai berry had a significantly shorter maximal QTc interval (Fredericia) versus placebo ( $340.4 \pm 42.2$  versus  $361.8 \pm 39.2$  milliseconds;  $p=0.008$ ), a result also seen when Bazett's formula was used. No adverse events were reported by any study participant.

**CONCLUSIONS:** A single dose of acai berry had a lower mean maximal QTc interval versus placebo with no significant change in BP, HR or other ECG variables seen.

## HIV/AIDS

### 95E. Ninety-six-week efficacy and safety of elvitegravir/cobicistat/emtricitabine/tenofovir DF – subgroup analyses by baseline HIV-1 RNA and CD4 cells.

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**PURPOSE:** Elvitegravir/cobicistat/emtricitabine/tenofovir DF (STB) demonstrated noninferiority at Week 48 to efavirenz/emtricitabine/tenofovir DF (ATR) (Study 102) and to ritonavir-boosted atazanavir (ATV/r) plus emtricitabine/tenofovir DF (TVD) (Study 103) with consistent efficacy across wide ranges of baseline HIV-1 RNA and CD4 cells in treatment naive patients. We report the integrated Week 96 data.

**METHODS:** Integrated analyses of efficacy and safety of two randomized, double blind, double dummy, active-controlled phase 3 clinical studies with subgroup analyses of efficacy by HIV disease characteristics.

**RESULTS:** Thousand four hundred and eight patients were randomized and treated (STB 701; ATR 352; ATV/r+TVD 355). High rates of virologic suppression (HIV-1 RNA < 50 c/mL) were maintained through Week 96 (84% versus 82% versus 82%). These findings were consistent across ranges of baseline HIV-1 RNA and CD4 cells (Table). Eleven of 19 STB patients with baseline CD4  $\leq 50$  cells/mm<sup>3</sup> achieved virologic suppression at Week 96; the remaining eight were considered nonsuppression due to premature discontinuation. Fewer STB patients, compared to ATR, reported all grade neuropsychiatric AEs (44% versus 66%;  $p < 0.001$ ) and rash AEs (21% versus 31%;  $p = 0.001$ ). Rates



of adverse events (AEs) leading to study drug discontinuation were similar in the three groups (5% versus 7% versus 6%), as were those of serious AEs (13% versus 9% versus 14%), and deaths (0.1% versus 0.6% versus 0.8%). Median changes in SCr (mg/dL) at Week 96 in three groups (+0.13 versus +0.01 versus +0.08) were unchanged from Week 48 (+0.13 versus +0.01 versus +0.08). STB had smaller median increase (mg/dL) in total and HDL cholesterol (versus ATR) (+12 versus +18;  $p=0.001$ ; +6 versus +8,  $p=0.002$ ) and smaller increase in triglycerides (versus ATV/r+TVD) (+4 versus +16;  $p=0.003$ ).

**CONCLUSION:** Through Week 96, STB demonstrated high rates of virologic suppression with a satisfactory safety profile. The efficacy of STB was consistent across wide ranges of baseline HIV-1 RNA and CD4 cell counts. Presented at Conference on Retroviruses and Opportunistic Infections; Atlanta, GA; March 3–6, 2013.

**96. Evaluation of the occurrence of antiretroviral and opportunistic prophylaxis medication errors within the inpatient setting.** Thomas Chiampas, Pharm.D., Melissa E. Badowski, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** Previous incidence rates of inpatient antiretroviral (ARV) and opportunistic infection (OI) medication errors have been as high as 77% of patients with an average of 1.75–2.7 errors/patient. The purpose of this research was to determine the causes and occurrence of inpatient ARV and OI med errors at our institution.

**METHODS:** This was a retrospective, chart review of HIV/AIDS patients, documented by ICD-9 code, admitted to our institution over 15 months. Pill burden, non-formulary (NF) status, specific ARV and OI medications, presence of a clinical pharmacist on service, and day and month of admission were compared to total number of errors, error types, and whether or not the error was corrected. Statistical methods used averages, descriptive statistics, and Spearman rank correlation.

**RESULTS:** Of 344 patients included, 132 experienced 190 med errors (1.44 errors/patient, range 1–4) based on their admission ARV/OI medications. Increased error rates were correlated in those with a higher pill burden (mean=4.4 pills/patient, range 1–10,  $p<0.0001$ ,  $r = 0.23$ ) and receiving at least 1 NF med ( $n=193$ ,  $p<0.025$ ,  $r = 0.12$ ). No difference in error occurrences was identified in services with a clinical pharmacist or day or month of admission. The most common errors were omitted or incomplete orders occurring in 51 patients and incorrect schedule occurring in 47 patients. Of 166 patients requiring OI prophylaxis, 37 patients experienced 39 OI errors. Any type of *Pneumocystis jirovecii* prophylaxis error accounted for 30 of 39 OI errors. Omission of OI prophylaxis occurred in 27 patients. Overall, 45 of 190 errors were corrected.

**CONCLUSION:** Compared with other data, our institution experienced similar incidence and fewer patient error rates. Being on a NF medication and higher pill burden were associated with increased errors. Omitted orders occurred most frequently. When a medication error occurred, it went uncorrected more than 75% of the time.

**97. Predictors of glycemic control among HIV-positive veterans with diabetes.** Marie Davies, Pharm.D., MSCR<sup>1</sup>, Melissa Johnson, Pharm.D., MHS, AAHIVP<sup>2</sup>, Jamie Brown, Pharm.D., BCPS<sup>3</sup>, Mary Townsend, Pharm.D., AAHIVP<sup>4</sup>; (1)Durham VA Medical Center, Durham, NC (2)Duke University Medical Center, Durham, NC (3)Pharmacy Service, Durham VA Medical Center, Durham, NC (4)Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC

**PURPOSE:** With the advent of antiretroviral therapy (ART), human immunodeficiency virus (HIV)-related morbidity and mortality has decreased. As these patients continue to age, adverse effects related to extended use of ART such as hyperglycemia and diabetes are increasing. The purpose of this study is to determine if there is a correlation between HIV and diabetes control and its association to ART adherence.

**METHODS:** This was an IRB-approved, single-center, retrospective study in veterans with diabetes and HIV-infection from 2007 to 2012. Patients had to be on the same ART and anti-diabetic medication regimen for  $\geq 3$  months. We assessed the correlation between HIV RNA viral load and A1c, CD4 count and A1c, proportion of subjects achieving an A1c goal  $< 7\%$ , A1c outcomes according to ART and anti-diabetic medications received, and the correlation between ART adherence and A1c outcomes. Statistical analysis included the use of linear regression and chi squared test of association.

**RESULTS:** We identified 56 patients with concomitant HIV-infection and diabetes. For each unit increase in  $\log_{10}$  viral load, A1c increased 0.67 units ( $p=0.0085$ ). There was no correlation between CD4 count and A1c. Overall, 50% of patients were at A1c goal. Only 38% of patients on a protease inhibitor (PI)-based regimen versus 56% of patients not on a PI, were able to achieve A1c goal ( $p=0.1864$ ). In addition, patients on an insulin-based regimen were less likely to be at A1c goal ( $p=0.018$ ). When assessing adherence to ART, patients that were  $< 95\%$  adherent were significantly less likely to reach A1c goal ( $p=0.0378$ ).

**CONCLUSION:** Patients with higher viral loads were more likely to have a higher A1c. Additionally, patients that were less adherent to ART were more likely to have a higher A1c. This demonstrates that poor adherence to ART leads to poor control of both disease states.

**98E. Simplification to abacavir/lamivudine (ABC/3TC) + atazanavir (ATV) from tenofovir/emtricitabine (TDF/FTC) + ATV/ritonavir (r) maintains viral suppression and improves bone biomarkers: 48 weeks ASSURE study results.** David A. Wohl, M.D.<sup>1</sup>, Laveeza Bhatti, M.D., Ph.D.<sup>2</sup>, Catherine B. Small, M.D.<sup>3</sup>, Howard E. Edelstein, M.D.<sup>4</sup>, Henry Zhao, Ph.D.<sup>5</sup>, David A. Margolis, M.D.<sup>5</sup>, Lisa L. Ross, M.S.<sup>5</sup>, Mark S. Shafer, Pharm.D.<sup>6</sup>;

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**PURPOSE:** ART simplification in HIV-infected, virologically suppressed patients may minimize long-term adverse effects and costs.

**METHODS:** ASSURE is an open-label, multicenter study of patients with HIV RNA  $< 75$  c/mL,  $\geq 6$  months' treatment with TDF/FTC +ATV/r as last regimen and eGFR  $\geq 50$  mL/min. Patients were randomized 2:1 to ABC/3TC + ATV or continue TDF/FTC + ATV/r.

**RESULTS:** Two hundred and ninety-six patients enrolled; 253/296 (85%) completed 48 weeks. Baseline (BL) demographics: median age 44 years; 79% male; 60% white; median HIV RNA  $< 40$  c/mL; median CD4 + 492 cells/mm<sup>3</sup>; demographics were similar between arms. The study met the primary endpoint demonstrating non-inferiority at 24 weeks.

Wk 48 Results (ITT-E Population)	ABC/3TC + ATV N=199	TDF/FTC + ATV/r N=97	p-value
HIV RNA $< 50$ TLOVR, n (%)	152 (76.4%)	77 (79.4%)	0.564 <sup>a</sup>
Protocol defined confirmed VF (cVF), n (%)	4 (2%)	1 (1%)	ND
Median CD4 + (cells/mm <sup>3</sup> ) change from BL (Q1, Q3)	90 (3, 181)	47 (-32, 121)	<b>0.026<sup>b</sup></b>
Median eGFR (MDRD) change from BL (Q1, Q3)	0.8 (-6, 7.8)	-1.3 (-6.2, 8.4)	0.5.66 <sup>b</sup>
Any drug-related Grade 2–4 AE from BL to Wk 48	17 (9%)	6 (6%)	0.645 <sup>c</sup>

<sup>a</sup>CMH test stratified by initial ART regimen; 95% CI (-13.0, 7.0); <sup>b</sup>Wilcoxon rank-sum test; <sup>c</sup>Fisher's exact test.

Bone biomarkers alkaline phosphatase, c-telopeptide, osteocalcin, parathyroid hormone and renal urine  $\beta 2$  microglobulin/creatinine ratio all declined significantly ( $p<0.001$ ) from BL for ABC/3TC + ATV arm, with no significant change for TDF

/FTC + ATV/r arm. Serum calcium remained stable while 25 (OH) Vit D declined slightly (4 ng/mL) but significantly in ABC/3TC arm. No significant change from BL was seen by treatment group for hsCRP, IL-6 or D-Dimer.

**CONCLUSION:** Simplification to ABC/3TC+ATV from an ATV/r-containing regimen maintained viral suppression, was well-tolerated, and led to improvements in specific bone and renal biomarkers through 48 weeks. Presented at to be Presented at Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10–13 2013.

**99. Adherence to antiretroviral therapy and the association with treatment experience among commercially insured and Medicaid HIV patients in the United States.** Jennifer Korsnes, MS<sup>1</sup>, Bridgett Goodwin, MS<sup>2</sup>, Sean Candrilli, Ph.D.<sup>1</sup>; (1) RTI Health Solutions, Research Triangle Park, NC (2) GlaxoSmithKline, Research Triangle Park, NC

**PURPOSE:** Achieving optimal outcomes in the treatment of HIV requires a high, sustained level of medication adherence to antiretroviral therapy (ART). Factors thought to affect treatment adherence include patient characteristics and treatment experience with ART. The objective of this study is to document differences in ART adherence according to patient population (i.e., US commercially insured or Medicaid) and treatment experience (i.e., treatment-naïve or treatment-experienced).

**METHODS:** Commercially insured and Medicaid patients in the US from the MarketScan claims databases with  $\geq 2$  diagnoses of HIV/AIDS between 6/1/2006 and 12/31/2011 who received an ART prescription between 6/1/2007 and 12/31/2010 were selected for initial study inclusion. For each patient, an index date was designated upon receipt of the initial ART prescription during that time. All patients were required to be  $\geq 18$  years of age on their index date and have  $\geq 12$  months of continuous health plan enrollment with drug benefits before and after their index date. Adherence was measured by patients' proportion of days covered (PDC) with a complete ART regimen during the 12-month post-index date period; patients with PDC  $\geq 80\%$  were considered adherent. Logistic regression models were estimated to assess the relationship between previous treatment exposure and adherence while controlling for demographic and clinical characteristics.

**RESULTS:** Of the 14,590 commercially insured patients who met inclusion criteria, 42% were treatment-naïve, 58% were treatment-experienced, and 59% achieved  $\geq 80\%$  adherence. Of the 5744 Medicaid patients who met inclusion criteria, 31% were treatment-naïve, 69% were treatment-experienced, and 42% achieved  $\geq 80\%$  adherence. After adjusting for confounders (e.g., baseline demographics and clinical characteristics), treatment-experienced patients were more likely to be adherent than treatment-naïve patients, among commercially insured (odds ratio [OR] = 1.30;  $p=0.0001$ ) and Medicaid patients (OR = 2.19;  $p<0.0001$ ).

**CONCLUSION:** After controlling for potential confounding factors, treatment-experienced patients had better adherence to ART, among commercially insured and Medicaid patients.

**100. Burden of illness among United States veteran treatment naïve human immunodeficiency virus infected patients.** Li Wang, MA, MBA, Ph.D.<sup>1</sup>, Seema Haider, M.Sc.<sup>2</sup>, Katherine Nedrow, MPH<sup>3</sup>, Richard Chambers, MSPH<sup>4</sup>, Margaret Tawadrous, M.D.<sup>2</sup>, Onur Baser, MS, Ph.D.<sup>5,6</sup>, Kit Simpson, DrPH<sup>7</sup>; (1) STATinMED Research, Dallas, TX (2) Pfizer, Inc. (3) East Coast Primary Care Inc. (4) Pfizer, Inc. (5) STATinMED Research, Ann Arbor, MI (6) The University of Michigan, Ann Arbor, MI (7) Department of Health Leadership and Management College of Health Professions, Medical University of South Carolina, Charleston, SC

**PURPOSE:** Few treatment-naïve human immunodeficiency virus (HIV) population-based cost analyses have been completed utilizing the Veterans Health Administration (VHA) population.

**METHODS:** US patients ( $\geq 18$  years) with an HIV diagnosis between 01 June 2007 and 31 May 2012 were selected from the VHA Medical SAS<sup>®</sup> datasets. Continuous eligibility at least 12 months pre- and post-index date (first HIV diagnosis date)

with no antiretroviral therapy (ART) prescription claims within 180 days pre-index date were required. At least one baseline CD4 count or HIV viral load measured within 3 months after HIV diagnosis date, or one ART anchor drug (non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitor (PI), integrase strand transfer inhibitor (INSTI) and CCR5 antagonist-based ART regimens) pharmacy claim post-index date were required. Follow-up 12 months all-cause healthcare costs and utilizations were evaluated. Propensity score matching (PSM) was used to adjust for baseline differences.

**RESULTS:** 11,371 treatment-naïve patients (mean age 50) were enrolled. Majority enrolled were male (95%) and non-Hispanic black (52%). Among patients with laboratory claims (CD4 count: N=4491; Viral load: N=3049), 14% had CD4 counts  $< 100$  cells/mm<sup>3</sup> and 21% had viral loads  $> 100,000$  copies/mL. PSM-adjusted total costs for patients with CD4 cell counts  $\leq 50$  cells/mm<sup>3</sup> or viral loads  $> 100,000$  copies/mL were significantly higher than all other CD4 cell count groups or viral load strata ( $p$ -values  $< 0.001$ ). Patients prescribed efavirenz incurred higher ART-related (\$8663 versus \$2846,  $p$ -value = 0.0266), but lower non-ART-related pharmacy costs (\$2339 versus \$6627,  $p$ -value=0.0042) than non-efavirenz treated patients. NNRTI-based cohort incurred lower total costs compare to PI-based cohort (\$32,829 versus \$39,073,  $p$ -value = 0.0005). There were no significant differences in total costs between NNRTI and INSTI cohorts.

**CONCLUSION:** Treatment-naïve HIV patients with lower CD4 cell count or higher viral load values incurred higher follow-up inpatient and total costs. NNRTI-based therapy incurred lower costs compared to PI-based therapy but overall costs were not significantly different between NNRTI and INSTI-based regimens.

**101E. Dolutegravir treatment response by baseline viral load and NRTI backbone in treatment naïve HIV infected individuals.** Joe Eron, M.D.<sup>1</sup>, Jurgen Rockstroh, M.D.<sup>2</sup>, Anton Pozniak, M.D.<sup>3</sup>, Julian Elliott, M.D.<sup>4</sup>, Catherine B. Small, M.D.<sup>5</sup>, Marc Johnson, M.D.<sup>6</sup>, Clare Brennan, DPT, MSPH<sup>7</sup>, Keith Pappa, Pharm.D.<sup>7</sup>, Robert Cuffe, MS<sup>8</sup>; (1) University of North Carolina at Chapel Hill, Chapel Hill, NC (2) University of Bonn, Bonn, Germany (3) Chelsea and Westminster Hospital, London, United Kingdom (4) The Alfred Hospital, Melbourne, Vic., Australia (5) New York Medical College, Valhalla, NY (6) Carolinas Medical Center, Charlotte, NC (7) GlaxoSmithKline (8) ViiV Healthcare

**PURPOSE:** In two 48 weeks studies in naïve subjects, dolutegravir with NRTI of choice has shown non-inferiority to raltegravir and, with ABC/3TC, superiority to Atripla. Factors that influenced choice of NRTIs included viral load, resistance and safety.

**METHODS:** Response rates and time to virologic failure by NRTI backbone and baseline viral load were analyzed. SPRING-2 randomised participants to DTG 50 mg QD or RAL 400 mg BID, in combination with either TDF/FTC or ABC/3TC. SINGLE randomised participants to DTG 50 mg + ABC/3TC QD or TDF/FTC/EFV QD. In SPRING-2, changes in serum creatinine were examined by INI and NRTI backbone.

**RESULTS:** The two studies treated 1655 subjects, 249 (15%) female, 388 (23%) non-white, 495 (30%) had HIV-1 RNA  $> 100,000$  c/mL, and 224 (14%) had CD4 count  $< 200$  cells/mm<sup>3</sup>. Subject Percentage with HIV-1 RNA  $< 50$  c/mL at Week 48 Primary analyses demonstrated non-inferiority of DTG to RAL in SPRING-2 ( $\Delta = 2.5\%$ ; 95% CI:  $-2.2\%$  to  $+7.1\%$ , excluding  $-10\%$ ), and superiority of DTG regimen in SINGLE (7.4%;  $+2.5\%$  to  $+12.3\%$ ). In SPRING-2, NRTI backbone response rates were comparable by viral load stratum. In SINGLE, there was a 7% difference in response (favoring DTG + ABC/3TC) in each viral load stratum. In SPRING-2, no significant differences were observed in serum creatinine change from baseline to Week 48 by NRTI backbones.

**CONCLUSION:** In SPRING-2 and SINGLE, DTG was effective with both ABC/3TC and TDF/FTC, and in subjects with high and low viral load. DTG was well tolerated in both studies. Renal safety also was similar by NRTI backbone. Presented at Presented at Eleventh International Congress on Drug Therapy in HIV Infection 11–15 November 2012 Glasgow, UK.

Subject Percentage with HIV-1 RNA &lt;50 c/mL at Week 48

	SPRING-2		SINGLE	
	DTG	RAL	DTG	EFV
OVERALL	361/411 (88%)	351/411 (85%)	364/414 (88%)	338/419 (81%)
<100,000 c/mL ABC/3TC	115/132 (87%)	110/125 (88%)	253/280 (90%)	
TDF/FTC	152/165 (92%)	154/170 (91%)		238/288 (83%)
>100,000 c/mL ABC/3TC	30/37 (81%)	32/39 (82%)	111/134 (83%)	
TDF/FTC	64/77 (83%)	55/77 (71%)		100/131 (76%)

### 102. Evaluating human immunodeficiency virus (HIV) screening and OraQuick® in-home HIV test knowledge: a survey of New Mexico pharmacists.

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**PURPOSE:** This study assessed the knowledge of HIV, HIV screening, and OraQuick® In-Home HIV Test of community pharmacists in the state of New Mexico.

**METHODS:** A cross-sectional survey of attendees at the New Mexico Pharmacists Association (NMPHA) 2013 Mid-Winter Meeting. The survey was an eighteen-item questionnaire, and data were captured using audience response technology.

**RESULTS:** Of the 168 participants, 87 identified themselves as community/clinic pharmacists. A total of 56/86 (65.1%) correctly recognized the minimum number of antiretrovirals required for an ideal HIV treatment regimen. Seventy-five of 86 (87.2%) responded correctly to the item asking how HIV antiretroviral medications work. Seventy of 83 (84.3%) respondents correctly identified known sources of HIV infection. Adequate knowledge threshold was not met on any HIV screening or OraQuick® In-Home HIV Test knowledge items. Pharmacists 50 years of age or younger had higher correct response rates on all 11 knowledge items, and significance was noted on six items when compared to pharmacists older than 50 years of age: how antiretrovirals work (95.2% versus 80.5%,  $p=0.048$ ); screening recommendations (27.9% versus 10.3%,  $p=0.044$ ); OraQuick® FDA approval (73.2% versus 45.0%,  $p=0.010$ ); specimen requirements (60.5% versus 31.7%,  $p=0.008$ ); repeat testing (46.5% versus 19.5%,  $p=0.009$ ); and result interpretation (25.6% versus 7.3%,  $p=0.025$ ).

**CONCLUSIONS:** New Mexico community pharmacists who attended the NMPHA 2013 Meeting possess adequate basic HIV/AIDS knowledge, but have limited HIV screening or OraQuick® In-Home Test knowledge. Future educational interventions aimed at improving pharmacists' knowledge in these areas are warranted.

### 103. Exploratory survey of Florida pharmacists' experience with, knowledge of, and perceptions about HIV pre-exposure prophylaxis.

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**PURPOSE:** To assess Florida pharmacists' experience with, knowledge of, and perceptions about HIV Pre-Exposure Prophylaxis (PrEP) and identify areas for pharmacist training.

**METHODS:** A cross-sectional anonymous survey was distributed to Florida pharmacists online and in person.

**RESULTS:** Survey respondents ( $n=170$ ) were predominately community pharmacists with mean age of 47.3 years and at least 20 years of experience. Pharmacists self-identified as non-HIV specialists (86%), white non-Hispanic (69%) and having fewer

than 10% HIV-positive patients. Most pharmacists lacked PrEP experience reporting no patient (82%) or provider (84%) inquiries and never dispensed a PrEP prescription (78%). While 54% of pharmacists surveyed were aware of the FDA approval of tenofovir/emtricitabine for PrEP, a majority were unaware of CDC PrEP guidelines, and 73% felt they did not have sufficient knowledge to counsel patients with PrEP prescriptions. About half of pharmacists answered they were comfortable counseling patients about PrEP (51%), but behavioral modification counseling was identified as an area of least comfort. When asked to rank their level of agreement, most pharmacists agreed PrEP would lead to risky behavior (68%), increased rates of sexually transmitted infections (63%), and also agreed that it is too costly to promote patient access (92%).

**CONCLUSION:** Surveyed Florida pharmacists self-reported little experience with PrEP and a lack of knowledge about PrEP prescription counseling. Pharmacists felt least comfortable discussing behavioral risk reduction strategies with patients and believed use of PrEP encourages risky behaviors and the sequelae that follow. Florida pharmacists would benefit from PrEP educational programs to dispel misconceptions and enhance behavior modification counseling skills.

## Infectious Diseases

### 104. Beta-lactam/beta-lactamase inhibitors versus carbapenems for the treatment of urinary tract infections caused by extended-spectrum beta-lactamase-producing bacteria: a retrospective cohort study.

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**PURPOSE:** There has been an increase prevalence of extended-spectrum beta-lactamase (ESBL)-producing Enterobacteriaceae in Singapore. Carbapenems are commonly used to treat infections caused by these organisms. However, the increased usage may result in selection of carbapenem-resistant strains. Beta lactam/beta-lactamase inhibitors (BLBLIs) could be options for treating urinary tract infections (UTIs) caused by ESBL organisms.

**METHODS:** A retrospective cohort study included patients diagnosed with the first episode of UTI caused by an ESBL-producing Enterobacteriaceae showing susceptibility to both carbapenems and BLBLIs. Outcomes studied were clinical response, microbiological clearance, length of hospitalization, in-hospital mortality and reinfection or recurrence rates.

**RESULTS:** A total of 511 patients with positive urine cultures were identified. However, the majority were excluded as patients were asymptomatic, had concomitant infections or because cultures were polymicrobial. Fifty four patients were included in the study; fifteen (27.8%) received carbapenems, while 39 (72.2%) received BLBLIs. Most were female, with a median age of 76.5 years old. The majority had pyelonephritis, and grew ESBL-producing *Escherichia coli*. The baseline characteristics did not differ significantly between the two groups. The median duration of antibiotics use was 7 days for carbapenem patients versus 9 days for the BLBLI group. All patients showed clinical response to treatment and survived. Most patients did not have follow-up urine cultures to document clearance. For those who did, microbiological clearance within 1 week of definitive treatment (carbapenem: 4/5 [80.0%] versus BLBLI: 8/12 [66.7%],  $p=1.000$ ) and overall microbiological cure without reinfection or recurrence (5/5 [100.0%] versus 12/12 [100.0%],  $p=1.000$ ) did not differ between groups. There was also no significant difference in



length of hospitalization (carbapenem: 13 days [inter-quartile range 8–18 days] versus 9 [6–14],  $p=0.070$ ).

**CONCLUSION:** This study suggests that treatment of UTIs caused by ESBL-producing organisms with BLBLIs, as compared to carbapenems, did not result in worsening of outcomes.

**105. Effects of early switching from intravenous to oral antibiotics on the outcomes of patients with bacteremia secondary to urinary tract infections.** *Wei Xiang Tong, B.Sc.*; Department of Pharmacy, Changi General Hospital, Singapore, Singapore

**PURPOSE:** Urinary tract infection (UTI) with gram-negative bacilli is common and bacteremia (with the same causative pathogen in blood cultures) complicating this infection is frequently seen. Duration of antimicrobial therapy for bacteremic patients is usually 14 days. In these cases, clinicians often prefer the parenteral route of administration. Early intravenous (IV) to oral switch has been shown to reduce risks of line infection, length of stay in hospitals as well as increase comfort level and mobility of patients. This project aims to evaluate the clinical outcomes of early switching from IV to oral antibiotics in patients with bacteremia secondary to UTI.

**METHODS:** Medical records of patients with bacteremia secondary to UTI were identified from the Antimicrobial Stewardship Programme (ASP) database and reviewed. Early switching in this study was defined as time to switch to oral antibiotics within the first 7 days of treatment. Mann-Whitney U test was used to evaluate the length of stay between the two groups and chi-squared test to evaluate the odds ratio of clinical complications and 30-day readmission in these groups.

**RESULTS:** Ninety-eight patients with bacteremia secondary to UTI were identified. Early switching in bacteremia secondary to UTI patients was shown to have significantly shorter duration of stay (median: 6 versus 12 days) in hospital ( $p<0.01$ ). Odds ratio for clinical complications in early switch group was 1.58 (95% CI 0.30–8.28), and for 30-day readmission was 0.75 (95% CI 0.12–4.72). They were both insignificant with  $p=0.714$ , and  $p=0.759$  respectively.

**CONCLUSION:** Early switching from IV to oral antibiotics has advantages in terms of length of stay. It does not however, confer benefits or disadvantages in terms of clinical complications. Evaluation on more variables such as mortality and monetary costs may be needed in a larger population group.

**106E. Antibiotic exposure among heart failure and pneumonia dual diagnosis patients: a descriptive analysis.** *Mary Vacha, Pharm.D.<sup>1</sup>*, Stacey Friedman, Pharm.D.<sup>2</sup>, Ryan Dull, Pharm.D.<sup>3</sup>, Dave Schmidt, Pharm.D.<sup>1</sup>; (1)Alegent Creighton Health, Omaha, NE (2)Creighton University School of Pharmacy and Health Professions, Omaha, NE (3)Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** The purpose of this study was to determine antibiotic exposure in heart failure (HF) and pneumonia dual diagnosis patients admitted to our institution's intensive care units (ICU).

**METHODS:** Electronic medical record (EMR) of patients admitted to an ICU between September and November 2011 with a diagnosis of HF and pneumonia were reviewed. Antibiotic exposure was defined using duration of antibiotic therapy, days of therapy per 1000 patient days, and antibiotic-free days. Patients were considered to have minimal clinical findings suggestive of bacterial infection if at least two of the following three criteria were not documented in the EMR: fever, sputum production, and white blood cell count more than 12,000 cells/ $\mu$ L. Descriptive statistics were used for continuous and nominal variables.

**RESULTS:** Eighty-one patients were reviewed and 19 met the inclusion criteria. Mean ( $\pm$ SD) age and APACHE II score were 78.9 years ( $\pm$ 11.9) and 19 ( $\pm$ 7.6), respectively. Thirteen (68%) patients had minimal clinical findings suggestive of bacterial infection documented in the EMR. Median (IQR) duration of therapy while hospitalized and days of therapy per 1000 patient

days were 6 days (4–8) and 2000 days of therapy/1000 patient days (1667–2250), respectively. Median (IQR) antibiotic-free days was 0 days (0–1).

**CONCLUSION:** Baseline antibiotic exposure for HF and pneumonia dual diagnosis patients admitted to our ICU includes a median of 0 antibiotic-free days. Approximately two-thirds of patients with minimal clinical findings suggestive of bacterial infection were administered antibiotics. Interventions that improve differential diagnosis could be useful for antimicrobial stewardship within this institution. These results may be used to evaluate the effectiveness of future interventions aimed at reducing antibiotic exposure.

Presented at the Midyear Clinical Meeting of the American Society of Health System Pharmacists, Las Vegas, NV, December 2–6, 2012.

**107. An economic model comparing linezolid and vancomycin for treatment of confirmed methicillin-resistant *Staphylococcus aureus* nosocomial pneumonia.** *Dipen A. Patel, Ph.D.<sup>1</sup>*, Andrew F. Shorr, M.D.<sup>2</sup>, Jean Chastre, M.D.<sup>3</sup>, Michael Niederman, M.D.<sup>4</sup>, Andrew Simor, M.D.<sup>5</sup>, Jennifer M. Stephens, Pharm.D.<sup>1</sup>, Gaurang Bhatt, MSIA<sup>6</sup>, Claudie Charbonneau, Ph.D.<sup>7</sup>, Xin Gao, Ph.D.<sup>7</sup>, Dilip Nathwani, M.D.<sup>8</sup>; (1)Pharmerit International, Bethesda, MD

(2)Washington Hospital Center, Washington, DC (3)Pitié-Salpêtrière Hospital, Paris, France (4)Winthrop-University Hospital, Mineola, NY (5)Sunnybrook Health Sciences Centre, Toronto, ON, Canada (6)Formerly of Pfizer Inc, Collegeville, PA (7)Pfizer P.I.O., Paris, France (8)Ninewells Hospital & Medical School, Dundee, United Kingdom

**PURPOSE:** We evaluated the economic impact of linezolid (LZD) versus vancomycin (VAN) for treatment of confirmed methicillin-resistant *Staphylococcus aureus* (MRSA) nosocomial pneumonia (NP).

**METHODS:** A 4-week decision model was developed capturing 1st- and 2nd-line therapy. Published literature (primarily Wunderink et al., 2012) and expert opinion provided clinical and resource use data, such as efficacy, mortality, adverse events (AEs), treatment duration, length of stay. Cost and health utility data were obtained from published literature. Base-case analysis used 10-day treatment duration. In event of treatment failure/severe AEs on 1st-line therapy, drug (LZD/VAN) was switched after 7 days. All costs reported in 2012 US dollars.

**RESULTS:** Key results from base-case model are summarized in Table. LZD was associated with lower costs and greater treatment success than VAN. About 80% of treatment costs related to hospital stay, primarily in ICU (75%). Drug therapy, physician visits, lab tests and AEs/treatment failure each accounted for  $\leq 5\%$  of total costs. Several scenarios were tested, e.g., varying treatment duration (7/14 days), allowing early discontinuation/drug switch (at 3/5 days) and including costs of specific AEs. In each scenario, LZD was associated with greater effectiveness and lower costs than VAN.

Table. Key Results of Base-case Economic Model Comparing LZD and VAN for Treatment of Confirmed MRSA NP.

Outcomes	LZD	VAN	Difference
Inpatient drug cost	\$2361	\$928	\$1433
Inpatient medical cost	\$43,807	\$46,063	(\$2256)
Total treatment cost	\$46,168	\$46,991	(\$824)
Proportion of successfully treated patients (effectiveness)	0.629	0.602	0.027
Incremental cost-effectiveness ratio (ICER)	ICER was significantly in favor of LZD compared with VAN; LZD has lower costs and higher effectiveness in the treatment of MRSA NP		

**CONCLUSIONS:** LZD is a cost-effective alternative to VAN for treatment of MRSA-confirmed NP, owing primarily to higher clinical response rate. Future analyses should use other country costs/resource use data to test result generalizability and could model the empiric treatment phase.

**108. Patient perceptions of pharmacist involvement in HCV management.** Linda Spooner, Pharm.D., BCPS<sup>1</sup>, George Abraham, M.D., MPH<sup>2</sup>; (1) School of Pharmacy-Worcester/Manchester, Massachusetts College of Pharmacy and Health Sciences University, Worcester, MA (2) Saint Vincent Hospital, Worcester, MA

**PURPOSE:** This study was designed to quantify patients' perceptions about the care provided by a clinical pharmacist in managing the treatment of hepatitis C virus (HCV) infection in an infectious diseases clinic.

**METHODS:** A patient satisfaction survey was developed to determine satisfaction with care provided by the clinical pharmacist. Six questions utilized a 5-point Likert scale to assess characteristics of the clinical pharmacist as well as perceptions of how patients perceived their knowledge of their HCV medications and the likelihood that they would recommend the services of the clinical pharmacist. Medical records of the 49 patients who received HCV treatment prescribed by the clinic physician between January 1, 2012 and December 31, 2012 were reviewed to obtain demographic information, HCV genotype, and HCV treatment regimen for each patient. The survey was administered via telephone interview to eligible patients.

**RESULTS:** Overall, 30 patients were reachable by phone and were administered the survey. Average satisfaction for the question pertaining to the pharmacist's provision of information to improve health was 4.93. Average satisfaction for the question regarding the helpfulness of the pharmacist in discussing how they should take their medications was 4.97. Patients rated a 4.83 average satisfaction rating for their use of pill boxes and brochures following demonstration by the pharmacist. The patients rated 4.97 average satisfaction for the last two questions on the survey which focused on overall health improvement and recommendations for pharmacist consultation for people they know who also suffered from HCV infection. Overall, the average patient satisfaction for services provided by the pharmacist for hepatitis C was 4.91.

**CONCLUSION:** Clinical pharmacist involvement with HCV treatment is known to be beneficial from the provider perspective, but is also perceived to be a satisfying experience from the patient perspective.

**109. Vancomycin treatment failures for MRSA bacteremia based on MIC.** Nicholas Mariani, Pharm.D. Candidate<sup>1</sup>, Pramodini Kale-Pradhan, Pharm.D.<sup>2</sup>, Sheila Wilhelm, Pharm.D., BCPS<sup>3</sup>, Shannon Jacobs, Pharm.D. Candidate<sup>4</sup>, Leonard Johnson, M.D.<sup>5</sup>; (1) Wayne State University, Detroit, MI (2) Department of Pharmacy Practice, Wayne State University and St. John Hospital and Medical Center, Detroit, MI (3) Department of Pharmacy Practice, Wayne State University and Harper University Hospital, Detroit, MI (4) Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI (5) St. John Hospital and Medical Center and Wayne State University, Detroit, MI

**PURPOSE:** Vancomycin is used to treat serious infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Clinical Laboratory Standards Institute (CLSI) defines vancomycin minimum inhibitory concentration (MIC) susceptibility breakpoint as 2 mcg/mL, reduced from 4 mcg/mL, for MRSA. It is unclear whether MRSA isolates with MIC 1.5–2 mcg/mL are successfully treated with vancomycin. This study examines vancomycin failure rates in MRSA bacteremia with a MIC < 1.5 mcg/mL versus ≥ 1.5 mcg/mL, and MIC ≤ 1 mcg/mL versus ≥ 2 mcg/mL.

**METHODS:** Two independent investigators conducted a literature search of PubMed (1966–2013) and Cochrane databases using MESH terms vancomycin, MRSA, bacteremia, MIC, treatment and vancomycin failure to identify appropriate human studies published in English. Retrospective studies of patients with MRSA bacteremia treated with vancomycin were included if they evaluated vancomycin failures, defined as mortality, and reported associated MICs determined by E-test. Study sample size, vancomycin failure rates, and corresponding MIC values were extracted and analyzed using RevMan 5.1.

**RESULTS:** Seven studies (n=1907) met all criteria. Five hundred and sixteen patients had isolates with a MIC of < 1.5 mcg/mL

while 1391 had a MIC of ≥ 1.5 mcg/mL. Therapeutic failure occurred in 141 cases with MIC < 1.5 mcg/mL and 324 with a MIC ≥ 1.5 mcg/mL (OR: 1.00, 95% CI 0.77, 1.30). Two hundred and seventy-seven patients had isolates with MIC ≤ 1 mcg/mL, 302 had a MIC ≥ 2 mcg/mL. Therapeutic failure occurred in 50 and 63 patients, respectively (OR 0.77, 95% CI 0.48, 1.21). A fixed effects model was used as the heterogeneity between the studies was low (I<sup>2</sup> < 50%).

**CONCLUSION:** The results of this meta-analysis indicate that patients with MRSA isolates with MIC of ≥ 1.5 mcg/mL have similar failure rates compared to those with MIC < 1.5 mcg/mL. Additionally, patients with MRSA isolates with MIC ≤ 1 mcg/mL had similar failure rates compared to those with MIC ≥ 2 mcg/mL. MIC may not be an optimal sole indicator of vancomycin treatment failure in MRSA bacteremia.

**110. Efficacy of vancomycin loading doses in patients with severe methicillin-resistant *Staphylococcus aureus* (MRSA) infections.**

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**PURPOSE:** This study was designed to compare clinical outcomes and incidence of nephrotoxicity between patients with severe MRSA infections treated with and without vancomycin loading doses.

**METHODS:** Medical records of 95 patients admitted to two hospitals within the Intermountain Healthcare system between June 1, 2009 and May 31, 2012 were reviewed. Primary outcomes were resolution of morbidity at day 5 (or day of discharge) and incidence of nephrotoxicity. Secondary outcomes included comparisons of first trough values, days to first therapeutic trough value, days to clearance of blood cultures, hospital length of stay (ICU and overall) and significant comorbidities.

**RESULTS:** There was not a statistically significant difference between resolution of morbidity at 5 days between the two groups (load- 41.5% versus no load-59.5%, p=0.08). In a regression model, size of first dose was inversely correlated with outcome at 5 days (p=0.042, OR = 0.925, 95% CI = 0.858–0.997). Additionally, a trend towards increased nephrotoxicity in the loading dose group (load-32.1% versus no load-19.0%, p=0.152) was discovered. Significant variables in the regression model included administration of IV contrast media (p=0.017, OR = 3.376, 95% CI = 1.238–9.203) and first trough value (p=0.016, OR = 1.06, 95% CI = 1.011–1.112). For secondary outcomes, significant differences existed between groups for first trough value and days to first therapeutic trough.

**CONCLUSIONS:** Results of this study indicate that use of a vancomycin loading dose does not affect time to resolution of illness or length of hospital stay in patients with severe MRSA infections. Although a cause-and-effect relationship cannot be inferred from a retrospective analysis, the findings of this study would suggest that the recommendation of a vancomycin loading dose for patients with severe MRSA infections should be reconsidered.

**111E. Activity of Vancomycin and Piperacillin-Tazobactam in combination against Methicillin-Resistant *Staphylococcus aureus* and VAN-intermediate *Staphylococcus aureus* in an *in vitro* pharmacokinetic/pharmacodynamic infection model.** Tom Dilworth, Pharm.D.<sup>1</sup>, Steve Leonard, Pharm.D.<sup>2</sup>, Renee Mercier, Pharm.D.<sup>3</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Northeastern University School of Pharmacy, Boston, MA (3) University of New Mexico, Albuquerque, NM

**PURPOSE:** Methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Staphylococcus aureus* (VISA) infections are associated with high rates of vancomycin (VAN) treatment failure. *In vitro* studies have shown synergy between β-lactams and VAN against MRSA and VISA. This study evaluated PT+VAN against MRSA and VISA using an *in vitro* pharmacokinetic/pharmacodynamics (PK/PD) model.

**METHODS:** Two MRSA strains (M3425, M494) and one VISA strain (Mu50) were selected. VAN and oxacillin minimum inhibitory concentrations (MICs) were determined by VITEK and PT MICs were determined by Etest. In a 72 hours PK/PD infection model all strains were tested in duplicate at  $\sim 10^7$  cfu/mL using: growth control, VAN, PT, and PT+VAN. The following human PK were simulated: VAN 1 g q12h and PT 13.5 g/24 hours continuous infusion. Time-kill curves were constructed and reduction in  $\log_{10}$  CFU/mL at all time points were compared between all antibiotics tested using one-way ANOVA with Tukey's test for multiple comparisons. MRSA isolates experiencing bacterial re-growth were tested for reduced susceptibility to VAN by population analysis using Mu3 as a control.

**RESULTS:** VAN and PT MICs (mg/L) for M3425, M494, and Mu50 were 1, 1, 8 and 1.5, 32, and  $>256$ , respectively. All isolates had an oxacillin MIC  $\geq 4$  mg/L. PT+VAN achieved a significant reduction in inoculum at 72 hours compared to VAN alone against all isolates ( $p \leq 0.015$  for all). This superiority of PT+VAN compared to VAN alone became detectable at 8 hours for M3425 ( $p < 0.001$ ) and 24 hours for M494 and Mu50 ( $p \leq 0.008$  for both). Reduced susceptibility to VAN at 72 hours for M3425 was confirmed using population analysis (0.77 AUC of Mu3 at 72 hours compared to 0.51 the AUC of Mu3 at baseline).

**CONCLUSION:** PT+VAN demonstrated superior antimicrobial activity against MRSA and VISA compared to VAN alone. Combination therapy with VAN and a  $\beta$ -lactam against MRSA and VISA warrants clinical consideration. Presented at Presented at the International Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10–13, 2013.

**112E. Characteristics and cultures of patients with healthcare-associated pneumonia.** Kimberly Toussaint, Pharm.D.<sup>1</sup>, Jason Gallagher, Pharm.D.<sup>2</sup>, Peter Axelrod, M.D.<sup>3</sup>, Kiran Paramatmani, M.D.<sup>3</sup>; (1) School of Pharmacy, Temple University School of Pharmacy, Philadelphia, PA (2) Temple University School of Pharmacy, Philadelphia, PA (3) Temple University Hospital, Philadelphia, PA

**PURPOSE:** The diagnosis of healthcare-associated pneumonia (HCAP) encompasses a heterogeneous group of patients at varying degrees of risk of infection by resistant pathogens. The purpose of this study was to characterize patients with presumed HCAP.

**METHODS:** We conducted a retrospective study of patients admitted to the Temple University Hospital (TUH) emergency department (ED) during 2012 with an ED diagnosis of HCAP. Inclusion criteria were age  $>18$  years old and receipt of  $>1$  dose of antibiotic within the first 24 hours of admission. Exclusion criteria were transfer from outside hospitals and requirement of long-term mechanical ventilation. The primary objective was to determine whether patients diagnosed with HCAP had culture results for organisms that warranted guideline-recommended broad-spectrum empiric therapy. The secondary objective was to assess the presence of guideline-recommended risk factors for HCAP.

**RESULTS:** Eighty patients were screened and 70 met inclusion criteria. The median age of the patients was 66 years (range 34–97), and 30 (43%) were male. 14 (20%) of patients were immunocompromised. 35 (21%) of patients were admitted from LTCFs. The median length of stay was 4.5 days (range 0–39) and antibiotic duration was 4 days (range 0–19). Sputum cultures were drawn in 31 patients (44%) and 10 of these yielded an organism (four enterobacteriaceae, three *pseudomonas aeruginosa*, one *burkholderia cepacia*, one MSSA and one MRSA). Blood cultures were drawn in 60 patients (86%). Empiric antibiotic coverage was given in 57 patients (81%) for *pseudomonas* and 59 patients (84%) for MRSA. In the 90 days prior to admission, 32 patients (46%) had been treated with antibiotics, 33 (47%) had been hospitalized for  $>2$  days, and 10 (14%) received outpatient hemodialysis. A final diagnosis of HCAP was made in 38 patients (54%).

**CONCLUSION:** Though most patients diagnosed with HCAP had risk factors for multi-drug resistant organisms, few had cultures that demonstrated a need for empiric broad-spectrum antibiotics.

Presented at Will be presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Denver, CO, September 10–13, 2013.

**113E. Effect of linezolid on methicillin-resistant *Staphylococcus aureus* (MRSA) panton-valentine leukocidin (PVL) production utilizing an enzyme linked immuno sorbent assay.** Monique Dodd, MLS, (ASCP), CM, Pharm.D. Candidate<sup>1</sup>, Julie Acosta, Pharm.D. Candidate<sup>2</sup>, Renee Mercier, Pharm.D.<sup>2</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) University of New Mexico, Albuquerque, NM

**PURPOSE:** Detection and quantitation of Pantone-Valentine Leukocidin (PVL) and other virulence factors have been assessed utilizing a number of immunological techniques including Western blot and Enzyme Linked Immuno Sorbent Assay (ELISA). Recently, there have been few studies evaluating MRSA virulence production based on varying antibiotic minimum inhibitor concentrations (MICs). This study assesses the effects of different linezolid (LZD) MICs on PVL production from MRSA isolates.

**METHODS:** CA-MRSA (USA300) and HA-MRSA (USA100) isolates (n=8) were selected utilizing a MRSA library. Broth microdilution was performed on each isolate according to CLSI guidelines to determine LZD MIC. PVL was isolated in supernatant through the cultivation of each isolate with an increasing twofold dilution of LZD MIC from 0.25 to 8 mcg/mL. The quantitation of PVL was determined utilizing a quantitative ELISA method as recommended by IBT BioServices with a few variations. Each isolate was run in duplicate for validity.

**RESULTS:** Of the eight isolates tested, three were determined to be USA300 and PVL positive while five were USA100 and PVL negative. The three PVL positive isolates were found to have a LZD MICs of 2 mcg/mL. Among these three isolates, PVL production was significantly decreased at subinhibitory concentrations of LZD from 0.5 to 1 mcg/mL with a  $p < 0.05$ . PVL production was undetectable at the LZD MIC determined for each isolate.

**CONCLUSION:** Utilization of an ELISA method provides detection and quantitation of PVL production at varying LZD MICs. LZD has shown to inhibit PVL production of CA-MRSA isolates. These results support establishing appropriate *in-vitro* LZD levels when used against MRSA to inhibit PVL production. Further investigation is needed to determine LZD effect on  $\alpha$ -hemolysin production.

Presented at Accepted and will be presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Denver, CO, September 10–13, 2013.

**114. *In vivo* evaluation of cardiac toxicity with caspofungin.** Kayla R. Stover, Pharm.D., BCPS<sup>1</sup>, John D. Cleary, Pharm.D.<sup>2</sup>; (1) School of Pharmacy, University of Mississippi School of Pharmacy, Jackson, MS (2) University of Mississippi Medical Center, Jackson, MS

**PURPOSE:** In *ex vivo* Langendorff studies, caspofungin (CASP) and anidulafungin (ANID) were found to cause decreases in cardiac contractility. The purpose of this study was to evaluate cardiac function after administration of CASP in an *in vivo* model.

**METHODS:** *In vivo* dose-ranging studies were performed using Harlan Sprague-Dawley rats. The internal jugular vein and carotid artery were isolated and catheterized for drug administration and cardiac monitoring, respectively. CASP (3–27 mg/kg) was administered over 10 minutes by slow IV push. Mean arterial pressure (MAP), heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressures were recorded by a pressure transducer at baseline, during medication administration, and for up to 120 minutes after administration. Time to maximal effect was also recorded.

**RESULTS:** CASP was associated with dose-dependent increases in HR and decreases in MAP, SBP, and DBP (See Table 1). Three animals given 27 mg/kg all died after dose administration. At 13.6 mg/kg, one animal had recovery of cardiac function to baseline; the second survived but had no recovery of cardiac function. Two animals given 6 mg/kg both survived and had par-



CASP dose (mg/kg)	MAP (%)	DBP (5)	SBP (%)	HR (bpm)	Time to max effect (min)
27	-73.6 ± 11.3	-71.5 ± 10.1	-74.7 ± 11.9	72 ± 13	5.5 ± 3.3
13.6	-65.7 ± 7.3	-62.2 ± 5.4	-58.1 ± 13.7	88 ± 27	22.8 ± 21.2
6	-67.0 ± 11.7	-26.0 ± 9.2	-48.5 ± 14.2	77 ± 17	46.9 ± 28.1
3	-59.4	-9.2	-30.3	76	103.3

tial recovery of cardiac function. One animal given 3 mg/kg had a full recovery in cardiac function by the end of the observation period. Time to maximal effect ranged from  $5.5 \pm 3.3$  minutes at 27 mg/kg to 103 minutes at 3 mg/kg. Table 1.

**CONCLUSION:** CASP was associated with reductions in MAP, DBP, SBP, and increases in HR in an *in vivo* model. Further dose-ranging studies are in progress to confirm the mechanism of toxicity and determine clinical effects.

**115. Clinical and economic evaluation of an empiric extended infusion piperacillin/tazobactam initiative.** Luigi Brunetti, Pharm.D.<sup>1</sup>, Shirin Poustchi, Pharm.D. Candidate<sup>1</sup>, Julie Kalabalik, Pharm.D.<sup>1</sup>, Daniel Cunningham, M.D.<sup>2</sup>, Ronald Nahass, M.D.<sup>3</sup>; (1)Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey, Piscataway, NJ (2)Somerset Medical Center, Somerville, NJ (3)ID CARE, Hillsborough, NJ

**PURPOSE:** Current medical center practice allows for the automatic conversion of all piperacillin/tazobactam orders from intermittent infusion to extended infusion. The goal of this study was to evaluate the clinical and economic impact of empiric extended infusion piperacillin/tazobactam.

**METHODS:** All consecutive patients treated with piperacillin/tazobactam from January 1, 2009 to October 1, 2012 were reviewed for inclusion in this pre and post implementation study. Only patients who received at least 2 days of therapy were included. Patients were placed in either Period 1: January 1, 2009 through December 1, 2010; intermittent piperacillin/tazobactam dosing (INT) or Period 2: January 1, 2011 through October 1, 2012; post-protocol implementation; extended infusion (EXT). Patient demographics and primary and secondary diagnoses were extracted from the hospital discharge database. The Charlson-Deyo comorbidity index was calculated for all patients. Outcomes evaluated between groups included in-hospital mortality, hospital associated *Clostridium difficile* infection, hospital length of stay, total doses dispensed per treatment course, and cost per treatment course.

**RESULTS:** A total of 4209 patients were included in the analysis (INT = 2274; EXT = 1935). Mean age and gender were similar between periods. After adjusting for age and comorbidity index, in-hospital mortality was similar between periods (odds ratio 0.88, 95% confidence interval 0.72–1.09). The incidence of *Clostridium difficile* infections was similar between periods (INT = 4.5%, EXT = 4.1%,  $p=0.67$ ). Hospital length of stay was significantly shorter ( $p=0.001$ ) during the EXT period ( $9.9 \pm 8.2$  days) compared with the INT period ( $11.2 \pm 15.6$  days). Both total doses dispensed and cost per treatment course were significantly reduced during the EXT versus INT period ( $17.4 \pm 8.5$  doses versus  $23.3 \pm 12.5$  doses and  $\$381.29 \pm \$187.93$  versus  $\$501.28 \pm \$286.00$ , respectively).

**CONCLUSION:** Empiric use of extended infusion piperacillin/tazobactam is associated with significant cost savings and reduced length of stay without compromising patient outcomes.

**116. Value of methicillin-resistant *Staphylococcus aureus* (MRSA) and carbapenemase-producing enterobacteriaceae (CPE) surveillance in predicting subsequent infections.** Tae Park, Pharm.D.<sup>1</sup>, Amy Asheroff, BA<sup>2</sup>, Roopali Sharma, BS, Pharm.D., BCPS, AAHIVP<sup>1</sup>, Michael Augenbraun, M.D.<sup>1</sup>; (1)SUNY Downstate Medical Center, Brooklyn, NY (2)CUNY Hunter College, New York, NY

**PURPOSE:** There have been studies assessing the likelihood of the surveillance cultures of organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) predicting subsequent infections

with the same organism. However, these studies have shown conflicting results for MRSA and limited data on carbapenemase-producing *Enterobacteriaceae* (CPE). The primary objective is to determine the association between the MRSA/CPE surveillance and subsequent MRSA/CPE infection. The secondary objective is to determine the factors associated with MRSA/CPE infection.

**METHODS:** This retrospective, case-control study included adult patients who were admitted to the intensive care units (ICUs) or Stepdown units between January 1, 2010 and December 31, 2012 at SUNY Downstate Medical Center. Microbiologic and demographic data were collected from medical records. Patients who had surveillance cultures obtained within 24 hours of admission and who had cultures drawn from blood, sputum, urine, catheter, wound, bone, or any body fluids within 72 hours of admission were included. Patients who had both MRSA and CPE surveillance cultures positive were excluded.

**RESULTS:** There were 130 patients in both the case and control groups, who were matched in 1:1 ratio. The positive predictive value of MRSA/CPE surveillance culture predicting MRSA/CPE infection was 11.5% and negative predictive value was 100% ( $p<0.001$ ). Positive MRSA/CPE surveillance cultures were more likely to be associated with subsequent infections with MRSA/CPE (MRSA, OR 2.23, 95% CI 0.66–7.32,  $p=0.15$ ; CPE, OR 4.94, 95% CI 1.47–16.77,  $p=0.004$ ). History of previous hospitalization within the past 90 days (OR 3.9, 95% CI 1.16–14.96,  $p=0.02$ ) and previous antibiotic use within the past 90 days (OR 6.86, 95% CI 2.00–23.5,  $p<0.001$ ) were the only factors associated with having MRSA/CPE infection.

**CONCLUSION:** Positive surveillance cultures as well as presence of certain demographic factors put patients at a higher risk of developing clinical infections with multi-drug organisms.

**117. Comparison of *in vitro* susceptibilities of extended spectrum  $\beta$ -lactamase (ESBL) producing *Escherichia coli* to imipenem and ertapenem in a four-hospital health system.** Robert Bush, Pharm.D., Eva Sullivan, Pharm.D., Harminder Sikand, Pharm.D., FCSHP, FASHP; Scripps Mercy Hospital, San Diego, CA

**PURPOSE:** To determine if susceptibility to imipenem in ESBL producing *E. coli* serves an appropriate surrogate marker for susceptibility to ertapenem. This would allow for the use of ertapenem as the carbapenem of choice for ESBL *E. coli*; preserving imipenem for pseudomonal infections.

**METHODS:** ESBL producing *E. coli* isolates were collected from August 2012 to April 2013. Samples from sputum, wound, urine, and blood cultures were analyzed. Isolates were excluded if they were collected from patients <18 years of age. Susceptibility to imipenem was determined on a standard microbiology panel, using the BD Phoenix™ System. Ertapenem susceptibility was determined by a manual Epsilon test (Etest), using the current Clinical Laboratory Standards Institute minimum inhibitory concentration (MIC) breakpoints. All intermediately-resistant organisms were considered resistant.

**RESULTS:** A total of 202 isolates were screened for inclusion criteria. Two isolates were excluded for age < 18 years, and twenty were excluded because of duplication. A total of 180 isolates were included for analysis. The primary source of isolates was urine (79%), wound cultures (13%), blood (5%), and sputum (3%). The isolates were found to be 178/180 (98.9%) susceptible to imipenem, and 177/180 (98.3%) susceptible to ertapenem (OR = 58.3, 95% CI, 2.91–1168.79,  $p=0.008$ ).

**CONCLUSION:** A statistically significant relationship in the susceptibilities of ESBL producing *E. coli* to imipenem compared to ertapenem was found. Overall, resistance to carbapenems in our

health system remains low, allowing for ertapenem to be used as the carbapenem of choice for ESBL *E. coli*. The generalizability of this data outside Scripps Health is limited due to low resistance rates seen in the isolates tested.

**118E. Thickened cell wall as a mechanism for increased telavancin minimum inhibitory concentration in methicillin-resistant *Staphylococcus aureus*.** Keenan Ryan, Pharm.D. Candidate<sup>1</sup>, Renee Mercier, Pharm.D.<sup>2</sup>, Stephen Jett, Ph.D.<sup>2</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) University of New Mexico, Albuquerque, NM

**PURPOSE:** Recent studies have shown a relationship between increased vancomycin (VAN) MIC and an increased telavancin (TLV) MIC. This study evaluated the relationship between TLV MIC and MRSA cell wall thickness (CWT).

**METHODS:** Twenty MRSA strains were categorized into four MIC groups: low TLV and VAN (LT/LV), low TLV high VAN (LT/HV), high TLV low VAN (HT/LV), and high TLV and VAN (HT/HV). MICs were considered high if TLV = 1 mg/L and VAN  $\geq$  2 mg/L. CWT was measured by transmission electron microscopy (TEM) in triplicate. Samples were prepared for TEM by dehydration in a graded ethanol series followed by embedding in Spurr's resin. Thin sections were obtained on a Leica UCT ultramicrotome, stained with uranyl acetate and lead citrate then imaged via Hitachi H7500 TEM equipped with an AMT XR60 camera. For each strain, *agr* function was assessed and MRSA strain typing. Differences in CWT were analyzed using t-test or ANOVA.

**RESULTS:** MIC distribution for the 20 isolates: 10 HT, 10 HV (2–8 mg/L), 10 LT (0.12–0.25 mg/L), 10 LV (0.5–1 mg/L). There were 10 USA100, eight USA300, one USA200, one USA600 and 14 strains had functional *agr*. CWT was significantly larger in the HT/HV group compared to all other groups of isolates ( $p < 0.001$ ). CWT was significantly larger for all HV compared to LV strains ( $p = 0.005$ ). CWT of HT was increased compared to LT ( $p = 0.054$ ). In USA100 strains CWT was significantly larger amongst HT than LT ( $p = 0.01$ ). No difference in CWT was detected between HT and LT within USA300 strains. CWT was not impacted by *agr* functionality.

**CONCLUSION:** Increased MRSA CWT is associated with decreased TLV susceptibility. Strain type influences the likelihood of increased CWT in MRSA. Other mechanisms of decreased TLV activity should be further investigated in MRSA strain with high TLV MIC and normal CTW. Presented at Presented at Inter-science Conference of Antimicrobial Agents and Chemotherapy.

**119E. Clinical utility of rectal swabs as a predictor of vancomycin-resistant enterococcal infections requiring antibiotic treatment.** Niyati Vakil, Pharm.D.<sup>1</sup>, Alexander Levine, Pharm.D.<sup>1</sup>, Hsin Lin, Pharm.D.<sup>1</sup>, Kelly Newman, Pharm.D.<sup>1</sup>, Christopher Lyman, Pharm.D.<sup>1</sup>, Daniel Yeh, M.D.<sup>2</sup>, David Hooper, M.D.<sup>3</sup>, Christy Varughese, Pharm.D.<sup>1</sup>; (1) Department of Pharmacy, Massachusetts General Hospital, Boston, MA (2) Department of Surgery, Massachusetts General Hospital, Boston, MA (3) Department of Infectious Diseases, Massachusetts General Hospital, Boston, MA

**PURPOSE:** Vancomycin-resistant enterococcus (VRE) rectal swabs are used to identify patients colonized with this organism. A positive result may be used as supportive data to empirically cover for VRE infection which leads to initiation of broad spectrum antibiotics without a clear indication. The purpose of this study is to assess whether the result of the swab can positively and/or negatively predict the presence of VRE infection.

**METHODS:** A prospective, observational study was conducted over a 5-month period at a large academic medical center. Patients were eligible for enrollment if they were at least 18 years of age, were admitted to an intensive care unit and had received a VRE rectal swab upon admission. Patients were excluded if they did not receive a rectal swab or if they received an anti-infective agent with VRE activity in the 7 days prior to the VRE rectal swab. Patients were followed for 30 days and only during

their first admission to the hospital. Infection was defined as at least one positive culture from blood or bile, or bacteruria (WBC  $> 10^3$ ) plus pyuria ( $> 10$  WBC/HPF).

**RESULTS:** Five hundred and forty-one patients were evaluated of which 503 were included. Of these, 447 had a negative rectal swab and 56 had a positive rectal swab. 25% (14/56) of patients developed VRE infection within the positive rectal swab group and 2% (8/447) of patients developed a VRE infection within the negative rectal swab group ( $p < 0.01$ ). The positive and negative predictive values, sensitivity and specificity of the rectal swab were 25%, 98%, 64%, 91% respectively.

**CONCLUSION:** The likelihood of having VRE infection with a positive rectal swab is low, while the probability of a negative VRE clinical isolate when the rectal swab is negative is very high. A negative rectal swab may help guide empiric antibiotic coverage and support deescalating antibiotics with VRE activity. Presented at to be presented at ID Week 2013, Infectious Diseases Society of America, San Francisco, CA, October 2–6, 2013. Pending acceptance.

**120. Population pharmacokinetic analysis of ceftolozane/tazobactam in healthy volunteers and patients.** Gurudatt Chandorkar, Ph.D.<sup>1</sup>, Samer Mouksassi, Pharm.D., Ph.D.<sup>2</sup>, Ellie Hershberger, Pharm.D.<sup>3</sup>, Gopal Krishna, Ph.D.<sup>3</sup>; (1) Department of Clinical Pharmacology, Cubist Pharmaceuticals, Lexington, MA (2) Pharsight Corporation, Montreal, QC, Canada (3) Cubist Pharmaceuticals, Lexington, MA

**PURPOSE:** Ceftolozane/tazobactam, an antipseudomonal cephalosporin and  $\beta$ -lactamase inhibitor, is in clinical development for treatment of complicated urinary tract (cUTI) and complicated intra-abdominal (cIAI) infections. The objectives of this analysis were to identify sources of variability in the pharmacokinetic (PK) parameters of ceftolozane/tazobactam and clinically relevant covariates.

**METHODS:** PK data from 10 studies that enrolled healthy volunteers and patients with cIAI and cUTI that were administered single and multiple doses of ceftolozane/tazobactam (range, 500–3000 mg) were used to develop a population PK model using non-linear mixed-effects modeling. The effects of covariates such as creatinine clearance (CrCL), body weight, age, race, gender, and infection status were evaluated. Visual predictive checks and bootstrapping were used to validate the final model.

**RESULTS:** A two-compartmental model best fit the data, parameterized with systemic (CL) and peripheral clearance (CL<sub>2</sub>) and central ( $V_c$ ) and peripheral volumes ( $V_p$ ) of distribution. For ceftolozane, CrCL was an important covariate explaining variability of CL while body weight was an important covariate of  $V_c$ ; the presence of infection was a determinant of both CL and  $V_c$ . For tazobactam, CrCL was an important covariate explaining variability of CL while infection was a determinant of  $V_c$ . The mean estimates of CL and  $V_c$  for healthy volunteers were 5.92 L/hour and 12.2 L for ceftolozane and 17.3 L/hour and 13.6 L for tazobactam, respectively. The presence of infection decreased ceftolozane exposure by 18% and increased tazobactam exposure by 20%, which was not considered clinically relevant. Other covariates tested had no clinically relevant effects on PK.

**CONCLUSION:** The final PK models adequately described the plasma concentrations of ceftolozane and tazobactam and form the basis for evaluation of probability of target attainment in a diverse population with varying demographics and degrees of renal impairment.

**121E. Methicillin-resistant *Staphylococcus aureus* infective endocarditis: a 10 years retrospective analysis from a tertiary care, academic medical center.** Tom Dilworth, Pharm.D.<sup>1</sup>, Jora Sliwinski, Pharm.D.<sup>2</sup>, Renee Mercier, Pharm.D.<sup>3</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Idaho State University, Pocatello, ID (3) University of New Mexico, Albuquerque, NM

**PURPOSE:** Methicillin-Resistant *Staphylococcus aureus* (MRSA) infective endocarditis (IE) is associated with significant morbidity

and mortality and high rates of treatment failure. This study describes the patient- and strain-level characteristics seen among individuals with MRSA IE over a 10 years period (2003–2012).

**METHODS:** A retrospective cohort study of patients  $\geq 18$  years of age who had at least one MRSA positive blood culture and met definitive or possible criterion for IE using the modified Duke criteria. The objectives of this study were to describe (i) changes in patient- and strain-level characteristics over time and (ii) treatment outcomes over time. Differences in patient- and strain-level characteristics and treatment outcomes over time were compared using chi-squared tests.

**RESULTS:** Sixty patients were included in the analysis. 70% were male, 46.7% were injection drug users (IDUs), 8.3% were on hemodialysis and the mean age was  $50.6 \pm 13.6$  years. Only 31.7% of patients experienced cure with vancomycin (VAN) alone, 25% required 2–3 antibiotics for cure, and 28.3% expired or experienced infection relapse. Of the patients who experienced treatment failure, 76.5% were Hispanic or Native American, 47.1% were IDUs, and 42.1% had chronic hepatitis C infection. Notable changes in strain-level characteristics were observed over time. Table 1. Changes in strain-level characteristics and treatment outcomes over time.

	2003–2008 (n=33) n (%)	2009–2012 (n=27) n (%)	p-value
Strain-level characteristics			
VAN MIC < 1 mg/L	30 (90.9)	6 (22.2)	<0.001
agr functional	29 (87.9)	21 (77.8)	0.296
USA300/USA100	25 (75.8)/8 (24.2)	14 (51.8)/13 (48.2)	0.087
Treatment outcomes			
Mortality	9 (27.3)	3 (11.1)	0.119
Infection relapse	1 (3.0)	4 (14.8)	0.100

**CONCLUSION:** Mortality from MRSA IE decreased over time although more frequent relapses were observed despite new agents. These findings correlated with an increase in VAN MIC and the number of USA100 isolates during the study period. Presented at Presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10–13.

**122E. High throughput screening identifies novel compounds with antifungal activity alone or in combination with fluconazole against a highly resistant clinical isolate of *Candida albicans*.** Sarah G. Whaley, Pharm.D.<sup>1</sup>, Elizabeth Berkow, MS<sup>1</sup>, Marcus Maddox, BS<sup>2</sup>, Richard E. Lee, Ph.D.<sup>2</sup>, P. David Rogers, Pharm.D., Ph.D.<sup>1</sup>; (1) University of Tennessee College of Pharmacy, Memphis, TN (2) St. Jude Children's Research Hospital, Memphis, TN

**PURPOSE:** Increasing resistance to *Candida albicans* has left clinicians with limited therapeutic options. One strategy for overcoming resistance is to reestablish the efficacy of failing drug regimens. We hypothesized that screening a highly resistant clinical isolate would identify compounds that could be used alone or in combination with fluconazole (FCZ) to overcome azole resistance in *C. albicans*.

**METHODS:** We conducted a high-throughput screen of the St. Jude bioactive compound collection (5600 compounds) with and without FCZ against a highly resistant clinical isolate, 12–99, that overexpresses the genes encoding *ERG11*, the *CDR1*, *CDR2*, and *MDR1* efflux pumps, and has a point mutation in Erg11 (FCZ MIC > 64  $\mu\text{g}/\text{mL}$ ). The susceptible clinical isolate, SC5314, was used as a control. Cell viability was measured by alamar blue. Hits were identified as treatments that were able to reduce viability by at least 75%. Selected hits were chosen for verification by susceptibility, checkerboard, and time kill assays.

**RESULTS:** Of the compounds tested, 72 and 63 showed activity against the susceptible and resistant clinical isolate, respectively. The hits increased to 356 for SC5314 and 65 for 12–99 when treated with the bioactive compound and FCZ. Only one compound had activity against 12–99, but not SC5314. Compounds known to be synergistic with FCZ against *C. albicans*, such as sertraline and cyclosporine showed activity against SC5314 in combination with FCZ, but not against 12–99. Compounds that exhibited

activity against 12–99 include several imidazoles, chloroquine, disulfiram, and pentamidine.

**CONCLUSION:** In addition to compounds with known activity against *C. albicans*, this screen identified compounds that have activity against both a susceptible and a highly resistant isolate that possesses all of the major mechanisms of azole antifungal resistance. These compounds and their derivatives have the potential for use alone or in combination with fluconazole against azole resistant strains of *C. albicans*.

Presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, CO, September 10–13, 2013.

**123E. Incidence of vancomycin-induced nephrotoxicity in hospitalized patients with and without concomitant piperacillin-tazobactam.** Lindsey Burgess, Pharm.D., Richard Drew, Pharm.D., MS, BCPS, FCCP; Duke University Hospital, Durham, NC

**PURPOSE:** While the antimicrobial vancomycin has been associated with the development of nephrotoxicity, such toxicity related to piperacillin-tazobactam (PT) is rarely reported. The addition of PT to vancomycin significantly increased the risk of acute kidney injury relative to vancomycin monotherapy in one report. The purpose of this study was to determine if the addition of PT leads to an increased incidence of nephrotoxicity in patients receiving vancomycin. We also explored potential confounding factors that may increase the risk of vancomycin-induced nephrotoxicity.

**METHODS:** This single-center, retrospective cohort study included adults  $\geq 18$  years old hospitalized at Duke University Hospital (DUH) during a 3-year period who received a minimum of 48 hours of vancomycin. A univariate analysis was performed to assess the effect of risk factors (concomitant nephrotoxic agents, age, steady state vancomycin trough concentration  $\geq 15$  mcg/ml, Charlson Comorbidity Score, or a total daily vancomycin dose  $\geq 4$  g) on the incidence of nephrotoxicity. The primary endpoint of nephrotoxicity (minimum 1.5-fold increase in serum creatinine) was then compared between vancomycin with and without PT in a multivariate model.

**RESULTS:** A total of 191 patients were included in the analysis. Nephrotoxicity was observed 8% (8/99) and 16.3% (15/92) in the vancomycin and combination groups, respectively (one-sided  $p=0.041$ ). In the univariate analysis, only vancomycin trough concentration  $\geq 15$  mcg/mL (OR: 3.67) was associated with an increased risk of developing nephrotoxicity. In the multivariate analysis, the addition of PT to vancomycin exhibited an increased risk of developing nephrotoxicity, with an OR of 2.48 (one-sided  $p=0.032$ ).

**CONCLUSION:** These study results confirm a previous finding of an increased incidence of nephrotoxicity in patients receiving PT concomitant with vancomycin. A steady-state vancomycin trough concentration  $\geq 15$  mcg/mL was also associated with an increased risk of developing nephrotoxicity. These findings should be confirmed in larger, randomized studies.

Presented at Presented at the Southeastern Residency Conference, Athens, GA, April 25–26, 2013.

**124. Evaluation of vancomycin dosing in obese patients: less may be more.** Zhe Han, Pharm.D., Natasha N. Pettit, Pharm.D., Benjamin D. Brielmaier, Pharm.D.; University of Chicago Medicine, Chicago, IL

**PURPOSE:** Vancomycin pharmacokinetics is altered in obese versus non-obese patients. The optimal dosing strategy in this patient population is not well defined. This retrospective cohort study evaluated empiric vancomycin dosing and initial target trough attainment at an academic medical center.

**METHODS:** A 25–30 mg/kg loading dose (maximum 2500 mg) followed by 15–20 mg/kg (maximum 2000 mg) every 12 hours is recommended at our institution for obese patients with normal renal function. Adult inpatients with total body weight (TBW)  $\geq 100$  kg and  $\geq 20\%$  above their ideal body weight (IBW) who received intravenous vancomycin between May 2009 and October 2011 were included. One-time doses, peri-procedural prophylaxis and patients requiring renal replacement therapy were excluded.



**RESULTS:** A total of 42 patients with median TBW of 110 kg were reviewed; body mass index (BMI [ $\text{kg}/\text{m}^2$ ]) < 30 (10%), 30–34.9 (24%), 35–39.9 (24%) and  $\geq 40$  (43%). Forty-three percent of vancomycin courses had initial therapeutic trough concentrations. Among non-therapeutic initial trough concentrations, 31% were subtherapeutic and 17% were supratherapeutic. Median vancomycin dose was similar across four BMI categories ( $p=0.339$ ) but the proportion of supratherapeutic initial trough concentrations was disproportionately higher (43%) among morbidly obese patients (BMI  $\geq 40$ ) ( $p=0.002$ ). Morbidly obese patients with supratherapeutic initial trough concentrations received higher doses of vancomycin (24.8 mg/kg/day) than those with therapeutic (20.5 mg/kg/day) and subtherapeutic (16.9 mg/kg/day) initial trough concentrations ( $p=0.192$ ). Incidence of vancomycin-associated nephrotoxicity was similar across four BMI categories (BMI < 30: 0%, BMI 30–34.9: 44%, BMI 35–39.9: 27%, BMI  $\geq 40$ : 39%) ( $p=0.530$ ).

**CONCLUSION:** Current institutional dosing recommendations result in frequent occurrence of supratherapeutic trough concentrations and vancomycin-associated nephrotoxicity in morbidly obese patients. A revised vancomycin protocol using lower total daily doses may improve target trough attainment in patients with BMI  $\geq 40$ .

**125. Population pharmacokinetics and pharmacodynamics of doripenem in obese patients.** Eun Kyoung Chung, Pharm.D.<sup>1</sup>, S. Christian Cheatham, Pharm.D.<sup>2</sup>, Megan R. Fleming, Pharm.D.<sup>3</sup>, Michael B. Kays, Pharm.D.<sup>1</sup>; (1) Department of Pharmacy Practice, Purdue University College of Pharmacy, Indianapolis, IN (2) Department of Pharmacy, Franciscan St. Francis Health – Indianapolis, Indianapolis, IN (3) Methodist Dallas Medical Center, Dallas, TX

**PURPOSE:** To evaluate the population pharmacokinetics (PK) and pharmacodynamics (PD) of doripenem in obese patients.

**METHODS:** Twenty adult patients with a body mass index (BMI) > 40  $\text{kg}/\text{m}^2$  or who were >100 pounds over their ideal body weight were enrolled. Ten patients were admitted to a general ward, and 10 patients were admitted to an intensive care unit (ICU). All patients received doripenem 500 mg IV q8h, infused over 1 hour. Serial blood samples ( $n=174$ ) were collected at steady state, and doripenem concentrations were determined by ultraperformance liquid chromatography with tandem mass spectrometry detection. Population PK analyses were performed using NONMEM, and model-derived PK parameters were systemic clearance (CL), volume of distribution of the central compartment (V1) and peripheral compartment (V2), and inter-compartmental distribution clearance (Q). Monte Carlo simulations (5000-patients) were performed to create doripenem PK profiles for 500 mg q8h. Probability of target attainment (PTA) for  $\geq 40\%$   $fT > \text{MIC}$  was calculated at MICs ranging from 0.125 to 16 mg/L.

**RESULTS:** Patient demographics were (mean  $\pm$  SD): age  $54 \pm 8$  years; total body weight (TBW)  $178 \pm 49$  kg; BMI  $62.3 \pm 22.3$   $\text{kg}/\text{m}^2$ ; creatinine clearance (CRCL)  $126 \pm 42$  mL/minute. Nine patients were male. A 2-compartment model best fit the PK data. CRCL, TBW, and ICU admission significantly affected doripenem PK. CRCL was significantly correlated with CL, TBW and ICU admission with V1, and TBW with V2. For all patients, PTA was > 90% at MICs  $\leq 1$  mg/L.

**CONCLUSION:** Doripenem PK is significantly associated with renal function, ICU admission, and TBW in obese patients. However, regardless of their body weight or site of hospital admission (ICU versus general ward), doripenem 500 mg IV q8h provides adequate PD exposures for bacterial pathogens with MICs  $\leq 1$  mg/L. Larger or alternative dosing regimens may be required for less susceptible pathogens.

**126. Association between vancomycin minimum inhibitory concentrations and patient outcomes in coagulase-negative staphylococci bacteremia.** Christopher B. Adams, Pharm.D.<sup>1</sup>, David T. Bearden, Pharm.D.<sup>2</sup>, Miriam R. Elman, MPH<sup>2</sup>, Vivian Tang, Pharm.D. Candidate<sup>2</sup>, Jessina C. McGregor, Ph.D.<sup>3</sup>;

(1) Department of Pharmacy Services, Oregon Health & Science University, Portland, OR (2) College of Pharmacy, Oregon State University, Portland, OR (3) Oregon State University/Oregon Health Science University, College of Pharmacy, Portland, OR

**PURPOSE:** While coagulase-negative staphylococci (CoNS) are common blood culture contaminants, they also have potential to cause life-threatening infections. Unlike *S. aureus*, little data exist as to the impact of vancomycin minimum inhibitory concentration (MIC) on patient outcomes for CoNS bacteremia.

**METHODS:** We conducted a retrospective cohort study of adult, hospitalized patients with CoNS bacteremia between May 2009 and December 2011 who received >2 days of vancomycin. Microbiology and Pharmacy databases were queried to identify patients. Demographics, comorbidities, antibiotic use, and outcomes (treatment failure, all-cause mortality, and length of stay [LOS]) were collected through chart review. Patients with concurrent *S. aureus* or Enterococcus infections or a history of methicillin-resistant *S. aureus* were excluded. MICs were dichotomized as low ( $\leq 1$   $\mu\text{g}/\text{mL}$ ) versus elevated ( $>1$ – $2$   $\mu\text{g}/\text{mL}$ ) and outcomes compared across strata using the chi-square and t-tests.

**RESULTS:** To date, chart reviews have been completed for 122 of 207 potential study subjects. After excluding 31 patients, 64 patients with low vancomycin MICs were compared versus 27 with elevated vancomycin MICs. All-cause mortality and treatment failure did differ significantly between low and elevated MICs: 23% versus 30% ( $p=0.53$ ) and 19% versus 26% ( $p=0.44$ ), respectively. Mean post-infection LOS also did differ significantly (low MICs:  $17.7 \pm 15.3$  days versus elevated MICs:  $13.2 \pm 8.8$  days;  $p=0.13$ ).

**CONCLUSION:** Though not statistically significant, mortality and treatment failure trended towards worsened outcomes in patients with elevated CoNS vancomycin MICs. Larger studies are needed to further investigate this association while controlling for potential confounders.

## Medication Safety

**127. Evaluation of the impact of a pharmacy-driven protocol on argatroban use.** Kathryn L. Krei, Pharm.D.<sup>1</sup>, Andrew J. Cranage, Pharm.D., BCPS<sup>2</sup>, Joy R. Abu-Shanab, Pharm.D., BCPS<sup>3</sup>; (1) St. Louis College of Pharmacy/Mercy Hospital St. Louis, St. Louis, MO (2) St. Louis College of Pharmacy, St. Louis, MO (3) Mercy Hospital St. Louis, St. Louis, MO

**PURPOSE:** An argatroban protocol was developed for implementation at a community teaching hospital. The objective of this study was to determine whether a pharmacy-driven protocol impacts the management of argatroban.

**METHODS:** Patients were included with confirmed or suspected heparin-induced thrombocytopenia (HIT) requiring argatroban from January to December, 2012 (pre-implementation) or from January to April, 2013 (post-implementation). Data including age, gender, serum creatinine, albumin, bilirubin, presence of ascites and/or hepatic encephalopathy, international normalized ratio, activated partial thromboplastin time (aPTT) values, argatroban dosage and duration, documented thrombotic event and bleeding events were collected. The primary outcome was the absolute difference in the proportion of patients with appropriate argatroban management before and after implementation of the pharmacy-driven protocol.

**RESULTS:** Fifteen patients were included in the pre-implementation group and eight in the post-implementation group. Patients were similar at baseline; however, the pre-implementation group had a mean age of 68 years compared to 60 years in the post-implementation group ( $p=0.0448$ ). No patients in the pre-implementation group were considered to be managed appropriately compared to 87.5% in the post-implementation group ( $p<0.0001$ ). Sub-analyses revealed that the appropriate starting dose was administered 26.7% of the time compared to 87.5% ( $p=0.0094$ ), and appropriate dose titrations occurred 22.4% of the time compared to 100% ( $p=0.004$ ) in the pre- and post-implementation groups, respectively. Additionally, patients in the post-implementation group were more likely to be at goal aPTT after the initial

dose than the pre-implementation group (62.5% and 6.7%,  $p=0.0086$ ). There were no documented thrombotic events and no difference in bleeding rates between the two groups.

**CONCLUSION:** Argatroban is a difficult medication to manage appropriately. Development and implementation of a pharmacy-driven protocol, including standards for dosing and monitoring, improved appropriate management of argatroban. Due to the severity of HIT and complexities of argatroban, small changes in appropriate management can lead to significant improvements in patient care.

**128. Care transitions service: a pharmacy-driven medication reconciliation program through the continuum of care.** *Jessica Conklin, Pharm.D.<sup>1</sup>, John Togami, Pharm.D.<sup>2</sup>, Allison Burnett, Pharm.D.<sup>2</sup>, Melanie Dodd, Pharm.D.<sup>1</sup>, Gretchen Ray, Pharm.D.<sup>1</sup>;* (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Department of Pharmacy, University of New Mexico Hospitals, Albuquerque, NM

**PURPOSE:** The current literature evaluates medication errors from two distinct perspectives: the inpatient/hospital setting and the post-discharge/ambulatory care setting. This study analyzes the implementation of an outpatient pilot extension of an ongoing inpatient care transitions medication reconciliation service and also the association of health literacy and the presence of medication related problems. This extension of the service completes the continuum of care defined as admission through post-discharge.

**METHODS:** A post-discharge medication reconciliation, conducted at the University of New Mexico Hospital Family Medicine clinic, was provided to patients who received an initial admission medication reconciliation from the inpatient care transitions service. The Newest Vital Sign was employed to assess health literacy.

**RESULTS:** Post-discharge medication reconciliation was conducted on 16 patients during a 2-month study period. Adherence barriers to therapy were identified in 62.5% of patients. The number of medication related problems (MRP) from inpatient to outpatient decreased. The maximum number of MRP per patient was three and occurred in 37.5% of patients, whereas 18.8% of patients had no MRP identified. Of the 16 patients, a total of 28 MRP were identified. Approximately 75% of the MRP identified were related to patient variables and patient non-adherence. Over 80% of patients had fewer MRP identified at their discharge appointment than were present during their initial medication reconciliation upon admission to the hospital. Eighty six percent of all MRP identified were new MRP while 14% of MRP persisted through the continuum of care.

**CONCLUSION:** MRP are prevalent throughout the continuum of care. Despite identification and resolution of MRP during hospital admission, new MRP developed between the time of discharge and first follow up appointment. In the majority of patients, admission medication reconciliation resulted in a lower number of MRP in the outpatient setting. MRP were present in patients with both adequate and limited health literacy.

## Men's Health

**129. Attitudes and perceptions of a rural Mississippi delta population toward prostate cancer treatments.** *Justin J. Sherman, M.C.S., Pharm.D., Laurie Warrington, Pharm.D., BC-ACP, Daniel M. Riche, Pharm.D., BCPS, CDE;* The University of Mississippi School of Pharmacy, Jackson, MS

**PURPOSE:** To compare a qualitative (focus group discussion) and quantitative analysis (survey instrument) of males and their significant others toward early stage prostate cancer treatments in a rural population.

**METHODS:** Males and their significant others (all females) within several Mississippi Delta communities were recruited for a one-time focus group and survey after approval by the institutional review board. Males aged 45–74 years who had a prostate specific antigen (PSA) taken within normal limits over the past 2 years were included. Seven focus groups, 2 hours each, were conducted in collaboration with healthcare clinics in four commu-

nities. For quantitative analysis, a survey included items that would influence treatment decisions and COMRADE subscales, which address risk communication (subscale 1) and confidence in decision-making (subscale 2). Fisher's Exact tests and t-tests compared survey data between males and females.

**RESULTS:** Of the 77 total participants, 42 were males and 35 were females. The average age overall was  $56.1 \pm 9$  years, with 91% African-American and 9% Caucasian. The qualitative analysis revealed that males were more likely to choose surgery and discuss options with a primary care physician if they were to be diagnosed with prostate cancer, while their significant others would choose active surveillance and discuss options directly with a specialist. The quantitative analysis was significant only for the significant others having a higher COMRADE subscale 1 ( $96.9 \pm 6.6\%$  versus  $88.3 \pm 20.1\%$ ;  $p=0.014$ ) and combined score ( $96 \pm 8.2\%$  versus  $88.5 \pm 19.4\%$ ;  $p=0.002$ ) when compared to males. Other influential marker comparisons were not significant.

**CONCLUSION:** For males not diagnosed with cancer but discussing treatment options for early stage prostate cancer, less importance than their significant others was placed on risk communication with healthcare providers during a quantitative analysis. However, focus group analysis revealed that males would more likely be influenced in their treatment decisions by their primary care physicians.

## Nephrology

**130E. Accuracy of urine collection methods compared to measured GFR in adults with liver disease.** *Joanna Q. Hudson, Pharm.D., BCPS, FASN, FCCP<sup>1</sup>, Asif Siddiqui, M.D.<sup>2</sup>;* (1) University of Tennessee, Memphis, TN (2) College of Medicine, University of Tennessee, Memphis, TN

**PURPOSE:** Accurate assessment of kidney function is necessary to appropriately stage kidney disease, dose medications and make decisions about organ allocation. Estimating equations that incorporate serum creatinine (SCr) are not consistently reliable in patients with liver disease since creatinine production is reduced in this population. Assessment of creatinine clearance (CrCl) using 24-hr urine collection methods to measure CrCl is cumbersome and prone to errors. The purpose of this study was to evaluate the accuracy of measured CrCl determined using shorter urine collection times compared to glomerular filtration rate (GFR) measured by  $^{125}\text{I}$ -iothalamate clearance ( $^{125}\text{I}$ -CL) in patients with liver disease.

**METHODS:** Adult patients with chronic liver disease (Childs Pugh Class B or C), able to make at least 1L per day of urine, and on a stable diuretic dose were enrolled. All patients received  $^{125}\text{I}$ -iothalamate and had a catheter placed for urine collection. Blood samples were collected at designated time points over 8 hours to determine plasma  $^{125}\text{I}$ -CL. CrCl was determined from a 1-hour and a 4-hour urine collection and compared to  $^{125}\text{I}$ -CL using the Wilcoxon signed rank test.

**RESULTS:** Patient characteristics for the eight patients enrolled were as follows (mean  $\pm$  SD): age  $52 \pm 6$  years; SCr  $1.2 \pm 0.4$  mg/dL; and MELD score  $13 \pm 3$ . All patients were Child-Pugh Class B. Mean estimates of kidney function (mean  $\pm$  SD, mL/minute/1.73 m<sup>2</sup>) by method were  $83 \pm 32$  for plasma  $^{125}\text{I}$ -CL,  $79 \pm 28$  for the 1-hour urine collection, and  $83 \pm 29$  for the 4-hour urine collection. CrCl using urine collection methods did not differ significantly from plasma  $^{125}\text{I}$ -CL ( $p=0.9453$  for 1-hour CrCl versus plasma  $^{125}\text{I}$ -CL and  $p=0.0781$  for the 4-hour CrCl versus plasma  $^{125}\text{I}$ -CL).

**CONCLUSION:** When urine collection methods are necessary for an individualized assessment of kidney function, shorter collection times can provide accurate results and would be more feasible for the patient. Published in *Am J Kidney Dis* 2013;61 (4):A47.

**131E. Sodium-dependent glucose co-transporter 2 (SGLT2) inhibition prevents the development of nephropathy in diabetic mice.** *Gerald Shiohita, Pharm.D.<sup>1</sup>, Liru Qiu, M.D.<sup>2</sup>, Xiaoxin Wang, Ph.D.<sup>2</sup>, Veronica Hogg-Cornejo, BS<sup>2</sup>, Chelle Parker, BS<sup>2</sup>, Jimmy*

Ren, Ph.D.<sup>3</sup>, Yin Liang, M.D., Ph.D.<sup>4</sup>, Moshe Levi, M.D.<sup>2</sup>; (1)Medical Affairs, Janssen Scientific Affairs (Janssen Pharmaceuticals), Boulder, CO (2)Division of Renal Diseases and Hypertension, University of Colorado School of Medicine, Aurora, CO (3)Department of Medical Affairs, Janssen Pharmaceuticals, Raritan, NJ (4)Department of Research and Development, Janssen Pharmaceuticals, Raritan, NJ

**PURPOSE:** The purpose of this study is to determine the effects of SGLT2 inhibition in the kidneys of mice with type 2 diabetes mellitus.

**METHODS:** In this controlled study, db/db-BKS type 2 diabetes mouse model were treated with a selective SGLT2 inhibitor at a dose of 0.7 g/kg diet or vehicle for 12 weeks. We measured metabolic parameters (body weight), urine and blood chemistry (blood glucose, urinary albumin and urinary TBARS), and kidney pathology (PAS staining for mesangial expansion, podocyte marker staining for podocyte loss, oil red O staining for renal lipid accumulation, extracellular matrix protein staining for renal fibrosis, and macrophage marker staining for inflammation) to evaluate the effects of SGLT2 inhibition on diabetic nephropathy.

**RESULTS:** After 12 weeks treatment, SGLT2 inhibition caused marked decreases in urinary albumin ( $745 \pm 36$  mg/g in db/db versus  $207 \pm 5$  mg/g in treated db/db,  $p < 0.001$ ) and urinary TBARS (thiobarbituric acid-reacting substances), ( $1.09 \pm 0.13$  mmol/g in db/db versus  $0.48 \pm 0.10$  mmol/g in treated db/db,  $p < 0.01$ ) an indicator of oxidative stress. SGLT2 inhibitor treatment also prevented mesangial expansion, accumulation of extracellular matrix proteins as determined by fibronectin and type IV collagen quantitative immunofluorescence microscopy, and podocyte loss as determined by WT1 and synaptopodin quantitative immunofluorescence microscopy (all  $p < 0.05$ ). In addition, in SGLT2 inhibitor treated mice, we found that SGLT2 inhibition prevented renal accumulation of macrophages as determined by CD68 immunofluorescence microscopy and renal neutral lipid accumulation as determined by Oil Red O staining.

**CONCLUSION:** SGLT2 inhibition normalizes blood glucose level and improves diabetic nephropathy in db/db mice of type 2 diabetes model, accompanied by the reduction in renal glomerular extracellular matrix deposition, renal macrophage infiltration and neutral lipid accumulation. In summary, our study results showed that SGLT2 inhibitor treatment prevents the development of nephropathy in db/db mice.

Presented at Presented at the American Diabetes Association Scientific Sessions, Chicago, IL, June 21–25, 2013.

**132E. Trimethoprim/sulfamethoxazole loss in modeled continuous renal replacement therapy.** A. Mary Vilay, Pharm.D.<sup>1</sup>, Jacob Kesner, Pharm.D. Candidate<sup>1</sup>, J. Michael Yardman-Frank, B.S. Candidate<sup>1</sup>, Ronald Schrader, Ph.D.<sup>1</sup>, Renee Mercier, Pharm.D.<sup>1</sup>, Dean Argyres, M.S.<sup>2</sup>, Craig Wong, M.D., M.P.H.<sup>1</sup>; (1)University of New Mexico, Albuquerque, NM (2)VA Cooperative Studies Program, Albuquerque, NM

**PURPOSE:** Drug adsorption to medical devices can be an important source of drug loss. Our objective was to characterize whether Trimethoprim (TMP) and/or sulfamethoxazole (SMX) adsorbs to the continuous renal replacement therapy (CRRT) circuit using an in vitro model.

**METHODS:** The model consisted of a glass chamber with human blood connected to an AN69 hemodiafilter (M100, Gambro) with polyvinylchloride tubing. TMP and SMX were added, a time 0 sample was collected, and blood circulation through the circuit was started. Blood samples were collected at predetermined times over 60 minutes. A second dose of TMP/SMX was administered. Blood samples were collected at 1 and 60 minutes post dose. This was repeated for a total of five TMP/SMX doses. One liter Lactated Ringers was added to the blood reservoir. Blood sample were collected at predetermined time points over the next hour to determine reversibility of adsorption. Experiments were repeated five times each with and without a hemodiafilter.

**RESULTS:** SMX concentrations decreased, suggesting adsorption, in circuits with a hemodiafilter after the first and fourth dose ( $p < 0.05$ ). TMP concentrations decreased with doses 1

through 5 in circuits with a hemodiafilter ( $p < 0.001$ ). With the first dose, SMX concentrations decreased by a mean of  $4 \pm 2\%$  while TMP concentrations decreased by a mean of  $28 \pm 10\%$ . Minimal to no SMX/TMP loss was observed in circuits without a hemodiafilter. SMX and TMP concentrations increased ( $p < 0.01$ ) after addition of Lactated Ringers to circuits with a hemodiafilter, suggesting that adsorption may be reversible.

**CONCLUSIONS:** Decreased blood concentration due to adsorption to the hemodiafilter occurred to varying degrees with SMX and TMP. SMX adsorption appeared to be minimal while TMP adsorption appeared to occur to a greater degree (mean 28% decrease after the first dose) and to be cumulative. TMP adsorption to CRRT circuits may have important clinical implications and should be verified with *in vivo* studies. Presented at American Association of Colleges of Pharmacy Annual Meeting, Chicago, IL, July 14, 2013.

## Nutrition

**133E. Improved safety with early de-escalation of intravenous insulin therapy for critically ill patients with renal failure.** Roland Dickerson, Pharm.D.<sup>1</sup>, Allison Lynch, Pharm.D.<sup>2</sup>, George Maish, III, M.D.<sup>1</sup>, Martin Croce, M.D.<sup>1</sup>, Gayle Minard, M.D.<sup>1</sup>, Rex Brown, Pharm.D.<sup>1</sup>; (1)University of Tennessee Health Science Center, Memphis, TN (2)Duke University Health System, Durham, NC

**PURPOSE:** Due to exaggerated risk for hypoglycemia with regular human insulin (RHI) therapy during renal failure, we previously modified our conventional RHI algorithm designed for patients without renal failure by allowing for greater changes in blood glucose (BG) concentrations before the RHI infusion rate was increased. Despite this modification, the rate of hypoglycemia was still unacceptable. These results prompted another modification whereby the RHI infusion rate was decreased at higher BG concentrations (e.g., early de-escalation). The intent of this study was to evaluate the safety and efficacy of our early de-escalation/slow escalation RHI infusion algorithm.

**METHODS:** Adult trauma patients with renal failure, who received continuous enteral or parenteral nutrition and at least 3 days of the re-modified RHI algorithm, were retrospectively evaluated. Patients with renal failure who received our previous slow escalation algorithm without the early de-escalation component served as historical controls. BG was evaluated for 7 days while receiving RHI. Target BG was 70–149 mg/dL. Glycemic control and incidence of hypoglycemia for both algorithms were compared.

**RESULTS:** Mean BG was higher for the early de-escalation/slow escalation RHI infusion group ( $n=25$ ) compared to the slow escalation RHI infusion group ( $n=21$ ):  $145 \pm 10$  mg/dL versus  $133 \pm 14$  mg/dL ( $p=0.001$ ). The early de-escalation/slow escalation RHI algorithm had less time within the target BG range ( $11.9 \pm 2.5$  versus  $16.1 \pm 3.3$  hours/days,  $p=0.001$ ) but was within 70–179 mg for  $16.3 \pm 2.6$  hours/days. Moderate hypoglycemia (40–60 mg/dL) was decreased with the early de-escalation/slow escalation RHI algorithm (32% versus 76%,  $p=0.001$ ) and severe hypoglycemia ( $BG < 40$  mg/dL) was eliminated (0% versus 29%,  $p=0.006$ ).

**CONCLUSION:** The early de-escalation/slow escalation RHI algorithm improved patient safety by significantly decreasing hypoglycemia yet maintained reasonable glycemic control particularly within a higher BG ceiling ( $< 180$  mg/dL).

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## Other

**134E. Institutional review board barriers and solutions encountered in the collaboration among pharmacists and physicians to improve outcomes now study: a national multicenter practice-based implementation trial.** Eric MacLaughlin, Pharm.D.<sup>1</sup>, Gail Ardery, Ph.D., R.N.<sup>2</sup>, Eric Jackson, Pharm.D.<sup>3</sup>, Timothy J. Ives, Pharm.D., M.P.H.<sup>4</sup>, Rodney B. Young, M.D.<sup>5</sup>, David S. Fike, Ph.D.<sup>6</sup>, Barry



Carter, Pharm.D.<sup>2</sup>; (1) Department of Pharmacy Practice, Texas Tech University Health Sciences Center, Amarillo, TX (2) University of Iowa College of Pharmacy, Iowa City, IA (3) University of Connecticut School of Medicine, Farmington, CT (4) University of North Carolina, Eshelman School of Pharmacy, Chapel Hill, NC (5) Texas Tech University Health Sciences Center School of Medicine, Amarillo, TX (6) University of the Incarnate Word, San Antonio, TX

**PURPOSE:** Categorize institutional review board (IRB) challenges and solutions in a multi-center practice-based research network (PBRN) study and assess the impact of IRB requirements on individual principal investigators (PIs) willingness to participate in future PBRN studies.

**METHODS:** The Collaboration Among Pharmacists and Physicians To Improve Outcomes Now (CAPTION) study is a multi-center, prospective, cluster-randomized study evaluating implementation of a collaborative model between physicians and pharmacists to improve outcomes in patients with hypertension or asthma. IRB barriers encountered and solutions were categorized for study sites (n=31). A survey of study-site PIs (n=28) was conducted with a correlational analysis assessing the impact of various IRB requirements and individual PI's willingness to participate in future PBRN studies.

**RESULTS:** IRBs posed a number of challenges, including bias regarding the source of the application, issues regarding study design, study instruments, access to patient records, study procedures, Spanish-only speaking subjects, role of clinic physicians, interdepartmental concerns, and updates at continuing review. Responses from the PI survey (n=21/28; 75% response rate) indicated that the willingness of an individual to serve as a PI in the future was inversely related to the perceived difficulty of obtaining initial and continuing IRB approval ( $r_s = -0.599$ ,  $p = 0.004$  and  $r_s = -0.464$ ,  $p = 0.034$  respectively).

**CONCLUSION:** Significant time and resources were required to address various challenges associated with IRB approval, which negatively impacted individual PI willingness to participate in future PBRN projects. A revision of current rules and regulations regarding human subjects protection for practice-based studies, improvement in IRB processes, and support from coordinating centers may decrease the burden associated with IRB approval and increase participation in practice-based research.

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**135. Medication beliefs and adherence among patients with diabetes mellitus.** Melanie Siaw, B.Sc.<sup>1</sup>, Rachel Chua, B.Sc.<sup>1</sup>, Esther Bek, M.Sc., BCPS, BCACP<sup>2</sup>, Joyce Lee, Pharm.D., BCPS, BCACP<sup>1</sup>; (1) Department of Pharmacy, Faculty of Science at National University of Singapore, Singapore (2) Department of Pharmacy, National Healthcare Group Pharmacy, Singapore

**PURPOSE:** Little is known about the intricate relationship between medication beliefs and adherence in patients with diabetes. This study was conducted to (i) determine medication beliefs of patients with uncontrolled diabetes, and (ii) investigate the association of medication beliefs in relation to adherence and number of antidiabetic agents used per day.

**METHODS:** This was a cross-sectional study conducted at nine government-owned primary care institutions. From August 2012 to January 2013, a 31-item self-administered questionnaire, consisted of patient demographics, BMQ (Beliefs about Medicines Questionnaire), and MMAS (Morisky 8-item Medication Adherence Questionnaire) were given to all patients aged  $\geq 21$  years with  $\geq 1$  antidiabetic agents. Patients who were unable to understand the content of the questionnaire were excluded from this study. Multiple linear regression was employed to assess the associations while controlling for age group, gender, ethnicity, education level and HbA1c values.

**RESULTS:** Of the 483 eligible patients, 272 (56.3%) completed the entire questionnaire. Most patients were aged between 61 and 70 years with mean HbA1c of  $8.28 \pm 1.5\%$ . Based on the responses, 77.6% believed that their prescribed medications were necessary. In addition, 79.4% believed that taking medications was beneficial and few believed that medications in general were

overused (48.5%) or harmful (23.5%). Multiple linear regression revealed that lower adherence was associated with stronger specific concerns ( $p < 0.001$ ), and stronger general beliefs that medications were overused ( $p < 0.001$ ), harmful ( $p = 0.012$ ), or risky ( $p < 0.001$ ). Greater number of antidiabetic agents taken per day was also associated with the belief that taking medications was risky ( $p = 0.042$ ).

**CONCLUSION:** Low rates of adherence were found in patients who believed in antidiabetic agents negatively or held greater concerns about the effects of these medications on their health. Adherence rates and number of antidiabetic agents taken per day were significantly associated with medication beliefs.

**136. Reversal of anticoagulation in patients presenting with an acute head injury.** Jennifer Petrie, Pharm.D.; School of Pharmacy, University of Wyoming, Laramie, WY

**PURPOSE:** This study documented drug therapy and/or blood product received by anticoagulated patients surviving an acute head injury in a Level II Trauma Center in order to 1) evaluate the time required to reverse anticoagulation, resulting in the best patient outcome, and 2) evaluate which treatment combination resulted in the most rapid reversal.

**METHODS:** Medical records of seven anticoagulated patients with acute head injury, requiring reversal, admitted to a Level II Trauma Center between January 1 and December 31, 2012 were reviewed. Patients' pertinent medical history, in-hospital course, and specific drug management prior to admission and during the hospital stay, were documented.

**RESULTS:** Reversal of anticoagulation (INR  $< 1.5$ ) occurred in 57% of the patients studied with the remaining patients' INR measuring  $< 1.8$ . Products utilized to decrease INR for each patient included: FFP (100%), PCC (0%), Factor VII (14%), and Vitamin K (29%). The following products were combined while attempting to reverse anticoagulation: FFP alone (57%), FFP and Factor VII (14%), FFP and Vitamin K (29%). The average amount of FFP administered was approximately 530 mL. The use of  $> 2000$  mL of FFP resulted in the most rapid reversal of anticoagulation (100 minutes from admission). One patient who was administered FFP and Vitamin K developed a DVT on post-injury day three. The average patient age was 75.7 years old. Forty-three percent of patients were discharged home alone or with home-care, 14% of patients were discharged to a skilled-nursing facility, 14% of patients were discharged to a rehabilitation facility, and 29% of patients died (family withdrew care).

**CONCLUSION:** The use of  $> 2000$  mL of FFP resulted in the most rapid reversal of anticoagulation. For enhanced patient outcomes, time from admission to reversal of anticoagulation should be determined through further research in this area, utilizing a larger sample size.

## Pain Management/Analgesia

**137. Lubiprostone for treatment of opioid-induced constipation does not interfere with opioid analgesic effects in patients with non-cancer pain.** Egilius L. H. Spierings, M.D. Ph.D.<sup>1</sup>, Taryn Joswick, BS, PMP<sup>2</sup>, Shadreck Mareya, Ph.D.<sup>2</sup>, Yijun Sun, Ph.D.<sup>2</sup>, Ryuji Ueno, M.D., Ph.D.<sup>3</sup>; (1) Headache & Face Pain Program, Tufts Medical Center, and Craniofacial Pain Center, Tufts University School of Dental Medicine, Watertown, MA (2) Sucampo Pharma Americas, LLC, Bethesda, MD (3) Sucampo AG, Zug, Switzerland

**PURPOSE:** This post-hoc analysis of pooled data from three 12-week, randomized, double-blind, placebo-controlled trials evaluated whether oral lubiprostone, recently approved for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, interferes with opioid analgesia.

**METHODS:** Patients  $\geq 18$  years old on a stable opioid dose and having  $< 3$  spontaneous bowel movements per week were randomized to twice-daily (BID) lubiprostone 24 mcg (n=659) or placebo (n=641). In one trial, patients receiving diphenylheptane opioids (methadone or propoxyphene) were excluded. Analgesic interfer-

ence was assessed using patient-reported Brief Pain Inventory–Short Form (BPI-SF) scores and by changes in morphine-equivalent daily (i.e., opioid) dose (MEDD). Scores for the BPI-SF domains of pain interference and pain severity (including “worst pain”) could range from zero (none) to 10 (maximum).

**RESULTS:** Mean BPI-SF domain scores were similar between the lubiprostone and placebo groups at baseline; these scores remained generally stable and were similar between the groups at months 1, 2, and 3. The mean changes from baseline in BPI-SF scores were statistically similar between treatment groups at each month. The mean changes from baseline in MEDD were also statistically similar between treatment groups at each month.

**CONCLUSION:** Lubiprostone 24 mcg BID did not interfere with the analgesic effect of opioids in adult patients with chronic non-cancer pain and OIC.

**138. Evaluation of the impact of a pharmacist provided non-malignant chronic opioid management education program to physicians in a primary care practice setting.** *Rebecca Bragg, Pharm.D., Amy M. Drew, Pharm.D., BCPS, Jamie M. Pitlick, Pharm.D., BCPS, St. Louis College of Pharmacy, St. Louis, MO*

**PURPOSE:** The objective of this study was to evaluate the impact of a pharmacist provided chronic opioid management education program on physician comfort levels at two independent primary care offices.

**METHODS:** All physicians practicing at the Mercy Clinic Family Medicine and John F. Kennedy Internal Medicine Clinic were invited to participate in the study. Physicians completed an electronic pre-education survey, in March 2013, consisting of questions addressing background education and baseline comfort with opioid prescribing. The intervention consisted of three informational handouts covering opioid pharmacology, dosing in respects to equianalgesic and formulation conversion, and use of opioid risk assessment tools. These handouts were distributed, in April 2013, to all physicians via email along with an audio recording reviewing key concepts. Physicians completed an electronic post-education survey consisting of the same comfort assessment questions at the end of April 2013.

**RESULTS:** The pre-education survey had a 26% response rate (n=14). Of the participants, 79% indicated “uncomfortable” or “neutral” comfort rating for managing chronic opioid patients and 56% indicated that they were “uncomfortable” or “very uncomfortable” using opioid risk assessment tools. There was not a statistically significant difference in the primary outcome of change in overall comfort score pre- and post-education (n=2, p=0.655). The post-education survey had a 23% response rate (n=12) and 81% indicated a “neutral”, “comfortable”, or “very comfortable” rating for the various aspects of opioid prescribing, including pharmacology, dosing and use of risk assessment tools.

**CONCLUSION:** This study did not find a significant improvement in self-reported comfort scores for opioid prescribing. The low comfort scores reported on the baseline survey indicates a need for opioid education for physicians in these clinics. Future education programs could include live teaching sessions, a longitudinal education series, and the incorporation of opioid risk assessment tools in the patient electronic medical records.

**139E. Treatment of episodic tension-type headache with a novel formulation of ibuprofen sodium.** *Elias Packman, ScD<sup>1</sup>, Rina Leyva, MS<sup>2</sup>, David Kellstein, Ph.D.<sup>2</sup>, (1) Institute for Applied Pharmaceutical Research, Philadelphia, PA (2) Pfizer Consumer Healthcare, Madison, NJ*

**PURPOSE:** To evaluate the efficacy and onset of analgesia of a novel formulation of ibuprofen sodium (IBU<sub>Na</sub>) tablets compared to standard IBU tablets and placebo in the treatment of episodic tension-type headache (ETTH).

**METHODS:** This randomized, double-blind, single-center, parallel-group study included subjects aged 18–65 years with a history of ≥4 ETTH attacks per month for the past 6 months. Subjects reporting at least moderately severe baseline headache pain were randomized 2:2:1 to single-dose IBU<sub>Na</sub> (2 × 256 mg; equivalent

to 400 mg standard IBU), Motrin<sup>®</sup> (IBU<sub>Mot</sub>; 2 × 200 mg), or placebo. Primary endpoints were the time-weighted sum of pain relief rating (PRR) and pain intensity difference (PID) scores over 3 hours (SPRID 0–3) and time to meaningful pain relief (TMPR), assessed by the double stopwatch method. Secondary endpoints included time to first perceptible pain relief (TFPR) confirmed by TMPR; sum of PRR and PID scores (PRID) at 1, 2, and 3 hours post-dose; and time-weighted sum of PRR, PID, and PRID scores over 2 and 3 hours.

**RESULTS:** Eligible subjects (N=226) were randomized to IBU<sub>Na</sub> (n=91), IBU<sub>Mot</sub> (n=89), and placebo (n=46). Both IBU<sub>Na</sub> and IBU<sub>Mot</sub> had significantly better mean SPRID 0–3 scores than placebo (p<0.001), but were not significantly different from each other. Results for summed secondary endpoints were similar. Median TMPR was significantly faster in both active treatment groups (IBU<sub>Na</sub> = 40.6 minutes; IBU<sub>Mot</sub> = 48.5 minutes) versus placebo (>180 minutes; p<0.001). Although TMPR was not significantly different between the IBU<sub>Na</sub> and IBU<sub>Mot</sub> groups in the prespecified analysis (p=0.253), a post-hoc analysis assigning higher weight to earlier timepoints indicated that IBU<sub>Na</sub> provided faster TMPR and TFPR than IBU<sub>Mot</sub> (p=0.022 and 0.020, respectively). No adverse events were reported.

**CONCLUSION:** IBU<sub>Na</sub> is effective and safe in the treatment of ETTH. A post-hoc analysis indicated that IBU<sub>Na</sub> provides an appreciably faster onset of analgesia than standard IBU. Funded by Pfizer Consumer Healthcare.

Published in 55th annual meeting of the American Headache Society (AHS) held in conjunction with the 16th biennial congress of the International Headache Society (IHS); June 27–30, 2013; Boston, MA.

**140E. A novel formulation of ibuprofen sodium is absorbed faster than standard ibuprofen tablets.** *Thomas Legg, D.O.<sup>1</sup>, Rina Leyva, MS<sup>2</sup>, David Kellstein, Ph.D.<sup>2</sup>, (1) CoxHealth, Springfield, MO (2) Pfizer Consumer Healthcare, Madison, NJ*

**PURPOSE:** To evaluate the rate and extent of ibuprofen (IBU) absorption from a novel IBU sodium (IBU<sub>Na</sub>) tablet versus other marketed IBU formulations.

**METHODS:** Two randomized, single-dose, open-label, 5-way crossover pharmacokinetic studies were conducted. In Study 1, subjects received IBU<sub>Na</sub> tablets (2 × 256 mg), Advil<sup>®</sup> Liqui-Gels<sup>®</sup> (IBU<sub>LG</sub>; 2 × 200 mg), and Motrin<sup>®</sup> IB tablets (IBU<sub>Mot</sub>; 2 × 200 mg), each equivalent to 200 mg IBU free acid, following an overnight fast; the same doses of IBU<sub>Na</sub> and IBU<sub>LG</sub> were administered within 20 minutes of a high-fat meal. In Study 2, fasting subjects received IBU<sub>Na</sub> tablets (2 × 256 mg), Advil<sup>®</sup> Fast-gel<sup>®</sup> liquid capsules (IBU<sub>FG</sub>; 2 × 200 mg) and Nurofen<sup>®</sup> Express caplets containing lysine (IBU<sub>Lys</sub>; 2 × 342 mg), each equivalent to 200 mg IBU free acid. The rate (maximum plasma concentration [C<sub>max</sub>]) and extent (area under the concentration-versus-time curve to last measurement [AUC<sub>L</sub>]) of IBU absorption were compared between IBU<sub>Na</sub> and the other marketed IBU formulations.

**RESULTS:** Analyses from the two studies revealed that IBU<sub>Na</sub> was bioequivalent to IBU<sub>LG</sub> in fasted and fed states and to IBU<sub>FG</sub> and IBU<sub>Lys</sub> in the fasted state. IBU<sub>Na</sub> demonstrated a bioequivalent extent of absorption with IBU<sub>Mot</sub>, IBU<sub>Adv</sub>, and IBU<sub>Nur</sub> while fasting, but the absorption of IBU<sub>Na</sub> was significantly faster compared with all three standard IBU tablets. Median time to C<sub>max</sub> (T<sub>max</sub>) for IBU<sub>Na</sub> was 30–35 minutes, and was comparable to IBU<sub>LG</sub>, IBU<sub>FG</sub>, and IBU<sub>Lys</sub> (median T<sub>max</sub> = 40, 40, and 35 minutes, respectively) but shorter than IBU<sub>Mot</sub>, IBU<sub>Nur</sub>, and IBU<sub>Adv</sub> (median T<sub>max</sub> = 120, 120, and 82 minutes, respectively). In the fed state, IBU<sub>Na</sub> and IBU<sub>LG</sub> had the same median T<sub>max</sub> (90 minutes). Adverse events (AEs) were balanced across treatments and mostly mild in severity. The most common AEs were headache and dizziness.

**CONCLUSION:** This novel IBU<sub>Na</sub> tablet formulation provides faster IBU absorption compared to standard IBU and may result in a more rapid onset of pain relief. Funded by Pfizer Consumer Healthcare.

Presented at 32nd Annual Scientific Meeting of the American Pain Society; May 8–11, 2013; New Orleans, LA.

**141E. A novel formulation of ibuprofen sodium has a faster onset of analgesia than standard ibuprofen tablets in the treatment of postoperative dental pain.** Patrick Brain, DDS<sup>1</sup>, Rina Leyva, MS<sup>2</sup>, David Kellstein, Ph.D.<sup>2</sup>; (1)Jean Brown Research, Salt Lake City, UT (2)Pfizer Consumer Healthcare, Madison, NJ

**PURPOSE:** A novel formulation of ibuprofen sodium (IBU<sub>Na</sub>) has been developed that is absorbed faster than standard IBU tablets. The clinical relevance of faster absorption was tested in a randomized, double-blind, single-center, 8-hour, inpatient study using the third molar extraction model of dental pain. The overall efficacy and onset of analgesia of IBU<sub>Na</sub> were compared with that of standard IBU tablets.

**METHODS:** Subjects (N=316) with at least moderate baseline pain were randomized 2:2:2:1 to receive a single dose of IBU<sub>Na</sub> (2 × 256 mg; equivalent to 400 mg IBU; n=95), Advil<sup>®</sup> (IBU<sub>Adv</sub>; 2 × 200 mg; n=86), Motrin<sup>®</sup> (IBU<sub>Mot</sub>; 2 × 200 mg; n=87), or placebo (n=48). Primary endpoints were time-weighted sum of pain relief and pain intensity differences over 8 hours (SPRID 0–8) and time to meaningful pain relief (TMPR) as assessed by the double stopwatch method.

**RESULTS:** Mean SPRID 0–8 score was significantly greater for IBU<sub>Na</sub> and the other active treatments versus placebo (p<0.001). The IBU<sub>Na</sub> group reported TMPR significantly earlier (median 42.4 minutes) than placebo (>8 hours), pooled IBU<sub>Adv</sub>/IBU<sub>Mot</sub> (median, 55.3 minutes), and IBU<sub>Mot</sub> (median, 60.7 minutes) (all p<0.001), and marginally faster than IBU<sub>Adv</sub> (median, 52.0 minutes; p=0.075). By study end, 22.9%, 95.8%, 88.4%, 94.2%, and 82.8% of subjects in the placebo, IBU<sub>Na</sub>, pooled IBU<sub>Adv</sub>/IBU<sub>Mot</sub>, IBU<sub>Adv</sub>, and IBU<sub>Mot</sub> groups, respectively, achieved MPR. Results for secondary endpoints, including time to first perceptible pain relief; SPRID scores over 2, 3, and 6 hours; time to treatment failure; and global evaluation of treatment, were similar. Most adverse events were mild or moderate gastrointestinal disorders (e.g., nausea and vomiting) and were similar across treatment groups. There were no serious adverse events or discontinuations due to adverse events.

**CONCLUSION:** This novel formulation of IBU<sub>Na</sub> provides more rapid onset of analgesia than standard IBU tablets and represents a new treatment option for rapid relief of acute pain. Funded by Pfizer Consumer Healthcare. Presented at 32nd Annual Scientific Meeting of the American Pain Society; May 8–11, 2013; New Orleans, LA.

**142. Medication use patterns among patients with chronic low back pain taking chronic opioids.** Margaret L. Wallace, Pharm.D., BCACP<sup>1</sup>, Aleksandra Zgierska, M.D., Ph.D.<sup>2</sup>, Jennifer Cox, BS<sup>2</sup>, Cindy Burzinski, MS<sup>2</sup>, Iliya Amaza, M.D.<sup>2</sup>, David Rabago, M.D.<sup>2</sup>; (1)Department of Family Medicine, University of Wisconsin, Madison, WI (2)University of Wisconsin, Madison, WI

**PURPOSE:** Chronic low back pain (CLBP) is a common, expensive, and disabling condition; it is often refractory to treatment. This study describes a pharmacological profile of adult opioid-treated CLBP patients in order to (i) describe medication use patterns, and (ii) identify potential areas for pharmacotherapy optimization in this population.

**METHODS:** This analysis is based on baseline, cross-sectional data of opioid-treated, CLBP adult participants in a randomized controlled trial of mindfulness-based intervention aimed at improving quality of life and decreasing the need for pain medication use among these patients. Study eligibility criteria included age > 21 years and at least 3 month-history of opioid-treated CLBP utilizing 30 mg or more of morphine equivalent dose (MED) per day. Demographic and self-reported medication use data, verified by participant's medication bottle information, were collected; MED was calculated for opioid medications. Basic descriptive statistics were conducted using Microsoft Excel.

**RESULTS:** All participants (N=35) completed the baseline medication use survey. They were on average 53 ± 9.5 years old, and 80% were female. On average, they reported taking 14 ± 6.8 medications/day (range: 3–32), including 4.6 ± 1.6 medications with analgesic properties: 100% used opioids (3% tramadol; 97% pure mu-agonists, with 57% long-acting, and 100%

short-acting preparations), 46% used gamma-aminobutyric acid (GABA) analogs, 46% used non-steroidal anti-inflammatory drugs (NSAID), 37% used skeletal-muscle relaxants, 26% used acetaminophen, and 26% used serotonin-norepinephrine reuptake inhibitors (SNRI). The average MED was 130 ± 110 mg/day. Participants used on average 4.5 ± 1.9 daily medications with sedating properties (range: 1–19): 31% used benzodiazepines, 17% used antiemetic medications, 17% used antihistamines, and 14% used non-benzodiazepine sedative hypnotic medications.

**CONCLUSIONS:** Findings of our study corroborate existing evidence of high medication burden among opioid-treated CLBP patients, and suggest that medication optimization may help improve treatment outcomes, and reduce medication burden and potential side effects, especially over-sedation, in this population.

**143. An analysis of hospital consumer assessment of healthcare providers and systems pain scores on an internal medicine service.** William Wilkie, Pharm.D.<sup>1</sup>, George Davis, Pharm.D.<sup>1</sup>, Kristy Deep, M.D.<sup>2</sup>, Sara Brouse, Pharm.D.<sup>1</sup>; (1)Department of Pharmacy Services, UK HealthCare, Lexington, KY (2)Department of Internal Medicine Services, UK HealthCare, Lexington, KY

**PURPOSE:** In 2001, the Joint Commission implemented an accreditation standard that required monitoring of patients' pain during hospitalization. In 2006, the Centers for Medicare and Medicaid Services began publicly reporting Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) results in which pain score was a component. Since the passage of the Affordable Care Act in 2010, Medicare reimbursement is connected to patient satisfaction, as pain management is a core question in the HCAHPS survey. Thus, hospitals have placed a high priority improving pain management practices to insure better scores. Pain control is more difficult in a subpopulation of patients who are at risk for opioid tolerance. Consequently, their satisfaction in relation to pain control will negatively impact the HCAHPS survey.

**METHODS:** This retrospective observation study analyzed patients admitted to the Internal Medicine (IM) service at UK Chandler Hospital between May 1, 2011 and September 30, 2012. Exclusion criteria include patients <18 years of age, patients transferred to the IM service from other hospital services, patients transferred from outside hospital with a length of stay >48 hours, and patients who had a hospital length of stay at UK < 24 hours.

**RESULTS:** Opioid tolerant patients are more likely than opioid naïve patients to rate lower the hospital staff to do all they can in controlling patient pain (32.8% versus 16.9%, p=0.032). Opioid tolerant patients are more likely to have their pain not controlled at 24 and 48 hours after admission than opioid naïve (61.4% versus 82.9%; p=0.005 and 67.1% versus 80.0%; p=0.04).

**CONCLUSION:** Opioid tolerant patients are more likely to report unfavorable HCAHPS scores related to pain than opioid naïve patients. Thus, recognizing these patients on admission and accordingly adjust their medications relative to pain, may improve HCAHPS pain scores.

## Pediatrics

**144. Gaining a unit specific understanding for the need of fungal prophylaxis in the intensive care nursery.** Tracy Sandritter, Pharm.D.<sup>1</sup>, Alexandra Oschman, Pharm.D.<sup>2</sup>; (1)Clinical Pharmacology/Toxicology, Children's Mercy Hospitals and Clinics, Kansas City, MO (2)Children's Mercy Hospital and Clinics, Kansas City, MO

**PURPOSE:** While fluconazole prophylaxis (FP) can prevent invasive fungal infections (IFI) in extremely low birth weight (ELBW) neonates, controversy exists regarding universal adoption of FP in ELBW neonates. With FP the rate of IFI does decrease but does not completely prevent disease. Hospital settings with high baseline IFI incidence rates have shown a benefit for FP. However, in settings with low baseline rates, the number needed to treat may approach 100 patients to prevent one IFI.



**METHODS:** IRB approved, retrospective study of patients with a culture positive fungal infections from 2005 to 2010. Primary objective: to determine the baseline fungal incidence rate, understand risk factors for culture positive fungal infections, and to determine if FP is warranted in specific populations in our unit. Medical records were reviewed for the presence of known risk factors for fungal infections.

**RESULTS:** Twenty-seven patients developed a culture positive fungal infection. Last 3-year mean incidence rate in ELBW infants was 2.5%. No consistent pattern or risk factors identified. Gestational age distribution:  $\leq 27$  weeks (12), 28–32 weeks (2), 33–37 weeks (6),  $> 38$  weeks (7). Of the 50% on antibiotics, 35% were  $< 1000$  g and 65% were 3.6–4.8 kg. Antibiotic exposure did not correlate with fungal infection. Seven of 14 patients developed fungal infection within the first 7 days after antibiotic exposure. Seventy percent had one positive site of infection; the most common site being blood (48%), followed by urine (29%). Other risk factors: 15% Necrotizing Enterocolitis, 18.5% steroids, 26% H2/PPI, 67% intubated, 70% lipids, 74% TPN, and 77% central lines.

**CONCLUSION:** Routine use of FP is not recommended but the decision should be individualized for patients in our institution. This is consistent with American Academy of Pediatrics recommendations that FP should be considered in ELBW infants only if the incidence rate is moderate or high.

**145. Metabolic monitoring in pediatric patients receiving second generation antipsychotics.** Yardlee S. Kauffman, Pharm.D., MPH<sup>1</sup>, Sheila Botts, Pharm.D.<sup>2</sup>, Kerri Gaughan, Pharm.D.<sup>2</sup>, Thomas Delate, Ph.D., MS<sup>2</sup>; (1)Pharmacy Department, Kaiser Permanente Colorado, Aurora, CO (2)Kaiser Permanente Colorado, Aurora, CO

**PURPOSE:** The purpose of this study is to describe a pediatric population newly initiated on an second generation antipsychotic (SGA) and identify percentages of patients who (i) received recommended monitoring at baseline and follow-up, (ii) developed a metabolic adverse effect subsequent to SGA initiation and (iii) received a pharmacologic or behavioral intervention for the metabolic adverse effect.

**METHODS:** This study was a retrospective cohort analysis at Kaiser Permanente of Colorado (KPCO). Patients  $< 18$  years of age, who purchased a newly initiated SGA between January 1, 2002 and June 30, 2011 at a KPCO outpatient pharmacy, were included. The primary study outcome was the percentage of patients who received all metabolic monitoring at baseline and follow-up after SGA initiation. Metabolic monitoring was defined as lipid, fasting blood glucose, blood pressure, and weight measurements. Patient characteristics and outcomes were compared using t-tests and chi-square tests for continuous and categorical data, respectively. Pharmacologic and behavioral interventions for patients who experienced a metabolic adverse effect were examined.

**RESULTS:** Five percent of 1023 patients received all recommended baseline monitoring and 3% received all recommended follow-up monitoring. The percentage of patients with monitoring for each parameter at baseline and follow-up, respectively: lipids (15% and 10%), glucose (8% and 12%), blood pressure (58% and 45%), and weight (55% and 43%). Metabolic effects occurred in 12.7 percent (130) of patients. Recommendations for weight and diet changes were recommended to 25% (33) of patients who experienced a metabolic adverse effect.

**CONCLUSION:** Metabolic monitoring rates within this setting were low during the study timeframe. Only a small proportion of patients received an intervention for a metabolic adverse effect. Future research should focus on designing and implementing interventions that improve metabolic monitoring rates in pediatric patients.

**146. Medication dosing alert rates at a pediatric institution.** Jeremy S. Stultz, Pharm.D., Milap C. Nahata, Pharm.D., MS; Ohio State University College of Pharmacy, Columbus, OH

**PURPOSE:** Dosing alerts are being used in pediatric institutions to prevent medication dosing errors and adverse events. Identification of highly alerted medications is important to direct institutional customization efforts and prevent alert fatigue. The objectives of this study were to determine the dosing alert rate for different medication classes and to compare the alert rate in adult and pediatric patients.

**METHODS:** A retrospective analysis was performed for all inpatient medication orders and all dosing alerts occurring during October 2011 and January, April, and July 2012 at a tertiary pediatric hospital. Medication orders were categorized by American Hospital Formulary Service pharmacologic-therapeutic class and patient age. 95% confidence intervals (CI) were used to describe proportions and alert rates were compared by Chi-Squared analysis.

**RESULTS:** There were 228,160 orders during the studied period with 89.8% (204,822 orders) being for pediatric patients ( $< 18$  years). Electrolyte, caloric, and water balance agents were ordered the most often (23.6% of orders, CI: 23.4–23.8). 11,083 orders (4.9% alert rate, CI: 4.8–5.0) had an alert presented to practitioners. The alert rate was highest for immunosuppressive agents (54%, CI: 49.27–58.68), followed by blood derivatives (26.3%, CI: 22.4–30.5), antineoplastic agents (18.0%, 16.4–19.62), cardiovascular drugs (15.1%, CI: 13.68–16.63), and blood formation, coagulation, and thrombosis agents (12.7%, CI: 12.0–13.4). The alert rate was lowest for skin and mucous membrane agents (0.06%, CI: 0.007–2.14). The alert rate was 5.7% (CI: 5.4–6.0) when orders were written for adult patients ( $\geq 18$  years) compared to 4.8% (CI: 4.7–4.9) for pediatric patients ( $p < 0.0001$ ).

**CONCLUSION:** Immunosuppressive agents and blood derivatives had the highest alert rate compared to other medication classes. The commonly alerted medications should be the focus for institutional customization and changes in dosing alert rule logic. Higher dosing alert rates were associated with orders for adult patients compared to those for pediatric patients.

**147. Pediatric assessment of vancomycin empiric dosing.** Daniel Rainkie, B.Sc.<sup>1</sup>, Mary H. H. Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS<sup>2</sup>, Roxane R. Carr, Pharm.D., ACPR, BCPS, FCSHP<sup>3</sup>; (1)Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada (2)The University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada (3)Children's & Women's Health Centre of British Columbia, The University of British Columbia, Vancouver, BC, Canada

**PURPOSE:** Pediatric studies and anecdotal experience suggest that current empiric vancomycin dosing does not reach serum concentration targets. This study reviewed vancomycin dosing and serum concentrations to: (i) determine the proportion of patients who reached initial target concentrations; (ii) describe pharmacokinetic (PK) parameters; and (iii) compare patient-specific area-under-the-curve (AUC) values to population estimates.

**METHODS:** Following ethics approval, data were extracted from medical records of 200 patients aged 1 month to 18 years, who received IV vancomycin and had at least two pharmacokinetically-evaluable serum concentrations. Patients who had extracorporeal life support, renal failure, or cystic fibrosis were excluded.

**RESULTS:** Trough vancomycin concentrations of 10–15 and 15–20 mg/L were achieved in 25 (29%) and 2 (2%) of patients receiving 15 mg/kg IV q6h and 22 (20%) and 9 (8%) of patients receiving 20 mg IV q8h, respectively. Patients were stratified in four age groups (1 month to 1, 1–6, 6–13 and 13–18 years). Median (IQR) PK parameters were: k 0.25 (0.09), 0.29 (0.07), 0.24 (0.10) and 0.22 (0.07) h<sup>-1</sup>; volume of distribution 0.55 (0.20), 0.60 (0.23), 0.45 (0.23) and 0.45 (0.18) L/kg; and half-life 2.8 (1.1), 2.37 (0.5), 2.9 (1.1) and 3.2 (1.0) h, respectively. Median (IQR) AUC were 465 (178), 338 (132), 501 (197) and 519 (211) and population-estimated AUC were 428 (79), 837 (320), 1560 (659) and 2886 (472) mg\*h/L ( $p < 0.05$  for 1–6, 6–13 and 13–18 years groups).

**CONCLUSIONS:** New initial dosing regimens are required to reach therapeutic vancomycin serum concentrations. Patient-spe-

cific AUC is significantly lower than the population-estimated AUC in all populations except infants. Based on these novel findings, we recommend vancomycin 70 and 90 mg/kg/day divided q6h for 10–15 and 15–20 mg/L, respectively (for age 1 month–6 years) and 60 mg/kg/day divided q8h and 70 mg/kg/day divided q6h, respectively (for age > 6 years) to undergo further testing as initial dosing regimens.

**148. Ciprofloxacin for the treatment of non-resolving pneumonia in a tertiary care pediatric hospital.** *Mohammed Habil, Sr, Master Degree of Pharmacology*; Department of Pharmacy, Al-Rantisy Specialized Pediatric Hospital, Gaza, Palestine

**PURPOSE:** Data regarding the use of ciprofloxacin in children with nonresolving pneumonia are scarce. The present study aims to evaluate the effect of ciprofloxacin therapy in pediatric patients with nonresolving pneumonia.

**METHODS:** Over the past year, 2012, all pediatric patients with nonresolving pneumonia who received ciprofloxacin treatment in the pulmonary unit of Al-Rantisy specialized pediatric hospital in Gaza, Palestine, were included in this retrospective study. Ciprofloxacin was given for all patients in a dose of 20 mg/kg/day divided into two doses. Patient demographic data, clinical symptoms recorded, sputum culture findings and ciprofloxacin therapeutic outcome were gathered. Data were analyzed using computer software SPSS version 11.

**RESULTS:** The study included 57 patients with nonresolving pneumonia, 36 males and 21 females with mean age of 3.4 years, ranged from 2 month to 8 years. Fever (73.7%) and cough (89.5%) were the most common symptoms. Positive culture was obtained in 42 (73.6%) patients while 15 (26.4%) showed negative results. The most common organism isolated in the positive cultures was *Pseudomonas aeruginosa* 26 (62.0%). Among the study sample, 23 (40.4%) patients received ciprofloxacin as empirical therapy and 34 (59.6%) received this drug depending on culture sensitivity results. There was a significant decrease in body temperature levels ( $p < 0.001$ ) at day 1, 2 and 3 of ciprofloxacin treatment. Overall, ciprofloxacin was effective in the treatment of 53 (93.0%) patients of the present study. Only 4 (7%) cases showed resistant to this therapy. The mean length of hospital stay was 7.5 days. No side effects were reported during the course of this study.

**CONCLUSION:** Data of the present study suggest that ciprofloxacin is effective and safe, including as initial monotherapy, for the treatment of pediatric patients with nonresolving pneumonia.

## Pharmacoeconomics/Outcomes

**149. Economical analysis of pharmacy intervention in the intensive care units in a medical center in Taiwan.** *Chun-Nan Kuo, Master, Pi-Yu Lee, Master*; Taipei Medical University-WanFang Hospital

**PURPOSE:** Pharmacy interventions in the intensive care unit (ICU) can prevent the injury from medication errors and also bring some economical benefits. A study showed that the potential cost avoidance of the documented interventions was USD 205,919–280,421. Owing to such economical benefits, we performed the economical analysis of pharmacists' intervention in the ICUs in WanFang hospital in Taiwan.

**METHODS:** Four clinical pharmacists documented the interventions made from December 2011 to February 2012 in 1st ICU and January 2012 to February 2012 in 2nd ICU. These data were retrospectively evaluated and we recorded type of intervention, changed prescription, days of the medication used before and after intervention, days of staying in ICU. We also collected patients' data by reviewing charts. Cost saving was calculated from the medical cost differentiation between prescriptions before and after pharmacists' interventions. For cost avoidance, the documented interventions were independently reviewed by two physicians to evaluate whether an actual or potential adverse health consequence would have occurred without the intervention, the probability that an adverse health consequence would have occurred without the intervention, and potential cost avoidance

of the intervention. Once the evaluations were completed, cost avoidance can be further calculated.

**RESULTS:** One hundred and forty-two interventions were made during this period. The most drug-related problems were inappropriate dose. The total cost saving was NTD 114,980. Antimicrobial agents were the major category in cost savings (90.73%). The average of total cost avoidance was NTD 1,074,288 (from NTD 778,411 to 1,301,075). Both physicians considered the most common impact of pharmacy intervention as preventing potential adverse drug events.

**CONCLUSION:** Based on the results of this study, providing pharmacy intervention in the critical care settings could not only ensure patient safety but also have financial impact.

**150. Cost-effectiveness of rivaroxaban compared with enoxaparin plus a vitamin K antagonist for the treatment of venous thromboembolism.** *Patrick Lefebvre, MA<sup>1</sup>*, Craig I. Coleman, Pharm.D.<sup>2</sup>, Brahim Bookhart, MBA, MPH<sup>3</sup>, Si-Tien Wang, M.Sc.<sup>4</sup>, Samir H. Mody, Pharm.D., MBA<sup>3</sup>, Kevin Tran, MPH<sup>4</sup>, Daisy Zhuo, BA<sup>4</sup>, Lynn Huynh, MPH, MBA, DrPH<sup>4</sup>, Edith A. Nutescu, Pharm.D.<sup>5</sup>; (1)Groupe d'Analyse, Ltée., Montreal, QC, Canada (2)University of Connecticut, Hartford, CT (3)Janssen Scientific Affairs, LLC, Raritan, NJ (4)Analysis Group, Boston, MA (5)University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** Venous thromboembolism (VTE), comprised of deep vein thrombosis (DVT) and pulmonary embolism (PE), is commonly treated with a low-molecular-weight heparin such as enoxaparin plus a vitamin K antagonist (VKA) to prevent recurrence. Administration of enoxaparin+VKA is hampered by complexities of laboratory monitoring and frequent dose adjustments. Rivaroxaban, an orally administered anticoagulant, has been compared with enoxaparin+VKA in the EINSTEIN trials. The current study evaluates the cost-effectiveness of rivaroxaban compared with enoxaparin+VKA as anticoagulation treatment for acute, symptomatic, objectively-confirmed DVT or PE.

**METHODS:** A Markov model was built to evaluate the costs, quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratios associated with rivaroxaban compared with enoxaparin+VKA in adult patients treated for acute DVT or PE. All patients entered the model in the 'on-treatment' state upon commencement of oral rivaroxaban alone or enoxaparin+VKA for 3, 6, or 12 months. Transition probabilities were obtained from the EINSTEIN trials during treatment and published literature after treatment. A 3-month cycle length, US payer perspective (\$2012), 5-year time horizon, and a 3% annual discount rate were used. The impact of uncertainty around model inputs was assessed using a series of one-way and probabilistic sensitivity analyses.

**RESULTS:** Treatment with rivaroxaban cost \$2448 less per patient and was associated with 0.0058 more QALYs compared with enoxaparin+VKA, making it a dominant economic strategy. One-way sensitivity analysis showed that the base-case model result of rivaroxaban being dominant over enoxaparin+VKA was robust, insensitive to variations in all model inputs except for when length-of-stay for the index VTE was longer for rivaroxaban. When no difference in length-of-stay between rivaroxaban and enoxaparin+VKA was assumed, the cost associated with rivaroxaban was lower by \$79. At a willingness-to-pay threshold of \$50,000/QALY, probabilistic sensitivity analysis showed rivaroxaban to be cost-effective compared with enoxaparin+VKA approximately 76% of the time.

**CONCLUSION:** Rivaroxaban is a cost-effective option for anticoagulation treatment of acute VTE patients.

**151. Tracking thrombosis and pain metrics in a status-post orthopedic surgical population: results from a participating institution in the surgical outcomes project.** *Nick Carris, Pharm.D.<sup>1</sup>*, Eric Dietrich, Pharm.D., BCPS<sup>2</sup>, Amy Schultz, Pharm.D.<sup>3</sup>, Joseph Alessandrini, Pharm.D.<sup>4</sup>, Lew Summers, BS<sup>4</sup>, John Gums, Pharm.D., FCCP<sup>2</sup>; (1)TriStar Centennial Medical Center, Nashville, TN (2)University of Florida College of Phar-

macy, Gainesville, FL (3)East Alabama Medical Center, Opelika, AL (4)Inspira Medical Center Vineland, Vineland, NJ

**PURPOSE:** Orthopedic surgeries are commonly performed throughout the United States. Complications range from mild to severe and include pain and venous thromboembolism (VTE). Opioids and anticoagulants are frequently used, but have significant side effects. The surgical outcomes project (SOS) is a collaborative, multi-institution project designed to capture patient-specific information to create a unique database allowing hospitals to document clinical and economic outcomes associated with orthopedic surgeries.

**METHODS:** Hospital data was mapped to a customized database for the project. The goal of mapping was to properly isolate discrete patient encounters to allow tracking of initial and follow-up visits. ICD-9 codes for knee, hip, spine, and shoulder surgery over a 12 month period were identified along with relevant demographic, medication, laboratory, and outcome data.

**RESULTS:** Pilot data from a single 657 bed hospital showed that 794 patients underwent knee, hip, spine, or shoulder surgery over the previous 12 months. Postoperative pain medication was used in 791 patients, with 99% receiving Class II opioids. Oxycodone/acetaminophen was the most common pain medication used (82.87%). VTE prophylaxis was used in 70.65% of patients with 67.76% of all patients receiving at least one non-aspirin anticoagulant. Four patients were coded for VTE, all of who received prophylaxis with a non-aspirin anticoagulant. Minor bleeding, nausea/vomiting, and constipation were coded for in 0.88%, 7.56% and 9.07% of patients, respectively. Patients coded for VTE, bleeding, or constipation experienced an increased mean length of stay of 8.0, 3.3, and 2.8 days, respectively.

**CONCLUSION:** This pilot study documents the potential of a new data model in the orthopedic surgical population that can be customized to individual institutions to serve as a cost- and time-saving tool. In the present study the model was able to document risk factors associated with increased length of stay and the frequency of medication use to help manage/prevent those risks.

**152. Cost effectiveness analysis of probiotic adjunct therapy in reducing the incidence and duration of clostridium difficile-associated diarrhea in hospitalized older adults.** *Bich Ngoc Hoang, Pharm.D. Candidate<sup>1</sup>, Paul Norris, Pharm.D. Candidate<sup>2</sup>, Shivan Acharya, Pharm.D. Candidate<sup>2</sup>, Adrienne Kowcz, Pharm.D. Candidate<sup>2</sup>, Austin Kang, Pharm.D. Candidate<sup>2</sup>;* (1)School of Pharmacy, Northeastern University, Boston, MA (2)Northeastern University, Boston, MA

**PURPOSE:** *Clostridium difficile*-associated diarrhea (CDAD) is a prevalent and severe form of antibiotic-associated diarrhea. A randomized controlled trial by Gao et al. (2010) shows that prophylactic probiotic therapy is associated with lower incidence and shorter duration of CDAD. Based on that efficacy data, the purpose of this analysis is to determine the cost-effectiveness of probiotic adjunct therapy to reduce the incidence and duration of CDAD in hospitalized older adults on antibiotics.

**METHODS:** A cost-effectiveness analysis was conducted from the third party payer's perspective. Three treatment options were compared: probiotics 100 billion colony-forming units (cfu)/day, 50 billion cfu/day, and placebo (usual care). Efficacy and cost data were extracted from published literature for the base case and sensitivity analyses. Cost effectiveness was evaluated as the incremental cost to treat and prevent CDAD relative to the days saved from CDAD.

**RESULTS:** Efficacy data showed that probiotic therapy had a dose-ranging effect and was superior to placebo in preventing and reducing the severity of CDAD (6.37 and 6.01 days of CDAD saved compared to 4.88 days saved with placebo). Base case results showed that probiotics were cost-saving compared to placebo; the average cost per patient was \$91.58 (100 billion cfu/day) and \$336.01 (50 billion cfu/day) for treatment arms and \$784.92/patient for the placebo arm. Because low-dose probiotic treatment was more effective and less costly than placebo, it dominated the placebo option. The higher dose of probiotic was also more effective and less costly than the lower dose, rendering it dominant over

lower dose. One-way sensitivity analyses for all efficacy data and cost data did not affect the dominance of treatment arms. In two-way sensitivity analyses, dominance remained unchanged.

**CONCLUSION:** Considering its safety and efficacy, high-dose probiotics adjunct therapy is cost-effective in reducing the incidence and duration of *Clostridium difficile*-associated diarrhea compared to placebo in hospitalized older adult patients.

**153. Estimated cost savings associated with A1c reductions among insulin-treated patients in a large US commercial health plan.**

*Michael Grabner, Ph.D.<sup>1</sup>, Scott Abbott, MS<sup>2</sup>, Matthew Nguyen, Pharm.D.<sup>2</sup>, Ralph Quimbo, MA<sup>1</sup>;* (1)HealthCore, Inc., Wilmington, DE (2)Valeritas, Inc., Bridgewater, NJ

**PURPOSE:** A claims analysis was combined with estimated cost data from published literature to predict cost savings at a health plan level when insulin-treated patients achieve specific A1c reductions.

**METHODS:** Adult patients with diabetes, continuous enrollment in 2011, and  $\geq 1$  insulin fill were selected from the HealthCore Integrated Research Database<sup>SM</sup>, representing a large national health insurer. The distribution of A1c levels in this sample was extrapolated to the health plan level. Estimated 1-year all-cause patient-level cost savings (medical plus pharmacy) associated with a mean A1c reduction of  $\geq 1\%$  were taken from published literature. Costs were adjusted to 2011 levels.

**RESULTS:** Among all identified patients (N=74,950) mean age was 56.7 years, 46.3% were female, 89.8% had type 2 diabetes and 50.0% had  $\geq 1$  OAD fill. A1c results were available for 16.4% of patients. Extrapolating the A1c distribution to the health plan level (with approximately 150,000 patients receiving insulin), 119,892 patients (79.9%) had an A1c  $\geq 7\%$  and 48,143 (32.1%) had an A1c  $> 9\%$ . Mean cost savings from an A1c reduction of  $\geq 1\%$  were estimated to be \$1169 per patient. Assuming that 50% of patients with poor diabetes control (A1c  $> 9\%$ ) experience a mean A1c reduction of  $\geq 1\%$ , the estimated cost savings are \$28.1 m ( $\pm 10\%$ : \$25.3–\$30.9 m). Alternatively, if 50% of patients above the ADA-recommended A1c level of  $< 7\%$  experience a mean A1c reduction of  $\geq 1\%$ , the estimated cost savings are \$70.1 m ( $\pm 10\%$ : \$63.1–\$77.1 m).

**CONCLUSION:** Nearly 80% of insulin-treated patients in this commercially insured population have A1c levels above the ADA-recommended level of  $< 7\%$ , and nearly a third had levels  $> 9\%$ . Modest improvements in A1c levels, especially among the most severe patients, would be associated with substantial cost savings at the health plan level.

**154. Risk of type-2 diabetes associated with statin therapy among elderly patients – a nested case-control study.**

*Manasi Datar, MS<sup>1</sup>, Yi Yang, M.D., Ph.D.<sup>1</sup>, Matthew Strum, Pharm.D., BCACP, CDE<sup>2</sup>, John Bentley, BS, MBA, Ph.D.<sup>1</sup>, Benjamin Banahan, III, Ph.D.<sup>3</sup>;* (1)Department of Pharmacy Administration, University of Mississippi School of Pharmacy, University, MS (2)Department of Pharmacy Practice, University of Mississippi School of Pharmacy, University, MS (3)Center for Pharmaceutical Marketing and Management, University of Mississippi School of Pharmacy, University, MS

**PURPOSE:** In 2012, the U.S. Food and Drug Administration (FDA) issued a warning label for statin medications indicating that they can potentially increase the risk of type-2 diabetes. The objective of this study was to assess the relationship between statin use and the risk of incident type-2 diabetes in the elderly Medicare population.

**METHODS:** A nested case-control study using the 5% Medicare claims from 2006 to 2008 was conducted. A cohort of diabetes-naïve and statin-naïve patients (age  $\geq 65$  years at the beginning of calendar year 2006) was identified. Cases were identified as patients developing type-2 diabetes (defined as having at least one ICD-9-CM code of 250.x0 or 250.x2 and at least one prescription for an oral hypoglycemic within 90 days) in 2007 or 2008. The first event date of their diabetes diagnosis was set as the index date. Patients who did not develop diabetes during the



entire study period were identified as controls. Each case was matched with one control on age and gender; controls were assigned the index date of corresponding cases. For both cases and controls, prescription drug claims were used to identify statin use prior to the index date. Conditional logistic regression models controlling for comorbidities and drug use were used to assess the impact of statin use on the risk of type-2 diabetes.

**RESULTS:** 8637 type-2 diabetes cases were matched with equal number of controls. The proportion of statin users among patients who developed type-2 diabetes was 46.3% as compared to 36.68% among those who did not develop diabetes. Statin users were significantly more likely to develop type-2 diabetes as compared to non-users (Adjusted OR: 1.41; 95% CI: 1.33–1.51).

**CONCLUSION:** Statin therapy was associated with increased likelihood of developing type-2 diabetes among elderly diabetes naïve individuals. Providers should be vigilant of this association when prescribing statins to elderly patients.

**155E. A randomized, controlled pragmatic trial of telephonic medication therapy management to reduce hospitalization in home health patients.** Alan J. Zillich, Pharm.D.<sup>1</sup>, Margie E. Snyder, Pharm.D., MPH<sup>1</sup>, Caitlin K. Frail, Pharm.D.<sup>1</sup>, Julie L. Lewis, MBA<sup>2</sup>, Donny Deshotels, BS<sup>2</sup>, Patrick Dunham, BSEE<sup>3</sup>, Heather A. Jaynes, RN, MS<sup>1</sup>, Jason M. Sutherland, Ph.D.<sup>4</sup>; (1)Purdue University College of Pharmacy, Indianapolis, IN (2)Amedisys, Inc., Baton Rouge, LA (3)HealthStat Rx, LLC, Smyrna, GA (4)University of British Columbia, Centre for Health Services and Policy Research, Vancouver, BC, Canada

**PURPOSE:** To evaluate the effectiveness of a telephonic medication therapy management (MTM) service on reducing hospitalizations among home health patients.

**METHODS:** Cluster-randomized, controlled, pragmatic trial with 60-day follow-up using 40 randomly selected, geographically diverse home healthcare centers in the United States. All Medicare-insured home healthcare patients were eligible to participate. Patients were asked to opt in to the study prior to randomization to usual care or MTM intervention. The MTM intervention consisted of the following: (i) initial phone call by a pharmacy technician to verify active medications, (ii) pharmacist-provided medication regimen review by telephone, and (iii) follow-up pharmacist phone calls at day seven and as needed for 30 days. Pharmacists intervened with prescribers and patients/caregivers to resolve identified drug therapy problems, and patients/caregivers received a medication action plan and personal medication record. The primary outcome was 60-day all-cause hospitalization. Multivariate logistic regression modeled the effect of the MTM intervention on the probability of hospitalization while adjusting for patients' baseline risk of hospitalization, number of medications taken daily, and other characteristics using OASIS-C data elements collected during the home health episode.

**RESULTS:** Eight hundred and ninety-five patients (intervention n=415, control n=480) were block-randomized to the intervention or usual care. Patients were 73 (SD 13) years of age taking 14 (SD 9) total medications. Overall, there was no significant difference in the 60-day probability of hospitalization between the MTM intervention and control groups (Adjusted OR: 1.26, 95% CI: 0.89–1.77, p=0.19). For patients within the lowest baseline risk quartile (n=232), the intervention group was three times more likely to prevent hospitalization at 60 days (Adjusted OR: 3.79, 95% CI: 1.35–10.57, p=0.01) compared to the usual care group.

**CONCLUSION:** The MTM intervention was not effective for all patients in this evaluation. However, for those with the lowest risk at baseline, the MTM intervention prevented patients from being hospitalized at 60 days. Presented at the Academy Health Annual Research Meeting, Baltimore, MD, June 23–25, 2013.

**156. Monotherapy of commonly used anti-hyperglycemic agents (AHA) for the treatment of type 2 diabetes mellitus (T2DM): patient characteristics and time to addition of subsequent therapy (augmentation).** Silas Martin, MS<sup>1</sup>, James Burke, Ph.D.<sup>2</sup>, Cheryl Neslusan, Ph.D.<sup>3</sup>, Jonathan Johnson, MS<sup>2</sup>, Robert Bailey, M.D.<sup>4</sup>;

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**PURPOSE:** T2DM affects more than 8% of the US population, and is one of the leading causes of long-term health complications. In 2012, the American Diabetes Association issued guidelines reconfirming the use of metformin as first-line therapy for most patients, and recommending therapy augmentation to maintain HbA1c < 7%. In this study, we examine real world characteristics of patients on monotherapy, and the timing of therapy augmentation.

**METHODS:** We identified T2DM patients in a large US health plan organization between 1/1/06 and 6/30/11. A minimum of 1 year continuous enrollment prior to and after starting monotherapy was required. We report demographics, therapy adherence, and time to augmentation. For a subsample with available lab values, we also report HbA1c levels closest to initiation and augmentation occurring ≤90 days before each timepoint.

**RESULTS:** A total of 51,994 AHA monotherapy episodes resulted in augmentation for T2DM. Mean (SD) age was 59 (12.4) years, 46% were female, and 83% had commercial insurance versus 17% Medicare Advantage. The most commonly used monotherapies were: metformin (51%), sulfonylureas (29%), thiazolidinediones (TZDs) (15%), and DPP-4s (1.86%). Approximately 80% were considered adherent (proportion days covered ≥0.8). For the adherent group, median/mean (SD) time to augmentation ranged from 71/185 (273) days for TZDs to 136/281 (332) days for metformin. On average, time to augmentation decreased with declining adherence. Median/Mean (SD) HbA1c prior to first therapy was 7.50%/8.05% (1.90), and 7.65%/8.11% (1.80) prior to augmentation (n=4160).

**CONCLUSION:** This study illustrates patient characteristics, adherence and time to augmentation for commonly used monotherapy AHAs. For the subsample with available HbA1c levels, the mean action level for augmentation was over 8%. These findings may suggest an opportunity for adding therapy earlier to optimize blood glucose control.

**157. Outcomes of systematic anticoagulation management in pharmacist versus nurse specialized clinics.** Beenish Manzoor, MPH<sup>1</sup>, Adriana Bautista, M.D., MPH<sup>2</sup>, Thomas Stamos, M.D.<sup>3</sup>, Weihua Gao, MS<sup>4</sup>, Edith Nutescu, Pharm.D.<sup>5</sup>; (1)Department of Pharmacy Systems, Operations, and Policy, University of Illinois at Chicago, College of Pharmacy, Chicago, IL (2)University of Illinois at Chicago, Chicago, IL (3)Section of Cardiology, Department of Medicine, University of Illinois at Chicago, Chicago, IL (4)University of Illinois at Chicago, CCTS, Chicago, IL (5)Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** To evaluate the effect of pharmacist versus nurse managed models of care on the quality of anticoagulation control and warfarin related hospitalizations and/or emergency department (ED) admissions.

**METHODS:** We conducted a retrospective observational cohort study of patients treated with warfarin and referred to a pharmacist-managed anticoagulation clinic (PMAC) or a nurse-managed anticoagulation clinic (NMAC) at the University of Illinois Hospital and Health Sciences System. The primary outcome measure was within-patient proportion of international normalized ratio (INR) levels spent in target therapeutic range (TTR). The secondary outcome measure was warfarin-related hospitalizations and/or emergency department (ED) admissions. Clinically-relevant variables from simple linear or logistic regression (p<0.05) were entered into forward-selection multivariate regression models (p<0.05) to evaluate the effect of the model of care (PMAC versus NMAC) on TTR and hospitalization/ED visits, respectively.

**RESULTS:** A total of 200 consecutive patients (100 PMAC and 100 NMAC) were enrolled. The majority of patients were females (58.5%) and the average age was 61.4 ± 14.6. The racial distribution of the sample was 49.5% African-American, 27.0%

Hispanic, 20.0% Caucasian and 3.5% other race. The average duration of therapy was  $1.8 \pm 0.6$  and  $2.1 \pm 0.1$  patient-years ( $p \leq 0.01$ ), and the average TTR was  $51.8 \pm 15.9$  and  $56.2 \pm 13.9$  ( $p=0.04$ ) in the PMAC and NMAC groups, respectively. Crude TTR was lower in the PMAC patients. After controlling for demographic/significant covariates, the adjusted TTR was not significantly different between the two models of care (NMAC versus PMAC) ( $\beta=-8.41$ ,  $p=0.07$ ). Patients in NMAC had 7.68 (95%CI: 1.06–55.94) times greater odds of hospitalization/ED admissions compared to PMAC patients, after controlling for demographic/significant covariates.

**CONCLUSION:** The quality of warfarin anticoagulation control did not differ between pharmacist and nurse managed models of anticoagulation care, however PMAC improved the rate of warfarin related hospitalizations/ED admissions.

## Pharmacoepidemiology

**158. Adverse drug events among older adults discharged from skilled nursing facilities to home.** *Abir O. Kanaan, Pharm.D.*<sup>1</sup>, Jennifer L. Donovan, Pharm.D.<sup>1</sup>, Terry S. Field, DSc<sup>2</sup>, Jessica Ogarek, MS<sup>2</sup>, Peggy Preusse, RN<sup>2</sup>, Devi Sundaresan, MS<sup>2</sup>, Shawn Gagne, BA<sup>2</sup>, Lawrence Garber, M.D.<sup>2</sup>, Jennifer Tjia, M.D., MSCE<sup>2</sup>, Sarah L. Cutrona, M.D., MPH<sup>2</sup>, Jerry H. Gurwitz, M.D.<sup>2</sup>; (1) MCPHS University, Worcester, MA (2) Reliant Medical Group, Meyers Primary Care Institute, A Joint Endeavor of the University of Massachusetts Medical School, Fallon Community Health Plan, Worcester, MA

**PURPOSE:** Older adults are often transferred from hospitals to skilled nursing facilities (SNFs) for post-acute care or rehabilitation. Patients may be at risk for adverse outcomes after SNF discharges. The purpose of this study was to describe the incidence, severity, and preventability of adverse drug events (ADEs) occurring within 45-days post SNF discharge to home.

**METHODS:** We studied 200 discharges from SNF to home in patients aged 65 and older who received care from a large multi-specialty medical group in Central Massachusetts. Two trained clinical pharmacists reviewed the ambulatory records of each discharged patient to identify drug-related incidents occurring during the 45-day period post-SNF discharge, which were subsequently presented to a pair of physician-reviewers who independently classified incidents as to whether an ADE 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 83 ADEs identified, of which 28% ( $n=23$ ) were deemed preventable. The majority (69% [ $n=57$ ]) occurred within the first 14 days after discharge. Of the ADEs, 13 were serious, one was life-threatening and 69 were less serious. Of the serious and life-threatening events, four were considered preventable, compared to 19 of the less serious events. There was at least one ADE identified in 30% ( $n=60$ ) of discharges during the 45-day period post-SNF. There were 12% ( $n=23$ ) of discharges that had at least one ADE that was deemed preventable.

**CONCLUSION:** ADEs are common among older persons discharged from SNF to home. The substantial portion of serious events that were considered preventable suggests opportunities for improving care during the post-SNF discharge period.

**159. Impact of FDA warnings on long-acting beta agonist use in a state medicaid program.** *Daniel Hartung, Pharm.D., MPH*, College of Pharmacy, Oregon State University, Portland, OR

**PURPOSE:** Long-acting beta agonists (LABAs) have been known to increase the risk of life-threatening asthma exacerbations for more than a decade. In February 2010, the US Food and Drug Administration (FDA) issued additional safety information about this risk and strengthened the boxed warning on all LABA containing products. The objective of this study was to quantify changes in LABA utilization following the FDA's 2010 announcement and product label changes.

**METHODS:** We used an interrupted time-series analyses to evaluate monthly LABA utilization over a 4 year period (20 months before and 28 months after the FDA warning) using state Medicaid administrative claims data. Changes in utilization were quantified as total prescription fills and incident fills in a rolling cohort of new users. Incident use was quantified overall and among a subgroup of those with a diagnosis of asthma.

**RESULTS:** During the study period, 11,850 unique Medicaid beneficiaries had at least one incident fill for a LABA containing product. A diagnosis of asthma was present in 61% the of study sample. At baseline, there were 7.9 new LABA starts per 10,000 enrollees per month. In the 20 months prior to the FDA's warnings, trends in total fills, new starts, and new starts among those with asthma were statistically stable. Following the FDA's warning, the trend in utilization declined for all three measures: total fills ( $-0.04$  fills/1000 enrollees/month;  $p=0.0007$ ), incident fills ( $-0.07$  starts/10,000 enrollees/month;  $p=0.06$ ), and incident fills among those with asthma ( $-0.08$  starts/10,000 enrollees/month;  $p=0.01$ ). The decline in utilization was largest among those with asthma, culminating in a 44% (95% CI  $-63\%$  to  $-25\%$ ) relative reduction in new starts by the last month of follow-up.

**CONCLUSION:** The FDA's strengthened warning was associated with significant declines in the trend of LABA fills and new starts in those with a diagnosis of asthma.

**160. Association between hydromorphone adverse reactions and obstructive sleep apnea: a case control study.** *Jeffrey Reitz, Pharm.D., MPH*<sup>1</sup>, Stephanie Wasserman, B.Sc.<sup>2</sup>; (1) Value Institute and Department of Pharmacy Services, Christiana Care Health System, Newark, DE (2) Department of Pharmacy Services, Christiana Care Health System, Newark, DE

**PURPOSE:** A series of adverse reactions associated with hydromorphone were observed among patients with obstructive sleep apnea (OSA). The purpose of this case control study was to assess whether OSA is a risk factor for hydromorphone adverse reactions (HAR).

**METHODS:** Cases were adult patients who were charged for at least one hydromorphone injection and naloxone injection during the same admission between July 2005 and December 2009, received the naloxone injection after hydromorphone, and were confirmed to have experienced a hydromorphone-associated adverse reaction by medical record review. Four controls were selected randomly from the population of adult patients during the same time period who received at least one hydromorphone injection, but not naloxone injection, during an admission. Information on patient age; gender; body mass index (BMI); estimated glomerular filtration rate; hydromorphone dose; diagnoses of OSA, COPD, & liver disease; use of patient-controlled analgesia; and the presence of concurrent orders for promethazine injection or a benzodiazepine. Logistic regression was used to compare the odds of a HAR among those with and without OSA before and after adjusting for the other variables collected.

**RESULTS:** Complete data were available for 256 cases and 999 controls. The odds of a HAR were increased in the presence of OSA (unadjusted OR 3.1, 95% CI 2.13, 4.51). OSA remained a risk factor after adjusting for the other variables (OR 2.47, 95% CI 1.56, 3.91). COPD (OR 3.7, 95% CI 2.64, 5.19) and liver disease (OR 2.32, 95% CI 1.37, 3.92) were also identified as risk factors, but not BMI (OR 1, 95% CI 0.98, 1.02).

**CONCLUSION:** OSA is a risk factor for an adverse reaction to hydromorphone.

**161. Azithromycin associated risk of cardiovascular death from arrhythmia: a review of the FDA adverse event reporting system database.** *Tina Khadem, Pharm.D.*<sup>1</sup>, Robbert Van Manen, M.S.<sup>2</sup>, Jack Brown, Pharm.D., MS<sup>3</sup>; (1) University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (2) Oracle Health Sciences Global Business Unit, Netherlands (3) Strong Hospital, University of Rochester Medical Center, NY

**PURPOSE:** Recent literature suggests that azithromycin (AZ) may be associated with increased risk of cardiovascular death

with a hypothesis that AZ may have proarrhythmic effects contributing to sudden cardiac death. Mixed results ranged from 0.9 to 2 times the risk when compared with penicillins and three times the risk when compared with no antibiotics. These studies evaluated death from cardiovascular causes including arrhythmias and non-arrhythmias. Our goal was to qualitatively and quantitatively review the adverse event reporting system (AERS) database in order to determine the comparative occurrence of fatal arrhythmias in reports of AZ.

**METHODS:** The AERS database was queried to compare the frequency of fatal arrhythmias in reports of AZ. With the use of proportional reporting ratios (PRR), AZ was compared to all macrolides (M), all antibacterial agents (AB), all antimicrobial agents (AM), and all agents listed in AERS. For example, the PRR for fatal AZ arrhythmias compared to fatal M arrhythmias is determined by the equation:  $\frac{[\text{fatal AZ arrhythmias/all reports of AZ use}]}{[\text{fatal M arrhythmias/all reports of M use}]}$ . Subsequent analyses substituted M in the denominator ratio with AB, AM and all agents listed in AERS.

**RESULTS:** It appears that AZ is associated with a higher occurrence of fatal arrhythmias, an effect which becomes more pronounced when the background is made less specific: AZ ratio compared to M ratio (PRR 1.34); AZ ratio compared to AB ratio (PRR 1.70); AZ ratio compared to AM ratio (PRR 1.98); and AZ ratio compared to all agents ratio (PRR 3.11).

**CONCLUSION:** To our knowledge, this is the first report of the association between AZ and fatal arrhythmias, whereas previous literature evaluated the association between AZ use and any cardiovascular death, including arrhythmias and non-arrhythmias. Investigative studies are needed to further explore these statistical associations.

**162. Impact of pharmacist-administered seasonal influenza vaccinations on influenza vaccination coverage rates for adults in New York State.** Tina Khadem, Pharm.D.<sup>1</sup>, Jack Brown, Pharm.D., MS<sup>2</sup>; (1) University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (2) Strong Hospital, University of Rochester Medical Center, Rochester, NY

**PURPOSE:** On December 3, 2008 legislation went into effect allowing certified pharmacists to immunize individuals 18 years of age and older against influenza and pneumococcal disease in New York State (NYS) in an attempt to increase overall vaccination rates. The purpose of this study was to determine the impact of pharmacist-administered influenza immunizations on the overall rate of adults immunized with influenza vaccine in NYS.

**METHODS:** Data was obtained from CDC FluVaxView Influenza Vaccination Coverage Reports and included estimates for adults 18 years of age and older in NYS for the 2009–2012 influenza seasons. Using U.S. census population estimates, coverage rates were translated into numbers of adults vaccinated. Numbers of pharmacist-administered influenza vaccinations were obtained from the NYSDOH Bureau of Immunization Certified Pharmacist Immunizer Survey Report from 2008 to 2011.

**RESULTS:** The number of pharmacist-administered influenza vaccines in adults 18 years of age and older per 100,000 individuals in NYS has increased: 2008–2009 (n=24); 2009–2010 (n=1,019); 2010–2011 (n=2, 848). The overall influenza immunization rate in adults 18 years of age and older per 100,000 in NYS has slightly decreased but remained steady over the last few years: 2009–2010 (n=42,000); 2010–2011 (n=41,400); 2011–2012 (n=37,200).

**CONCLUSION:** It appears that legislation allowing pharmacists to administer influenza vaccine has not affected the overall rates of influenza immunizations among adults in NYS thus far. This may be explained by a shift in location of vaccine administration. Further investigation is required to confirm these trends.

## Pharmacogenomics/Pharmacogenetics

**163E. Prevalence of CYP2C19 variant alleles and pharmacodynamic variability of aspirin and clopidogrel in American Indians.** Julie H. Oestreich, Pharm.D., Ph.D.<sup>1</sup>, Lyle G. Best,

M.D.<sup>2</sup>, Brody W. Crowe, Pharm.D. Candidate<sup>3</sup>, Paul P. Dobesh, Pharm.D., FCCP, BCPS<sup>3</sup>; (1) Department of Pharmacy Practice, University of Nebraska Medical Center, Omaha, NE (2) Turtle Mountain Community College, Belcourt, ND (3) University of Nebraska Medical Center, Omaha, NE

**PURPOSE:** The prevalence of important genetic polymorphisms of the CYP2C19 gene has been determined in most groups, but not in American Indians. Furthermore, the effectiveness of clopidogrel and aspirin has not been studied in the American Indian population, even though this group has some of the highest mortality rates for cardiovascular disease and diabetes.

**METHODS:** We recruited and obtained consent from 50 American Indians of the Oglala Sioux Tribe with coronary artery disease (CAD) taking aspirin and clopidogrel. Whole blood was collected for analysis by the VerifyNow P2Y12 and aspirin tests. Saliva samples from the CAD patients and 50 additional healthy volunteers (n=100 total) were genotyped for known CYP2C19 variants (\*2, \*3, and \*17).

**RESULTS:** The observed genotype distributions were in Hardy-Weinberg equilibrium. Genotype frequencies were: CYP2C19 \*1/\*1, n=62; \*1/\*2, n=20; \*2/\*17, n=2; \*1/\*17, n=13; \*17/\*17, n=1. Twenty-two percent of American Indians were heterozygous for the \*2 loss-of-function allele (allele frequency = 11%; 95% CI = 7–16%), and 16% of American Indians carried at least one CYP2C19\*17 allele (allele frequency = 9%; 95% CI = 5–13%). The pharmacodynamic effectiveness of clopidogrel in American Indians (median=194 P2Y12 reaction units [PRU], range = 29–400) was not statistically different from a historical control of primarily Caucasian patients (median=186 PRU, range = 85–331; p=0.70). There was no significant effect of genotype on platelet aggregation as measured by the VerifyNow P2Y12 test (p=0.72). The median aspirin reaction units (ARU) for American Indians was 437 (range = 350–659), and 73% had ARU values < 550.

**CONCLUSION:** The variability to aspirin and clopidogrel in American Indians of the Oglala Sioux Tribe is consistent with reported values for other groups as measured by the VerifyNow assay. However, the tested CYP2C19 genotypes (\*2, \*3, and \*17) did not explain the variability of clopidogrel response. Published in *Journal of Thrombosis and Haemostasis*. 2013;11: A761.

**164. A prospective evaluation to determine an association between genetic mutations on genes VDR, CYP2R1, DHCR7, and GC with vitamin D deficiency status.** Nicole Slater, Pharm.D.; Department of Pharmacy Practice, Bernard J Dunn School of Pharmacy, Shenandoah University, Winchester, VA

**PURPOSE:** Vitamin D insufficiency is linked to osteoporosis and increased fractures but the cause is not clear and several studies have suggested a possible correlation between certain genes and vitamin D levels. The purpose of this study was to determine if vitamin D associated gene variants on VDR, CYP2R1, DHCR7, and GC are more prominent in individuals with current or a history of vitamin D insufficiency (25(OH)D < 30 ng/mL).

**METHODS:** Total serum vitamin D concentrations were obtained weekly from January 30, 2013 through March 30 2013 in consecutive patients who were regularly scheduled for laboratory work at a private family practice site. An additional blood sample was collected for genetic analysis. Patients were categorized into two groups by the lowest vitamin D level available and analyzed for variant alleles on VDR, CYP2R1, DHCR7, and GC to determine if those alleles influenced total serum 25(OH)D concentrations. Demographics and use of supplementation were analyzed for effect on vitamin D level status.

**RESULTS:** One-hundred and eighty patients were enrolled with 16.1% found to be sufficient and 83.9% found to be insufficient. The four alleles (rs2228570, rs10741657, rs12785878, and rs2282679) selected for this study were not correlated with the vitamin D level, or vitamin D category based on the lowest documented vitamin D level. The mean age for the sufficient group and insufficient group were 68.41 ± 11.84 and 61.17 ± 10.77 respectively (p=0.001). Older patients were 3.2 times more likely to be sufficient in vitamin D if taking supplementation (OR 3.2; 95% CI: 1.4–7.5).



**CONCLUSION:** Variant alleles on VDR (rs2228570), CYP2R1 (rs10741657), DHCR7 (rs12785878), and GC (rs2282679) were not correlated with vitamin D insufficiency ( $[25(\text{OH})\text{D}] < 30 \text{ ng/mL}$ ). However, due to the limited number of subjects found to be sufficient, one cannot exclude that a correlation does not exist.

**165. The effect of SCN1A, SCN2A, ABCC2, and UGT2B7 genetic polymorphisms on oxcarbazepine dose requirements in Chinese Han patients with epilepsy.** *Chun-Lai Ma, Ph.D.<sup>1</sup>, Xun-Yi Wu, M.D.<sup>2</sup>, Zheng Jiao, Ph.D., Ming-Kang Zhong, Ph.D.;* (1)Department of Pharmacy, Huashan Hospital, Fudan University, Shanghai, China (2)Department of Neurology, Huashan Hospital, Fudan University, Shanghai, China

**PURPOSE:** Oxcarbazepine (OXC), a second-generation antiepileptic drug, is a keto-substituted analog of carbamazepine. The purpose of this study is to investigate the effects of SCN1A/2A, ABCC2 and UGT2B7 genetic polymorphisms on OXC pharmacokinetics in Chinese Han patients with epilepsy.

**METHODS:** The study included 184 Chinese Han patients with epilepsy receiving OXC monotherapy for more than 8 weeks to reach a maintenance dose. After obtaining written informed consent, peripheral venous blood was collected predose in the morning to determine monohydroxy carbamazepine (MHD), the major active metabolite, plasma concentration by HPLC. SCN1A IVS5-91G>A, SCN1A c.3184A>G, SCN2A c.56G>A and SCN2A IVS7-32A>G, ABCC2 3972C>T and c.1249 G>A, UGT2B7 c.802T>C genotypes were detected by using a TaqMan probe technique and high resolution melting curve method. The Concentration-Dose ratios (CDRs) were calculated by dividing the mean steady-state MHD plasma concentration by the OXC daily dose (mg/kg/day). Natural logarithm transformation of the CDRs were taken before analysis.

**RESULTS:** Correlation analysis of the steady-state MHD plasma concentrations and the maintenance doses (dose/weight) revealed that these two parameters were positively correlated ( $r = 0.583$ ,  $p < 0.001$ ). Patients with SCN1A IVS5-91 AA genotypes required higher maintenance OXC dosages than GG ( $16.95 \pm 6.56$  versus  $14.54 \pm 4.74$ ,  $p = 0.046$ ) and GA ( $16.95 \pm 6.56$  versus  $14.42 \pm 5.18$ ,  $p = 0.007$ ). The carriers of the variant UGT2B7 c.802T>C and ABCC2 c.1249 G>A allele required higher OXC dosages than non-carriers ( $p < 0.05$ ). In CDRs in patients with SCN1A IVS5-91 differed by genotypes in the following order: GG>GA>AA. In addition, the multiple regression model of lnCDRs revealed that genetic variants in SCN1A IVS5-91G>A affected the concentration-dose ratio of OXC ( $p < 0.05$ ).

**CONCLUSION:** Results from this study revealed that SCN1A, UGT2B7 and ABCC2 gene polymorphisms are genetic factors associated with OXC therapy optimization and would be useful for individualization of OXC therapy in epileptic patients.

**166. Impact of CYP2D6 polymorphisms on the clinical response and tolerability of immediate release metoprolol.** *Issam Hamadeh, Pharm.D.<sup>1</sup>, Taimour Y. Langae, Ph.D.<sup>1,2</sup>, Yan Gong, Ph.D.<sup>1,2</sup>, Ben M. Burkley, M.S., Todd C. Skaar, Ph.D.<sup>1,2</sup>, Julie Johnson, Pharm.D., BCPS, FCCP, FAHA<sup>2</sup>;* (1)Pharmacotherapy and Translational Research, University of Florida, Gainesville, FL (2)UF Health Personalized Medicine Program, Department of Pharmacotherapy and Translational Research, Center for Pharmacogenomics, University of Florida, Gainesville, FL

**PURPOSE:** Metoprolol is a cornerstone therapy for the treatment of several cardiovascular diseases. In clinical practice, it is administered as a racemic mixture of R- and S- enantiomers which undergo extensive metabolism by the polymorphic enzyme, CYP2D6. The primary purpose of this study was to determine whether CYP2D6 polymorphisms influence the clinical efficacy and tolerability of metoprolol.

**METHODS:** Following antihypertensive washout, participants took 50 mg twice daily with titration to 100 mg twice daily, guided by clinical response. CYP2D6 genotyping and copy number assessment were performed by Pyrosequencing. Patients were assigned genotype-derived metabolism phenotypes of poor (PM),

intermediate (IM), extensive (EM), or ultrarapid (UM) metabolizers, and appropriate parametric analyses were conducted. Adverse events defined as occurrences of fatigue, tiredness, dizziness, depression, wheezing and bradycardia were monitored to assess metoprolol tolerability.

**RESULTS:** Among 218 patients, there were 11 (5%) PMs, 17 (8%) IMs, 181 (83%) EMs, and 9 (4%) UMs. Heart rate (HR) response to metoprolol differed significantly by CYP2D6 phenotype, but systolic and diastolic blood pressure did not (Table). Adverse event rates were comparable, 14% in PMs and IMs versus 10% in EMs and UMs ( $p = 0.5$ ).

Clinical response	Extensive & ultra rapid metabolizers	Poor & intermediate metabolizers	p-value
Change in systolic blood pressure (mmHg)	-7.1 ± 9.7	-8.7 ± 10.4	0.43
Change in diastolic blood pressure (mmHg)	-7.1 ± 6.5	-9.1 ± 6.4	0.13
Change in heart rate (beats/min)	-11.4 ± 6.7	-17.5 ± 6.0	<0.0001

**CONCLUSION:** Other than a significant difference in the HR response, CYP2D6 polymorphism was not a determinant of the variability in response & tolerability to metoprolol therapy. PMs and IMs may have greater HR lowering with metoprolol, but otherwise are expected to respond similarly to EMs and UMs.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**167E. Pharmacokinetic analysis of piperacillin administered with tazobactam in critically ill, morbidly obese surgical patients.** *Ashley W. Sturm, Pharm.D., BCPS<sup>1</sup>, Nichole Allen, Pharm.D., BCPS<sup>1</sup>, Kelly D. Rafferty, Pharm.D., BCPS<sup>1</sup>, Douglas N. Fish, Pharm.D., BCPS<sup>2</sup>, Eric Toschlog, M.D., FCCS<sup>1</sup>, Mark Newell, M.D.<sup>1</sup>, Brett Waibel, M.D.<sup>1</sup>;* (1)Vidant Medical Center, Greenville, NC (2)University of Colorado Anschutz Medical Campus, Aurora, CO

**PURPOSE:** The study objective was evaluate the steady-state pharmacokinetic and pharmacodynamic parameters of piperacillin in morbidly obese, surgical intensive care patients. Nine morbidly obese (body mass index [BMI]  $\geq 40.0 \text{ kg/m}^2$ ) hospitalized patients admitted to the trauma and surgical intensive care service were treated with piperacillin-tazobactam 4.5 g every 6 hours, administered as a 30-minute infusion.

**METHODS:** Patients' blood samples were collected after the administration of the fourth, fifth, or sixth dose (i.e., at steady state). Serum piperacillin concentrations were determined by using a validated high-performance liquid chromatography assay; these concentrations were used to estimate pharmacokinetic parameters, and 5000-patient Monte Carlo simulations were performed. The probability of target attainment for  $\geq 50\%$  of the dosing interval during which free (unbound) drug concentrations exceeded the minimum inhibitory concentration ( $\%T > \text{MIC}$ ) of likely pathogens was calculated for piperacillin at various MICs.

**RESULTS:** Patient demographic and clinical characteristics included a mean  $\pm$  sd total body weight of  $164 \pm 50 \text{ kg}$ , BMI of  $57 \pm 15.3 \text{ kg/m}^2$ , and age  $57 \pm 11$  years; and a median APACHE II score of 22 (interquartile range 21–26). Compared to values previously reported in other populations, the volume of distribution was increased in the study patients, and total system clearance was decreased. The net result was a mean  $\pm$  SD half-life of  $3.7 \pm 1.2$  hours compared to approximately 1 hour reported in other populations. This contributed to an extended  $\%T > \text{MIC}$  for likely pathogens. Results from all nine patients showed  $\%T > \text{MIC}$  of 100% at the susceptibility breakpoint MIC of 16 mg/L and  $\geq 85\%$  at an MIC of 32 mg/L.

**CONCLUSION:** The pharmacokinetics of piperacillin are altered in morbidly obese, surgical intensive care patients. The use of

standard-dosage piperacillin-tazobactam 4.5 g intravenously every 6 hours was shown to be an appropriate dosage for this study population.

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**168. Dabigatran etexilate is metabolized to its active metabolite by carboxylesterases.** S. Casey Laizure, Pharm.D., Zheyi Hu, Ph.D., Vanessa Herring, B.S., Robert B. Parker, Pharm.D.; Department of Clinical Pharmacy, University of Tennessee, Memphis, TN

**PURPOSE:** Dabigatran etexilate (DABE) is a double prodrug that is rapidly converted to the active thrombin inhibitor, dabigatran (DAB), by hydrolysis. The aim of this study was to determine the role of carboxylesterases in the formation of DAB.

**METHODS:** Dabigatran etexilate was incubated in human carboxylesterase 1 (CES1), human carboxylesterase 2 (CES2), a mixture of CES1 and CES2, and in human liver S9 fractions (HLS9). The formation of the ethyl ester hydrolysis product (M1), the carbamate ester hydrolysis product (M2), and the active moiety, DAB, were quantified by an LC-MS/MS.

**RESULTS:** Individual incubations in CES1 hydrolyzed the ethyl ester producing M1 and in CES2 hydrolyzed the carbamate ester producing M2 with negligible amounts of DAB formed. In HLS9 and CES1 + CES2 incubations DABE declined rapidly accompanied by the formation of DAB, the M1 concentrations remained high at the end of the incubations while the M2 concentrations were near zero. These results show that M2 efficiently undergoes hydrolysis by CES1 to form DAB, but that M1 is not efficiently converted to DAB by CES2. These data suggest that the most efficient pathway for the formation of DAB from DABE by carboxylesterases is the sequential hydrolysis of DABE by CES2 to form M2 followed by CES1 hydrolysis forming DAB.

**CONCLUSION:** The most likely pathway in humans after oral administration of DABE is the conversion of DABE to M2 by CES2 in the gut followed by the conversion of M2 to DAB in the liver by CES1. This proposed pathway is consistent with the high first-pass metabolism of DABE in humans and the perturbations in metabolite disposition that occur in patients with hepatic disease. Knowledge of this pathway is critical to understanding factors affecting the variation in the formation of DAB, which will determine both the therapeutic anticoagulant effect and the bleeding risk in patients.

**169. Dabigatran etexilate metabolism is not affected by alcohol, a known inhibitor of carboxylesterase activity.** Robert B. Parker, Pharm.D., Zheyi Hu, Ph.D., S. Casey Laizure, Pharm.D.; Department of Clinical Pharmacy, University of Tennessee, Memphis, TN

**PURPOSE:** Alcohol is a known inhibitor (*in vitro*) of carboxylesterase 1 (CES1) and carboxylesterase 2 (CES2), and has been shown to inhibit the hydrolysis of the CES1-substrate drugs cocaine, methylphenidate, and oseltamivir in normal volunteers. Dabigatran etexilate (DABE) is a double prodrug that requires hydrolysis by CES1 and CES2 to form the active metabolite, dabigatran (DAB). The objective of this study was to determine if alcohol inhibited the hydrolysis of DABE by CES1 or CES2.

**METHODS:** Incubations in recombinant human carboxylesterase enzymes (CES1 and CES2), and in hepatic S9 fractions were performed to assess the effects of alcohol on cocaine hydrolysis (positive control) and DABE hydrolysis. Incubations were performed with substrate alone, substrate with alcohol, and substrate with the universal carboxylesterase inhibitor, bis(4-nitrophenyl)phosphate (BNPP). All drug concentrations were determined by a liquid chromatography/triple quadrupole mass spectrometry assay.

**RESULTS:** Cocaine was hydrolyzed to benzoylecgonine by CES1 and ecgonine methyl ester by CES2. Increasing concentrations of alcohol caused a progressive inhibition of hydrolysis and increased formation of the transesterified metabolite, cocaethylene. DABE underwent hydrolysis of the ethyl ester and carbamate ester by CES1 and CES2, respectively. Alcohol even at concentrations exceeding 100 mmol/L failed to significantly inhi-

bit the hydrolysis by CES1 or CES2 and no transesterified product was formed. In contrast, the carboxylesterase inhibitor, BNPP, potently inhibited the hydrolysis of DABE by both CES1 and CES2 in a concentration dependent manner.

**CONCLUSION:** Though alcohol is a documented inhibitor of several CES1-substrate drugs suggesting that it will have a generalized inhibitory effect on CES1 hydrolysis, DABE hydrolysis by both CES1 and CES2 was not inhibited by alcohol. These data suggest that the consumption of alcohol is unlikely to alter the formation of the active metabolite (DAB) in patients taking DABE. However, *in vivo* disposition studies are needed to confirm this finding.

**170. Renal N-acetyltransferase expression and activity in HK-2 cells.** Ellen Huang, BS<sup>1</sup>, Aila Spiegel, Pharm.D.<sup>1</sup>, Hui Yang, Ph.D.<sup>2</sup>, Linhao Li, Ph.D.<sup>2</sup>, Thomas Dowling, Pharm.D., Ph.D.<sup>3</sup>;

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**PURPOSE:** Human-derived proximal tubule (HK-2) cells have been proposed as a model to predict *in vitro-in vivo* correlations and renal transport/metabolism. Inter-individual variability in renal metabolic activity may be associated with polymorphic Phase II enzymes such as N-acetyltransferase (NAT). We previously observed that the *n*-acetyl metabolite of para-aminohippurate (aPAH) was actively secreted in human urine during PAH infusions, and intra-renal acetylation was hypothesized. We investigated NAT1 and NAT2 expression and activity in cultured HK-2 cells.

**METHODS:** HK-2 cells were grown in DMEM/F-12 media and harvested after 5 days of incubation at 37°C with 5% CO<sub>2</sub>. Western blot was accomplished using a mouse polyclonal antibody raised against full-length human NAT1 and NAT2 protein (Sigma-Aldrich) and secondary anti-mouse IgG. HK-2 cells were incubated with PAH (200 mcg/mL) or PBS (control), and supernatant aliquots were obtained at 4, 8 and 18 hours in triplicate. aPAH concentrations were quantified by HPLC.

**RESULTS:** NAT-1 protein was expressed, however NAT-2 was absent. HK-2 cells metabolized PAH in a time-dependent fashion, with aPAH concentrations of 345 ± 50, 820 ± 80 and 2030 ± 109 ng/well at each interval in cells incubated with PAH, but was absent in control samples.

**CONCLUSION:** The results of this experiment indicate that NAT-1 is constitutively expressed in human renal proximal tubular cells, and likely contributes to intra-renal acetylation of PAH. Use of the HK-2 model of human renal tubular cells for studying other Phase 2 drug metabolism pathways is needed.

**171. Impact of prolonged magnesium infusion on serum magnesium level.** Michelle Nadeau, Pharm.D.<sup>1</sup>, Rachel Eyler, Pharm.D., BCPS<sup>2</sup>, Eric M. Tichy, Pharm.D., BCPS<sup>3</sup>;

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**PURPOSE:** To assess the effect of infusion duration on magnesium serum levels (MSL) by comparing 4 and 1 hour magnesium sulfate infusions.

**METHODS:** Patients receiving 2 g magnesium infusions were included in this retrospective observational study. Patients were excluded if baseline or repeat MSL were not drawn or if they received multiple courses of magnesium. Demographic and laboratory data collected included age, gender, serum creatinine, and baseline MSL. Duration of infusion and time between end of infusion and repeat MSL were recorded. The primary outcome was the net change in MSL for 1 versus 4 hours infusion. Student's t-tests and chi-square tests were used to assess differences between groups. Bivariate and multivariate linear regressions were performed to assess the increase in MSL associated with each covariate.

**RESULTS:** A total of 176 patients (96 male, 80 female, mean age 61 years) were included. The group receiving the 1 hour infusion was significantly younger (58 versus 64 years, p=0.038). Mean increase in MSL was 0.42 versus 0.35 mg/dL for 4 versus 1 hour

infusions ( $p=0.098$ ). Unadjusted analyses revealed no significant difference in the change in MSL for age ( $p=0.594$ ), gender ( $p=0.915$ ), or selected concomitant medications ( $p=0.906$ ). In the multivariate analysis, there was no significant difference in the change in MSL between the 4 and 1 hour infusions (mean difference 0.041 mg/dL;  $p=0.300$ ). Baseline MSL, serum creatinine, and time between the infusion and the repeat MSL were significantly correlated with changes in MSL ( $p<0.001$ ,  $p=0.022$ ,  $p=0.002$ ).

**CONCLUSIONS:** Prolonging infusion time of magnesium does not result in a significantly higher increase of MSL.

**172. Pharmacokinetics and pharmacodynamics of long-term tocilizumab therapy in patients with systemic juvenile idiopathic arthritis.** Fabrizio De Benedetti, M.D., Ph.D.<sup>1</sup>, Hermine Brunner, M.D., M.Sc., MBA<sup>2</sup>, Scott Feltner, BA<sup>3</sup>, Caroline Keane, Ph.D.<sup>4</sup>, Clare Devlin, Ph.D.<sup>4</sup>, Jianmei Wang, Ph.D.<sup>4</sup>, Nicolino Ruperto, M.D., MPH<sup>5</sup>; (1)IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy (2)Cincinnati Children's Hospital Medical Center, PRCSG, Cincinnati, OH (3)Hoffmann-La Roche, Nutley, NJ (4)Roche, Welwyn Garden City, United Kingdom (5)PRIN-TO, Genoa, Italy

**PURPOSE:** Increased interleukin-6 (IL-6) levels correlate with clinical manifestations of systemic juvenile idiopathic arthritis (sJIA). TENDER is a randomized, placebo-controlled, phase 3 trial of tocilizumab (TCZ) in sJIA. Herein, long-term pharmacokinetic (PK) and pharmacodynamic (PD) data from 75 patients receiving TCZ are reported.

**METHODS:** In part 1 (12-week controlled phase), patients received TCZ (12 mg/kg for patients <30 kg and 8 mg/kg for patients  $\geq 30$  kg) or placebo every 2 weeks. Patients completing part 1 subsequently entered part 2 (92-week, open-label extension). Predose serum samples for PK (TCZ) and PD (IL-6 and soluble IL-6 receptor [sIL-6R]) assessments were obtained at various times through week 104.

**RESULTS:** Mean predose TCZ concentrations stabilized by week 12 in both dose groups, with no further increase through week 104. TCZ concentrations in both groups were comparable through week 104. Mean IL-6 levels rapidly increased by week 2, declined to near baseline levels by week 52, and remained so thereafter. Mean sIL-6R levels also increased rapidly, reaching plateau after week 12. Changes in IL-6 and sIL-6R levels were similar between dose groups. No correlation was observed in part 2 between Juvenile Arthritis Disease Activity Score-27 and average  $C_{\text{trough}}$  exposure in patients who were treated at 8 or 12 mg/kg or who switched treatments at any time during part 2. Proportions of patients with JIA-American College of Rheumatology 30 responses with no fever were comparable across exposure quartiles. Neither adverse events nor serious adverse events increased with greater TCZ exposure (exception: twofold increase in the number and rate of subcutaneous tissue disorders at the highest TCZ exposure quartile).

**CONCLUSION:** Comparable TCZ exposures through week 104 were achieved in each dose group. Throughout the study, efficacy endpoints were maintained across exposure quartiles, and there were no clear trends for increased adverse events with increasing exposure.

**173. Pharmacokinetics and pharmacodynamics of long-term tocilizumab therapy in polyarticular juvenile idiopathic arthritis.** Scott Feltner, BA<sup>1</sup>, Peng Lu, M.D., Ph.D.<sup>1</sup>, Joy Hsu, Ph.D.<sup>1</sup>, Caroline Keane, Ph.D. Ph.D.<sup>2</sup>, Jianmei Wang, Ph.D.<sup>2</sup>, Nicolino Ruperto, M.D., MPH<sup>3</sup>, Fabrizio De Benedetti, M.D., Ph.D.<sup>4</sup>, Hermine Brunner, M.D., M.Sc., MBA<sup>5</sup>; (1)Hoffmann-La Roche, Nutley, NJ (2)Roche, Welwyn Garden City, United Kingdom (3)PRIN-TO, Genoa, Italy (4)IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy (5)Cincinnati Children's Hospital Medical Center, PRCSG, Cincinnati, OH

**PURPOSE:** Elevated interleukin-6 (IL-6) levels are associated with disease activity in juvenile idiopathic arthritis (JIA). Herein, pharmacokinetic (PK) and pharmacodynamic (PD) data for CHERISH, a 3-part study of tocilizumab (TCZ) in polyarticular JIA (pJIA), are described.

**METHODS:** In part 1 (16 weeks), 188 patients received TCZ Q4W. Patients weighing <30 kg were randomized 1:1 to 10 (group 1) or 8 (group 2) mg/kg TCZ; patients  $\geq 30$  kg received 8 mg/kg TCZ (group 3). In part 2 (24 weeks), patients achieving  $\geq$ JIA-ACR30 response were randomized 1:1 to placebo or TCZ. Patients who escaped due to ACR30 flare or who completed part 2 received open-label TCZ in part 3 (64-week extension). Blood samples for PK-PD assessments were collected throughout the study.

**RESULTS:** Mean IL-6 and soluble IL-6 receptor (sIL-6R) levels increased by week 1. IL-6 levels declined to baseline by week 4 and remained low through week 40; sIL-6R levels fluctuated through week 40, were similar between groups 1 and 3, and were ~50% lower in group 2. Median C-reactive protein (CRP) level and erythrocyte sedimentation rate (ESR) decreased by weeks 1–2, remained below upper limit of normal through week 40, and were most comparable between groups 1 and 3. Through week 40, mean TCZ concentrations and estimated PK parameters in group 3 were slightly higher than group 1; group 2 TCZ exposures were lower than the other groups. TCZ, CRP, and ESR remained at relatively stable levels through part 3 (week 104). Analysis of JIA-ACR responses by PK exposure quartiles in part 1 indicated lower exposure resulted in lower clinical efficacy. No consistent trends for adverse event rates versus PK exposure were observed.

**CONCLUSION:** TCZ exposures and PD responses following 10 mg/kg in pJIA patients <30 kg were more comparable to those following 8 mg/kg in patients  $\geq 30$  kg than 8 mg/kg in patients <30 kg.

**174. Development of a prodrug database.** Shin-Yu Lee, Pharm.D.<sup>1</sup>, S. Joshua Swamidass, M.D., Ph.D.<sup>2</sup>, Anne Rogers, Pharm.D. Candidate<sup>1</sup>, Margaret Riley, Pharm.D. Candidate<sup>1</sup>; (1)Pharmacy Practice Division, Saint Louis College of Pharmacy, Saint Louis, MO (2)Division of Laboratory and Genomic Medicine<sup>LGM</sup>, Department of Immunology and Pathology, Washington University, St. Louis, MO

**PURPOSE:** The goal of this research project is to make an accurate and up-to-date database with each prodrug and what converts the drugs to their active form.

**METHODS:** A list of over 1500 medications collected from another database commonly used in research, DrugBank. If a medication was determined to be a prodrug, further information gathering took place to identify the name of the active form and the converting entity. For each of these sections, a minimum of three resources were used to confirm all information gathered. The most commonly used resources were Micromedex, Lexicomp, Facts and Comparisons, PharmGKB, Drug Bank, and Clinical Pharmacology. These sources were listed on the input section as well as a place to add other sources when the information was not available on the aforementioned electronic resources. Each drug was assigned to a minimum of two researchers who independently gathered information on the drug. Any questions or conflicting data were addressed by contacting the lead professors of the project and by consensus of all researchers.

**RESULTS:** Research is still ongoing, but over 200 prodrugs have been identified to date. There are drugs active before metabolism which also have active metabolites (equal or greater potency) and require further discussion.

**CONCLUSION:** The availability of a comprehensive prodrug database has the potential to greatly aid in future research, discovery, and quick information access.

## Psychiatry

**175. A pilot study on clozapine-induced blood dyscrasias among singaporean inpatient clozapine users.** Celine Tan, Pharm.D.<sup>1</sup>, Boon Tat Ng, M(ClinPharm)<sup>2</sup>, Pei Shi Ong, Ph.D.<sup>3</sup>; (1)Department of Pharmacy, Institute of Mental Health, Singapore, Singapore (2)Institute of Mental Health, Singapore, Singapore (3)Department of Pharmacy, National University of Singapore, Singapore, Singapore



**PURPOSE:** The incidence of Clozapine-induced blood dyscrasias is not known locally. This study aims to: (i) estimate the first-year incidence rate and time-to-onset of Clozapine-induced blood dyscrasias, (ii) estimate the second- and third-year incidence rates and times-to-onset of blood dyscrasias and to (iii) determine the presence of associated factors for pertinent blood dyscrasias.

**METHODS:** A retrospective cohort study was done in inpatients. Full blood count results were traced for first-time Clozapine users at relevant time-points for the first year of therapy and beyond. Out-of-range values, time-to-first-onset and associated causes were recorded. Demographics and clinical characteristics of patients with pertinent blood dyscrasias were compared to those without, using Chi-square, Fischer's exact or Mann-Whitney U tests for the comparison of between-group differences. The incidence rate for each blood dyscrasia was calculated.

**RESULTS:** Thirty-seven inpatients were included in the analysis. Agranulocytosis was not reported in this cohort. The blood dyscrasias with the highest first-year incidence were anemia (65.2%), eosinophilia (48.5%), neutrophilia (44.1%), leukocytosis (43.2%), erythrocytopenia (41.27%), monocytosis (41.2%) and lymphocytopenia (37.5%). A large proportion of blood dyscrasias occurred within the first 18 weeks of therapy. The following associated factors were found: longer treatment duration for erythrocytopenia (154 versus 72 weeks,  $p=0.0022$ ), absence of psychiatric comorbidities for anemia (14 versus three patients,  $p=0.045$ ), older age for lymphocytopenia (51.7 versus 43.0 years,  $p=0.011$ ) and male gender for monocytosis (14 versus eight patients,  $p=0.013$ ).

**CONCLUSION:** Clozapine-induced blood dyscrasias are not limited to agranulocytosis, leukopenia and neutropenia. The long-term effects of other blood dyscrasias should be explored.

**176. Medication adherence in returning Iraq and Afghanistan war veterans with risk of mild traumatic brain injury.** Alina Kuo, Pharm.D., BCPS<sup>1</sup>, Bruce Capehart, M.D., MBA<sup>2</sup>, Carol Smith Hammond, Ph.D.<sup>2</sup>, Karen Tucker, Ph.D.<sup>2</sup>, Artin Armagan, Ph.D.<sup>3</sup>, Jamie Brown, Pharm.D., BCPS<sup>4</sup>; (1) Inova Fairfax Hospital, Falls Church, VA (2) Durham VA Medical Center, Durham, NC (3) Duke University Medical Center, Durham, NC (4) Pharmacy Service, Durham VA Medical Center, Durham, NC

**PURPOSE:** Poor medication adherence is associated with suboptimal clinical outcomes and increased health care expenses. The purpose of this study is to assess medication adherence in a subset of Operation Enduring Freedom (OEF) and Iraqi Freedom (OIF) veterans with risk of combat related mild traumatic brain injury (TBI).

**METHODS:** Returning OEF/OIF veterans who screened positive for possible mild TBI between April 2007 and December 2009 were assessed in this retrospective, IRB-approved study. Electronic refill records were evaluated, and overall medication adherence was determined using a medication possession ratio (MPR) where adherence was established at  $\geq 0.8$ . Age, cognitive deficits, home living arrangement, mental health diagnoses, number of medications prescribed, and use of electronic medication-assist devices were evaluated as predictors of medication adherence using linear regression analyses. Adherence rates between medication classes were also evaluated.

**RESULTS:** Less than half of the 104 patients included in the study were considered adherent with a mean MPR of  $0.59 \pm 0.41$ . Only age was considered a significant predictor of increased medication adherence (odds ratio 1.08; 95% confidence interval, 1.68–2.01;  $p=0.004$ ). No difference in medication adherence was seen between maintenance medication classes.

**CONCLUSION:** OEF/OIF veterans with risk of mild TBI may have decreased adherence to maintenance medications. Older age in these patients is a predictor for increased medication adherence.

**177. Evaluation of a pharmacy-provided education on measurement of testosterone levels in older males with depression.** Danielle Hebel, Pharm.D., Jamie M. Pitlick, Pharm.D., BCPS, Amy M. Drew, Pharm.D., BCPS; St. Louis College of Pharmacy, St. Louis, MO

**PURPOSE:** Depression in older males is a significant health issue that has many possible contributing factors, most of which cannot be objectively measured. Testosterone deficiency is a possible etiology for depression and can be objectively measured. The Endocrine Society Clinical Practice Guidelines recommend measuring testosterone levels in older males with any clinical manifestations of hypogonadism, including symptoms of depressed mood. The purpose of this study was to determine whether a pharmacy-driven educational intervention increased the measurement of testosterone as part of the depression assessment of older males in the outpatient setting.

**METHODS:** Males > age 40 seen for depression February 1–May 1, 2012 (pre-intervention) or March 1–June 1, 2013 (post-intervention) were included. An online survey to gauge perceptions of measuring testosterone was administered to physicians prior to the intervention. The educational intervention consisted of two newsletters focusing on when to measure testosterone and testosterone replacement therapy. These were distributed to physicians via email in February 2013. The primary outcome was the difference in number of testosterone levels being ordered before and after the intervention.

**RESULTS:** Seventy-five patients were included in both the pre- and post-intervention groups. There was not a significant increase in number of testosterone levels being ordered before ( $n=0$ ) compared to after ( $n=1$ ) the intervention ( $p=1.000$ ). The survey results illustrated that > 90% of physicians seldom or almost never order testosterone levels in male patients with depression, but that 65% are neutral about whether measuring testosterone levels in this patient population is of value.

**CONCLUSION:** Implementation of a pharmacy-driven educational intervention did not significantly increase the number of testosterone levels ordered in older male patients with depression in the outpatient setting. An approach that includes more direct educational strategies or potential protocol implementation may be necessary for improved future outcomes.

## Pulmonary

**178. Assessment of the inpatient treatment of COPD exacerbations and the effect on patient outcomes.** Sheila Wilhelm, Pharm.D., BCPS<sup>1</sup>, Elisa Bahry, Pharm.D. Student<sup>2,3</sup>, Emily Fisher, Pharm.D.<sup>2,3</sup>, Geoffrey Morgan, Pharm.D.<sup>4</sup>; (1) Pharmacy Practice, Wayne State University and Harper University Hospital, Detroit, MI (2) Wayne State University, Detroit, MI (3) Spectrum Health System, Grand Rapids, Detroit, MI (4) Harper University Hospital, Detroit, MI

**PURPOSE:** To improve patient outcomes, treatment of Chronic Obstructive Pulmonary Disease (COPD) exacerbation should follow guideline recommendations. Objectives: (i) Determine whether patients hospitalized for COPD exacerbation are managed with appropriate medication classes, and determine the relationship between Charlson comorbidity score, length of stay (LOS) and number of inpatient COPD medications. (ii) Establish whether season affects length of stay, COPD admission rates, 30-day readmission rates and documentation of influenza and pneumococcal vaccines.

**METHODS:** A retrospective chart review within a large academic institution was performed. Patients 18–89 years admitted between December 2010 and August 2012 with ICD9 code indicating COPD were included if they had documented shortness of breath due to COPD exacerbation in an initial inpatient note. Patient demographics, pulmonary medications, season of admission, LOS, readmission, and Charlson Comorbidity score were collected. ANOVA and Spearman Rank Correlation were used for parametric and nonparametric data, respectively.

**RESULTS:** Six hundred and fifteen patients were screened; 91 were included. COPD exacerbation was treated with short-acting beta-agonists (98.9%), short-acting anticholinergics (81.3%), systemic corticosteroids (81.3%), and antimicrobials (73.6%). No correlation was found between Charlson comorbidity score and LOS or number of inpatient COPD medications ( $r = 0.039$ ,  $-0.016$ , respectively;  $p > 0.05$  for both comparisons). A weak

positive correlation was found between LOS and number of medications ( $r = 0.23$ ,  $p=0.0281$ ). LOS did not differ by season ( $p=0.55$ ). More admissions/month occurred in fall (8.0 admissions/month) versus winter, spring or summer (3.83, 5.17 and 3.5, respectively). Readmissions/month followed a similar trend (1, 0.83, 1, and 3 readmissions/month in winter, spring, summer, fall, respectively). Rate of documented influenza and pneumococcal vaccinations remained consistent throughout the winter and spring months (51–56%) and decreased slightly in the fall (44%). During summer, influenza vaccination documentation decreased (10%), while pneumococcal vaccination documentation remained consistent (62%).

**CONCLUSION:** COPD exacerbations are treated according to guidelines. Documentation of vaccination is an area for improvement.

**179. Examining appropriate inhaler usage among indigent patients.** *Jonathan Newsome, Pharm.D.*; Pharmacy Practice, South College School of Pharmacy, Knoxville, TN

**PURPOSE:** This study documented whether indigent patients with chronic obstructive pulmonary disease (COPD) or asthma used their inhalers appropriately by assessing their adherence to and understanding of their inhaler regimen.

**METHODS:** During medication therapy reviews, patient understanding of and adherence to inhaler therapy was assessed by determining the answers to three questions: (i) is the patient aware of which medications are rescue and maintenance; (ii) is the patient adherent to the prescribed directions; and (iii) were additional medications needed to help control symptoms?

**RESULTS:** It was determined that 66.7% of the patients counseled were aware of the difference between a rescue and maintenance inhaler. Patients with a lack of understanding regarding the purpose of their inhalers were more likely to be non-adherent to multiple inhalers (71.4%) compared to patients with an understanding (14.3%). Overall, 85.7% of the patients counseled were not compliant with the prescribed directions to either the rescue, maintenance, or both inhalers.

**CONCLUSION:** Patient awareness regarding which medication is for rescue or maintenance seemed to have no correlation with whether the patient was adherent to the overall inhaler therapy. Patient awareness did appear to effect whether the patient was not compliant with one inhaler versus multiple inhalers.

**180. Evaluation of a therapeutic interchange of scheduled ipratropium to tiotropium for in hospitalized patients with chronic obstructive pulmonary disease.** *William Ngo, Pharm.D.*<sup>1</sup>, *Katie Buehler, Pharm.D.*<sup>2</sup>, *Nicholas Hampton, Pharm.D.*<sup>3</sup>, *Michael Daly, Pharm.D., MSCI*<sup>2</sup>; (1) Department of Pharmacy, Missouri Baptist Medical Center, Saint Louis, MO (2) St. Louis College of Pharmacy, Saint Louis, MO (3) BJC Center for Clinical Excellence, Saint Louis, MO

**PURPOSE:** This study compared the efficacy of scheduled ipratropium to tiotropium following a therapeutic interchange (TI) for acutely ill hospitalized patients. Prior studies have examined the clinical impact of this TI in the outpatient setting, and concluded tiotropium is associated with improved trough FEV1 values at 12 weeks while not increasing rescue bronchodilator usage.

**METHODS:** This retrospective, quasi-experimental, single-center study evaluated a hospital-approved TI from scheduled ipratropium (ipratropium or albuterol-ipratropium metered dose inhaler) to tiotropium in hospitalized patients with chronic obstructive pulmonary disease (COPD). The TI went into effect May 15th, 2012. Electronic medical records were reviewed for evaluation of eligible patients admitted between May 15, 2011 and December 18, 2012. Patient demographics, documentation of pulmonary disease and associated medications, and outcomes related to scheduled and as needed bronchodilator use were collected and analyzed. The primary outcome was number of puffs of rescue bronchodilator in the first 5 days of hospitalization.

**RESULTS:** A total of 194 patients received either scheduled ipratropium (130 patients) or tiotropium (64 patients). There was

no difference found in the primary outcome (use of rescue bronchodilator) or length of stay. There was a significant increase in compliance with tiotropium compared with scheduled ipratropium (96.1% versus 86.9%,  $p<0.001$ ). More doses of ipratropium were administered per admission compared to tiotropium (11.4 versus 3.53,  $p<0.001$ ). In patients with a COPD exacerbation, no differences were found for any of the evaluated outcomes.

**CONCLUSION:** The TI from scheduled ipratropium to tiotropium resulted in a lower rate of scheduled doses of anticholinergic bronchodilator being missed by patients and no difference in rescue bronchodilator usage. Previous studies evaluating a similar therapeutic substitution concluded that a potential cost savings may occur when tiotropium is substituted for scheduled ipratropium.

## Substance Abuse/Toxicology

**181. Addiction to the synthetic cannabinoid analog AM-2201.** *S. Casey Laizure, Pharm.D.*; Department of Clinical Pharmacy, University of Tennessee, Memphis, TN

**PURPOSE:** The smoking of herbal incense products referred to as "Spice" containing various cannabinoid analogs is a growing drug abuse problem. Many synthetic analogs have a higher affinity for the cannabinoid-1 receptor than delta-9-tetrahydrocannabinol suggesting that the risk for addiction is a concern; however, there are no cases reported. This case describes addiction to the cannabinoid analog AM-2201 observed in a patient undergoing inpatient drug treatment.

**METHODS:** A case of substance dependence, as defined by DSM-IV criteria, was evaluated in a patient admitted to a drug treatment facility who smoked herbal incense. The use of the cannabinoid analog AM-2201 was verified by inspection of empty bottles of the products smoked by the patient.

**RESULTS:** This 53 year-old female was a regular marijuana smoker who started smoking herbal incense in an attempt to quit marijuana. She smoked Cush, Ripits, Dank, and Da Blubonic Chronic products, but ultimately only smoked Da Blubonic Chronic as it produced the greatest effect. A police crime lab has confirmed that Cush, Dank, and Da Blubonic Chronic contain AM-2201. Her use escalated over several months to the point that she was smoking from the time she woke up in the morning until she went to bed, and her entire day was consumed with obtaining and using this product. She was unable to quit and sought inpatient treatment. Her pattern of use was consistent with an Axis-I diagnosis of AM-2201 dependence, fulfilling six out of the seven criteria for substance dependence.

**CONCLUSION:** This case illustrates that the abuse of herbal incense tainted with synthetic cannabinoid-1 analogs is a problem that carries a significant risk of addiction. Though numerous cannabinoid analogs including AM-2201 are now illegal, there are a multitude of other analogs that remain legal and could be used as additives to marketed herbal incense products.

## Transplant/Immunology

**182. Corticosteroid withdrawal after kidney transplantation: 4-year real-world efficacy and safety outcomes from the prospective mycophenolic acid observational renal transplant study.** *Kimi Ueda, Pharm.D.*<sup>1</sup>, *Anne Wiland, Pharm.D., BCPS*<sup>2</sup>, *Kevin McCague, M.A.*<sup>2</sup>, *V. Ram Peddi, M.D.*<sup>3</sup>; (1) Department of Transplantation, California Pacific Medical Center, San Francisco, CA (2) Novartis Pharmaceuticals Corporation, East Hanover, NJ (3) California Pacific Medical Center, San Francisco, CA

**PURPOSE:** To examine long-term outcomes following corticosteroid withdrawal by month 3 (CSW) or corticosteroid continuation (CSC) after kidney transplantation in routine clinical practice.

**METHODS:** Prospective data were analyzed from the observational, 4-year mycophenolic acid observational renal transplant (MORE) study of *de novo* adult kidney transplant patients receiving mycophenolic acid (MPA) at 40 US centers, managed according to local practice. CSW was defined as withdrawal of steroids by month 3 post-transplant.

**RESULTS:** Three hundred and sixty-three CSW and 509 CSC tacrolimus-treated patients were analyzed, with panel reactive antibodies <30% in 89.9% and 77.0% of cases ( $p<0.01$ ), respectively, and 46.3% and 40.7% living donors ( $p=0.09$ ). Thymoglobulin induction was used in 62.3% CSW versus 58.6% CSC patients ( $p=0.02$ ) and alemtuzumab in 23.7% versus 4.7% ( $p<0.01$ ). Tacrolimus trough levels were comparable. At 4 years post-transplant, biopsy-proven acute rejection (BPAR; CSW 10.1% versus CSC 14.3%;  $p=0.12$ ) and patient survival (95.6% versus 95.0%;  $p=0.65$ ) were similar but graft survival was higher with CSW (96.9% versus 93.7%;  $p=0.03$ ). Cox regression analysis comparing CSW versus CSC confirmed that BPAR was similar (hazard ratio 0.75; 95% CI 0.46, 1.21;  $p=0.25$ ), graft loss was lower (0.35; 0.12, 0.86;  $p=0.03$ ) and death was similar (0.82; 0.31, 2.09;  $p=0.68$ ). Mean estimated GFR for CSW versus CSC was 59.5 versus 57.5 mL/min/1.73 m<sup>2</sup> ( $p=0.84$ ) at 1 year and 57.7 versus 58.1 mL/min/1.73 m<sup>2</sup> ( $p=0.44$ ) at 3 years (numbers at 4 years were too low for meaningful analysis). Hematological adverse events (primarily leukopenia and neutropenia) occurred in 64.2% CSW patients versus 34.2% CSC patients ( $p<0.01$ ), with infections in 24.8% versus 30.8%, respectively ( $p=0.06$ ). Other adverse events by organ system were similar, including cardiovascular disease and diabetes.

**CONCLUSION:** CSW is associated with higher 4-year graft survival than CSC in routine practice, possibly due to lower immunological risk and a trend to more living donors. Other than hematological events, adverse events were similar in CSW and CSC patients.

**183E. Adherence with immunosuppressive therapy to 4-years after kidney transplantation: prospective data from the observational mycophenolic acid observational renal transplant study.** Demetra Tsapepas, Pharm.D., BCPS<sup>1</sup>, Anthony Langone, M.D.<sup>2</sup>, Laurence Chan, M.D.<sup>3</sup>, Anne Wiland, Pharm.D., BCPS<sup>4</sup>, Kevin McCague, M.A.<sup>4</sup>, Marie Chisholm-Burns, Pharm.D.<sup>5</sup>; (1) NY-Presbyterian Hospital-Columbia University Medical Center, New York, NY (2) Vanderbilt University Medical Center, Nashville, TN (3) University of Colorado School of Medicine, Aurora, CO (4) Novartis Pharmaceuticals Corporation, East Hanover, NJ (5) University of Tennessee Health Science Center, TN

**PURPOSE:** To identify factors influencing long-term adherence with immunosuppression after kidney transplantation under real-life conditions.

**METHODS:** Prospective data were analyzed from the 4-year, observational mycophenolic acid observational renal transplant (MORE) study of *de novo* adult kidney transplant patients receiving mycophenolic acid (MPA) as enteric-coated mycophenolate sodium (EC-MPS) or mycophenolate mofetil (MMF) at 40 US sites under routine management. Adherence was assessed using the Immunosuppressant Therapy Adherence Scale (ITAS): total score 0–12 (12, adherence; <12, non-adherence).

**RESULTS:** 808/946 patients (85.4%) provided  $\geq 1$  ITAS score; 49.8% (402/808) were non-adherent at  $\geq 1$  timepoint. Mean (SD) total ITAS score at months 3, 6, 12, 24, 36 and 48 was 11.5 (1.0), 11.4 (1.2), 11.3 (1.2), 11.2 (1.2), 11.3 (1.1) and 11.4 (1.1), respectively, with non-adherence in 24.8%, 31.5%, 33.0%, 39.8%, 35.4% and 26.4% of patients. Mean score was higher with EC-MPS versus MMF at months 24 (11.3 [1.0] versus 10.9 [1.4],  $p=0.001$ ) and 36 (11.4 [1.0] versus 11.1 [1.3],  $p=0.024$ ). The prescribed MPA dose was taken by 94.6% EC-MPS patients versus 91.5% MMF patients at month 12 ( $p=0.083$ ), and 92.8% versus 87.7% ( $p=0.033$ ) at month 24. The odds ratio for non-adherence was 1.60 (95% CI 1.17, 2.19;  $p=0.003$ ) for African Americans versus non-African Americans, and 1.29 (95% CI 0.97, 1.70;  $p=0.077$ ) for living versus deceased donor recipients. Age, gender and delayed graft function did not predict non-adherence. The rate of biopsy-proven acute rejection was 12.7% (51/410) in non-adherent patients versus 11.3% (46/406) in adherent patients ( $p=0.59$ ); graft loss was 4.7% (19/412) versus 3.0% (12/406) ( $p=0.20$ ); death was 1.5% (6/402) versus 4.7% (19/406) ( $p=0.013$ ).

**CONCLUSION:** During the first 24 months post-transplant, adherence to immunosuppression decreased progressively, after

which limited data prohibited robust conclusions. African American ethnicity, but not other demographic characteristics, predicted non-adherence. Adherence was higher with EC-MPS versus MMF at specific timepoints. Mortality was lower in non-adherent patients versus adherent patients but absolute numbers were low. Presented at Presented at the American Transplant Congress, Seattle, WA, May 18–22, 2013.

**184E. Everolimus facilitated reduction of tacrolimus in *de novo* liver transplant recipients (LTxR): 12–24 month data from North America.** W. C. Chapman, M.D., FACS<sup>1</sup>, R. S. Brown, Jr, M.D., MPH<sup>2</sup>, D. Sudan, M.D.<sup>3</sup>, K. D. Chavin, M.D., Ph.D.<sup>4</sup>, B. Koneru, M.D.<sup>5</sup>, M. A. Huang, M.D., MS<sup>6</sup>, G. Junge, M.D., MBA<sup>7</sup>, J. M. Hexham, Ph.D., M.Sc.<sup>8</sup>, G. Dong, Ph.D.<sup>8</sup>, A. Wiland, Pharm.D., BCPS<sup>8</sup>, D. Patel, M.D.<sup>8</sup>, J. Fung, M.D.<sup>9</sup>; (1) Washington University School of Medicine, St Louis, MO (2) Columbia University Medical Center, New York, NY (3) Duke University Medical Center, Durham, NC (4) Medical University of South Carolina, Charleston, SC (5) University of Medicine and Dentistry- New Jersey Medical School, Newark, NJ (6) Henry Ford Hospital, Detroit, MI (7) Novartis AG, Basel, Switzerland (8) Novartis Pharmaceuticals Corporation, East Hanover, NJ (9) Cleveland Clinic, Cleveland, OH

**PURPOSE:** In Study H2304, everolimus (EVR) facilitated early tacrolimus (TAC) minimization with comparable efficacy and better renal function versus std TAC at 12 months (M) after liver transplantation. At randomization (RDN), North America (NA) recipients (versus other regions) had higher mean Model for End-Stage Liver Disease (MELD) score (22.7 versus 17.6 in Europe/18.5 in rest of world), lower eGFR (76 versus 84/79 mL/min/1.73 m<sup>2</sup>), and higher incidence of diabetes and hepatitis C virus. Here we report 12 and 24 months results for the NA subpopulation.

**METHODS:** Twenty-four months, multicenter, open-label study with 211 *de novo* LTx recipients from NA randomized after a 30-day run-in period with TAC  $\pm$  mycophenolic acid to receive either EVR (C0 3–8 ng/mL)+reduced TAC (C0 3–5 ng/mL; EVR+rTAC, n=65), EVR (C0 6–10 ng/mL)+TAC withdrawal at M4 (TAC-WD, n=68), or std TAC (C0 6–10 ng/mL; TAC-C, n=78); all with steroids. Primary endpoint at M12 (amended protocol) was the composite efficacy failure rate of treated biopsy proven acute rejection (tBPAR), graft loss, or death.

**RESULTS:** Enrollment in TAC-WD arm was prematurely terminated due to a higher rate of tBPAR. Efficacy results were similar at 12 and 24 months with improved renal function in the EVR+rTAC versus TAC-C (table). Adverse events (AEs)/infections and discontinuations due to AEs were similar between EVR+rTAC (96.9% and 18.5%) and TAC-C (94.9% and 14.1%).

**CONCLUSION:** In patients from NA, EVR facilitated TAC reduction from M1 showed comparable efficacy and improved renal function over std TAC.

	EVR+rTAC (n=65)	TAC-C (n=78)	Differential risk (95% CI) EVR+rTAC versus TAC-C
Composite efficacy failure rate* n (%) (months)			
12	7 (10.9)	10 (13.1)	-2.1% (-12.9, 8.6)
24	9 (14.1)	13 (17.2)	-3.0% (-15.1, 9.0)
tBPAR n (%) (months)			
12	4 (6.2)	9 (11.5)	-3.9% (-7.7, -0.1) <sup>†</sup>
24*	5 (8.1)	10 (13.2)	-5.1% (-15.4, 5.1)
Graft loss or death* n (%) (months)			
12	4 (6.3)	1 (1.3)	4.9% (-1.5, 11.4)
24	5 (7.9)	4 (5.4)	2.5% (-5.9, 10.9)
Change in eGFR (MDRD4) from RDN, mL/min/1.73 m <sup>2</sup> (months)			
12	3.71	-4.48	-
24	2.72	-6.64	-

\*Kaplan-Meier incidence rates; <sup>†</sup> $p=0.047$ ;  $p<0.05$  versus TAC-C.

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**185. Efficacy and safety of delayed outpatient rabbit anti-thymocyte globulin induction in de-novo african american kidney transplant recipients.** Tracy M. Sparkes, Pharm.D.<sup>1</sup>, Jennifer Trofe-Clark, Pharm.D., BCPS<sup>2</sup>, Simin Goral, M.D.<sup>2</sup>, Peter P. Reese, M.D., MSCE<sup>2</sup>, Diane Jakobowski, MSN, RN<sup>3</sup>, Stacey Doll, MPA<sup>3</sup>, Peter L. Abt, M.D.<sup>4</sup>, Deirdre Sawinski, M.D.<sup>2</sup>, Roy D. Bloom, M.D.<sup>2</sup>; (1)Department of Pharmacy, Hospital of the University of Pennsylvania, Philadelphia, PA (2)Renal Electrolyte and Hypertension Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (3)Penn Transplant Institute, Hospital of the University of Pennsylvania, Philadelphia, PA (4)Division of Transplant Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

**PURPOSE:** To reduce hospital length of stay (LOS), our center instituted a protocol to administer a portion of the rabbit anti-thymocyte globulin (rATG) induction doses to kidney transplant recipients as outpatients. The purpose of this study was to evaluate 6 month safety and efficacy of outpatient rATG administration in African American (AA) patients.

**METHODS:** Retrospective study of AA kidney alone recipients transplanted January 1, 2008 to December 31, 2011 who received at least three rATG induction doses, our center's standard. Outpatient rATG induction, consisting of two or more inpatient doses followed by >1 outpatient dose, was compared to the standard of all inpatient administration (inpatient rATG). Follow-up was censored at 6 months.

**RESULTS:** Of 171 patients, 71% received 162 (median 1, range 1–3) outpatient rATG doses. The first outpatient dose was the 3rd rATG dose in 60% of patients. There were no significant differences between inpatient and outpatient rATG groups with respect to demographics, donor source, prior transplant history, maintenance immunosuppression, rates of sensitization, DGF, and de novo donor specific antibody (DSA) formation by 6 months post-transplant. Compared to inpatient rATG, outpatient rATG decreased LOS ( $4 \pm 2$  versus  $6 \pm 3$  days,  $p < 0.01$ ) without increasing 30 day readmission (39% versus 35%,  $p = 0.64$ ) or 6 month rejection rates (14% versus 10%,  $p = 0.51$ ). Outpatient rATG patients received a greater cumulative rATG dose ( $5.4 \pm 1.4$  versus  $4.8 \pm 1.2$  mg/kg,  $p < 0.01$ ) and required less dose reduction for leukopenia or thrombocytopenia, with no increase in opportunistic infections at 6 months. Two patients per group had graft loss; one outpatient rATG patient died. Outpatient rATG avoided 162 hospital days that would have been required for inpatient rATG administration.

**CONCLUSIONS:** Outpatient rATG lowered LOS without compromising efficacy or safety in AA recipients.

**186. Incidence and severity of isometric tubular vacuolization in renal transplant recipients treated with CMVig or IVIg-glycine.**

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**PURPOSE:** Intravenous immunoglobulins are commonly used with plasmapheresis to treat antibody-mediated rejection (AMR) in renal transplant recipients (RTRs). Immunoglobulin products stabilized by carbohydrates are associated with isometric tubular vacuolization (ITV). The primary objective of this study was to compare the incidence and severity of ITV in RTRs treated with IVIg-glycine (Gamunex-C, Grifols) or CMVig (Cytogam, CSL-Behring). Secondary objectives included the incidence of CMV infection and time to sufficient HLA-antibody lowering.

**METHODS:** RTRs were included if they received IVIg-glycine for AMR from August 2012 to April 2013. They were matched with RTRs who received CMVig for AMR from January 2011 through September 2012 in a consecutive 3:1 fashion. Kidney biopsies obtained within 3 months of receiving immunoglobulins were reviewed by a single pathologist for the presence and severity of ITV. ITV was graded on a scale of 0–4 depending on the percentage of proximal tubules showing vacuolization, as previously described. Serum creatinine and tacrolimus troughs were collected 14 days before biopsy and 14, 30, 60, and 90 days after biopsy.

**RESULTS:** Thirty-four RTRs were included in the CMVig cohort and 12 in the IVIg-glycine cohort. There was no observed difference in the incidence of ITV between cohorts (86.1% versus 80.0%,  $p = 0.64$ ). There was a trend towards an increase in ITV severity in the CMVig cohort (median vacuolization grade 1.75 versus 1.0,  $p = 0.07$ ). There was a significantly higher percentage of patients with ITV grade > 2 in the CMVig cohort (50.0% versus 10.0%,  $p = 0.03$ ). There were no differences observed in time to HLA antibody clearance or incidence of CMV infection or disease.

**CONCLUSION:** This study did not reveal a difference in the incidence of ITV associated with IVIg-glycine versus CMVig when used to treat AMR in RTRs. However, CMVig use was associated with a higher severity of ITV compared to IVIg-glycine.

**187E. Increased risk of breakthrough infection among cytomegalovirus donor positive/recipient negative kidney transplant recipients receiving lower dose valganciclovir prophylaxis.** Daniel R. Stevens, Pharm.D.<sup>1</sup>, Jennifer Trofe-Clark, Pharm.D., BCPS<sup>1</sup>, Emily Blumberg, M.D.<sup>2</sup>, Marissa Wilck, M.D.<sup>2</sup>, Blair Weikert, M.D.<sup>2</sup>, Simin Goral, M.D.<sup>3</sup>, Melissa Bleicher, M.D.<sup>3</sup>, Deirdre Sawinski, M.D.<sup>3</sup>, Peter L. Abt, M.D.<sup>4</sup>, Matthew H. Levine, M.D., Ph.D.<sup>5</sup>, Paige Porrett, M.D., Ph.D.<sup>6</sup>, Nicholas Galanakis, Pharm.D. Candidate<sup>7</sup>, Roy D. Bloom, M.D.<sup>3</sup>; (1)Department of Pharmacy Services, Hospital of the University of Pennsylvania, Philadelphia, PA (2)Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (3)Renal Electrolyte and Hypertension Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (4)Division of Transplant Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (5)Department of Transplant Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (6)Department of Transplant Surgery, Perelman School of Medicine, Philadelphia, PA (7)University of the Sciences Philadelphia College of Pharmacy, Philadelphia, PA

**PURPOSE:** To compare the effectiveness of lower dose (LD, 450 mg/day for 6 months) to standard dose (SD, 900 mg/day for 6 months) valganciclovir prophylaxis (VGV PPX) for prevention of cytomegalovirus (CMV) in donor positive/recipient negative (high-risk) kidney recipients.

**METHODS:** Retrospective cohort study to compare CMV rates in high-risk kidney recipients receiving LD or SD VGV PPX. All patients followed from transplant to 11/1/12 or development of CMV, death, or loss to follow-up; CMV screening was only done if suggestive symptoms or abnormal labs present. Our immunosuppressive protocol did not differ between periods.

**RESULTS:** Thirty-three patients initiated SD VGV PPX in the 18 months pre-PPX update and were included. One patient developed CMV while PPX was on hold. In the 16 months post-PPX update, 45 patients receiving LD VGV PPX were evaluable: five developed CMV while receiving PPX ( $p = 0.24$ ). Ganciclovir resistance was confirmed in one patient in the LD PPX group. Late onset CMV infection occurred in 9 (27%) SD patients and 7 (16%) LD, respectively ( $p = 0.21$ ). Overall rates of BK viremia occurring during the period of PPX did not differ between SD and LD VGV PPX (12% versus 9%, respectively). More patients in the SD group developed leukopenia (73% versus 44%,  $p = 0.01$ ) and required dose reductions in VGV PPX (30% versus 11%,  $p = 0.04$ ). There were no significant differences in mean estimated renal function or mean tacrolimus troughs at any time during the

study period. Overall mean follow-up ( $\pm$ standard deviation) was 520 days ( $\pm$ 106) in SD group and 282 days ( $\pm$ 141) in LD group ( $p < 0.0001$ ).

**CONCLUSION:** Breakthrough CMV infection while receiving VGV PPX occurred more often in LD VGV-treated patients. Given the increased risk of ganciclovir resistance when PPX is under-dosed, SD VGV should be used in all CMV high-risk kidney recipients.

Presented at Presented at the American Transplant Congress, a joint meeting of the American Society of Transplantation and the American Society of Transplant Surgeons, Seattle, WA, May 18–22, 2013.

**188. Tacrolimus interaction with azole antifungals in kidney transplant recipients: is fluconazole or clotrimazole a worse offender?.** Jane Revollo, Pharm.D.<sup>1</sup>, Benjamin Duhart, Jr, M.S., Pharm.D.<sup>2</sup>, Alison Apple, DPh, MS<sup>1</sup>, Amy Krauss, Pharm.D., BCPS<sup>1</sup>; (1)Department of Pharmacy, Methodist University Hospital, Memphis, TN (2)Department of Pharmacy, University of Tennessee Health Science Center/Methodist University Hospital, Memphis, TN

**PURPOSE:** Tacrolimus (TAC), a calcineurin inhibitor used for maintenance immunosuppression in renal transplant recipients, may increase risk for opportunistic fungal infections, particularly oral-esophageal candidiasis. Renal transplant patients at Methodist University Hospital (MUH) are given antifungal prophylaxis for 2–3 months posttransplant. Both fluconazole (FCZ) and clotrimazole (CTMZ) inhibit CYP3A4/5 to elevate TAC levels, however systemic absorption of CTMZ is minimal, potentially limiting the magnitude of interaction with TAC and dose readjustment required after azole discontinuation. Prophylaxis was recently changed from FCZ to CTMZ at our institution. This study compared the change in TAC dose: trough level ratio and subsequent TAC dose adjustments required after FCZ versus CTMZ discontinuation.

**METHODS:** Medical records of adult kidney transplant recipients at MUH from March 2009 – September 2011 were reviewed. Patients receiving maintenance immunosuppression with TAC and prophylaxis with FCZ or CTMZ were included. Medication doses, TAC levels, co-interacting medications, eGFR, first year biopsy proven acute rejection (BPAR), and demographics were documented.

**RESULTS:** The average change in TAC dose: trough ratio 4–8 weeks after azole discontinuation was greater following FCZ compared to CTMZ (FCZ +92.9% versus CTMZ +43.4%,  $p = 0.004$ ). The proportion of patients requiring  $\geq 30\%$  TAC dose increase was 70% with FCZ versus 45% with CTMZ ( $p = 0.006$ ). Choice of antifungal did not affect the number of subtherapeutic TAC levels, the proportion of patients with subtherapeutic levels pre- or post-discontinuation, or incidence of BPAR. Despite wide variability in both groups, the mean TAC dose: trough ratios for African-Americans (AA) were nearly double those of non-AA at all timepoints, and average percent change from pre- to post-azole was similar for both ethnicities.

**CONCLUSION:** Switching antifungal agents from FCZ to CTMZ reduced the magnitude of change in TAC dose required to maintain target TAC blood levels. However, under current dosing adjustment algorithms, no meaningful impact on early clinical outcomes was observed.

**189. Potential association between mycophenolate, but not tacrolimus, exposure and neutropenia in steroid-free renal transplant recipients.** Tony K. L. Kiang, BSc, Ph.D., ACPR<sup>1</sup>, Nilufar Partovi, Pharm.D.<sup>1</sup>, Trana Hussaini, Pharm.D.<sup>1</sup>, Rebecca Jean Shapiro, M.D.<sup>2</sup>, Mary H. H. Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS<sup>3</sup>; (1)Department of Pharmacy, Vancouver General Hospital, Vancouver, BC, Canada (2)Department of Nephrology, Vancouver General Hospital, Vancouver, BC, Canada (3)The University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

**PURPOSE:** Over 50% of renal transplant recipients in our center develop neutropenia in the first year while on mycophenolate

(MPA) and tacrolimus (TAC) immunotherapy. Although the mechanisms remain unknown, overexposure of MPA and/or TAC may lead to neutropenic episodes. The purpose of this pilot study was to examine associations between MPA/TAC exposure and neutropenia in steroid-free kidney transplant patients.

**METHODS:** Age, absolute neutrophil count (ANC), white blood cell count (WBC), MPA daily dose (g), TAC daily dose (mg), C<sub>1</sub>–C<sub>4</sub> MPA levels (mg/L), and C<sub>0</sub>–C<sub>2</sub> TAC levels ( $\mu$ g/L) were collected prospectively in adult kidney recipients within 20–40 days post transplant, following written informed consent ( $N = 7$ ). Area-under the curves (AUCs) of MPA and TAC were determined using newly developed and validated limited sampling strategies (LSS) specific to steroid-free regimens (Ther Drug Monit; 33:50–55, 2011). Linear regression and Spearman rank correlation analyses between dose-normalized MPA or TAC and ANC or WBC were conducted (SigmaStat, v3.5 for Windows). Significance was set *a priori* at  $p = 0.05$ .

**RESULTS:** Study sample characteristics (mean  $\pm$  sd) included: age ( $52 \pm 16$  years), ANC ( $4.4 \pm 1.8 \times 10^3$  cells/ $\mu$ L), WBC ( $6.7 \pm 2.3 \times 10^3$  cells/ $\mu$ L), MPA dose ( $1.9 \pm 0.2$  g/D), TAC dose ( $8.3 \pm 3.4$  mg/D), LSS-predicted dose-normalized MPA AUC ( $27 \pm 8$  mg\*hr/L/g), and LSS-predicted dose-normalized TAC AUC ( $20 \pm 8$   $\mu$ g\*h/L/mg). Statistical analyses revealed a *potential* inverse association between ANC ( $r^2 = 0.30$ ) or WBC ( $r^2 = 0.24$ ) and MPA exposure, but no such associations were observed for TAC exposure (with  $r^2 = 0.02$  for ANC and  $r^2 = 0.06$  for WBC, respectively).

**CONCLUSION:** To our knowledge, this is the first study to examine association between MPA or TAC exposure (calculated using the new steroid-free LSS) and neutropenia in steroid-free kidney transplant recipients. Our novel findings suggest a *potential* association between MPA, but not TAC, exposure with ANC. More patients are being enrolled to confirm this observation and the utility of the LSS in predicting adverse hematological effects.

**190. Evaluation of alemtuzumab versus basiliximab induction in lung transplantation.** Laura Whited, Pharm.D.<sup>1</sup>, Mike Latran, Pharm.D.<sup>1</sup>, Chadi Hage, M.D.<sup>2</sup>, Michael Duncan, M.D.<sup>2</sup>, I-Wen Wang, M.D., Ph.D.<sup>2</sup>, David Roe, M.D.<sup>2</sup>, Thomas Wozniak, M.D.<sup>2</sup>; (1)Department of Pharmacy, IU Health Methodist Hospital, Indianapolis, IN (2)IU Health Methodist Hospital, Indianapolis, IN

**PURPOSE:** Incidence of acute cellular rejection (ACR) and chronic rejection (CR) continues to be a major problem in lung transplantation (LT) with a 5 year survival rate of approximately 50%. Repeated ACR increases the risk of CR post LT. Induction immunosuppression (IS) is increasingly used to minimize early ACR while possibly allowing for minimization of maintenance IS. Recently, our LT program changed our primary induction agent to alemtuzumab in combination with low-dose maintenance immunosuppression (MI), from basiliximab in combination with standard dose MI. The objective of this study was to compare outcomes between these two groups within the first 6 months post-transplant.

**METHODS:** This was a retrospective, cohort review of patients >18 years old who received a lung transplant between January 2010 and September 2012. The primary outcome was comparison of average biopsy score at 6 months. Secondary outcomes included comparing the development of grade A2 or higher rejection, infectious outcomes, and overall survival.

**RESULTS:** At 6 months, there was a significant difference in the average biopsy score between the basiliximab and alemtuzumab groups with a mean score of  $0.74 \pm 0.67$  versus  $0.12 \pm 0.29$  ( $p < 0.0001$ ). A statistically significant difference in the development of grade A2 or higher rejection within the first 6 months post-transplant was found, occurring in 20 (46.5%) basiliximab patients versus 1 (2.2%) alemtuzumab patients ( $p < 0.0001$ ). Multivariate analysis found that only induction with basiliximab was a significant risk factor for Grade A2 or higher rejection (OR 38.2 95% CI 7.2–707.7). There was no difference in infectious outcomes or overall survival between the two groups.

**CONCLUSION:** Alemtuzumab induction in combination with low dose MI provided a safe and effective alternative when

compared to basiliximab induction in combination with standard dose MI in this cohort of lung transplant recipients.

**191. Epidemiology and clinical outcomes of multidrug resistant urinary tract infection in renal transplant recipients: single center study.** *Grace Shyh, Pharm.D.<sup>1</sup>, Yi Guo, Pharm.D.<sup>1</sup>, Kwaku Marfo, Pharm.D., MPH<sup>2</sup>*; (1)Department of Pharmacy, Montefiore Medical Center, Bronx, NY (2)Montefiore-Einstein Center for Transplantation, Montefiore Medical Center, Bronx, NY

**PURPOSE:** Urinary Tract Infections (UTI) remains the most common bacterial infection in renal transplant recipients (RTR). Since the prevalence of multidrug resistant (MDR) bacterial isolates have increased in the last few years, precipitating factors associated with bacterial MDR UTI in RTR needs to be elucidated. The objective of this study was to determine the risk factors and clinical outcomes of MDR UTI in RTR.

**METHODS:** Medical records of RTR with clinically confirmed urinary tract infection were reviewed for the following baseline characteristics: donor source, previous transplant, induction therapy, duration of Foley catheter, JP stent placement, history of urologic complications, prior UTI, previous antibiotic treatment in the past year, causative microorganism and antibiotic sensitivities. Clinical outcomes for microbiological and clinical success at the end of therapy; patient and graft outcomes were evaluated.

**RESULTS:** Analysis was performed on 90 RTR with confirmed UTI (45 patients with MDR-UTI versus 45 non-MDR UTI). Age, history of urologic complications and anti-thymocyte globulin induction were identified as independent risk factors for MDR-UTI. The mean age for the MDR-UTI cohort was 56 ± 12 compared to a mean age of 50 ± 12 in the non-MDR cohort,  $p=0.0317$ . There was a statistically higher incidence of UTI recurrence in the MDR cohort (62%) compared to the non-MDR cohort (16%),  $p=0.0001$ . The most common MDR organisms were *E. coli* and *Enterococcus*. There was a trend to higher incidence of graft rejection after the UTI episode in the MDR group. However, patient and graft survival was similar between the two cohorts, (96% versus 93%,  $p=1.000$ ) and (89% versus 89%,  $p=1.000$ ), respectively.

**CONCLUSION:** Renal transplant recipients with MDR-UTI have similar patient and graft outcomes as patients without MDR-UTI. However, these patients have a higher risk of UTI-recurrence which may lead to higher utilization of healthcare resources.

**192E. Sex and haplotype associations with adverse effects of calcineurin inhibitors post-renal transplant.** *Calvin Meaney, Pharm.D., BCPS<sup>1</sup>, Dan Brazeau, Ph.D.<sup>2</sup>, Rocco Venuto, M.D., FASN<sup>3</sup>, Shirley Chang, M.D.<sup>3</sup>, Aijaz Gundroo, M.D.<sup>3</sup>, Nicolae Leca, M.D.<sup>3</sup>, Sarah Morse, BS<sup>4</sup>, Joseph Consiglio, MS<sup>5</sup>, Louise Cooper, MS<sup>4</sup>, Kathleen Tornatore, Pharm.D., FCCP<sup>1</sup>*; (1)Translational Pharmacology Research Core, NYS Center of Excellence in Bioinformatics and Life Sciences, University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (2)University of New England College of Pharmacy, Buffalo, NY (3)University at Buffalo School of Medicine and Biomedical Sciences, Buffalo, NY (4)University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (5)University at Buffalo School of Public Health, Buffalo, NY

**PURPOSE:** P-glycoprotein (P-gp), an ABC efflux transport protein contributes to the interpatient pharmacokinetic and pharmacodynamic variability of calcineurin inhibitors (CNI), tacrolimus (TAC) and cyclosporine (CYA). *ABCB1* encodes P-gp and the single nucleotide polymorphisms (SNPs) c.1236C>T, c.2677G>T/A, c.3435C>T may alter protein expression or function. Our objective was to examine the association of *ABCB1*/haplotypes, sex and race with chronic CNI adverse effects (AEs) in renal transplant recipients (RTR).

**METHODS:** A meta-analysis of three prospective observational studies was completed in 149 stable RTR ( $GFR = 51 \pm 17$  mL/minute/1.73 m<sup>2</sup>) using identical inclusion and exclusion criteria in 62 African Americans (AA) and 81 Caucasians (C) treated with either CYA (troughs: 50–150 ng/mL) and mycophenolate mofetil

or TAC (troughs: 5–10 ng/mL) and mycophenolate sodium. Each RTR had AEs assessed using standardized objective scales by study physicians. A Cumulative AE ratio was determined using 14 AEs. Separate gastrointestinal (GI), central nervous system (CNS), and aesthetic AE ratios were also assessed. DNA from peripheral blood mononuclear cells was collected to characterize *ABCB1* SNPs via polymerase chain reaction with haplotype computation by THESIAS program. Regression modeling with SAS was utilized.

**RESULTS:** All genotypes were in Hardy-Weinberg equilibria. AA had a greater frequency of C-G-C haplotype (SNPs: 1236–2677–3435) compared to C (71.6% versus 44.2%;  $p<0.001$ ). A gender difference was noted for Cumulative ( $p<0.001$ ); GI ( $p=0.022$ ); aesthetic ( $p=0.0001$ ) and CNS ( $p=0.022$ ) AE ratios with greater AE ratios in females. Increased Aesthetic AE ratio was associated with haplotype T-T-C ( $p=0.008$ ). Haplotype C-T-T was associated with increased GI AE ratio ( $p=0.02$ ) though the effect was not significant with sex as a covariate ( $p=0.13$ ). Race had no associations with AEs.

**CONCLUSION:** RTR receiving CNI based immunosuppression within the therapeutic range exhibited interpatient variability in AE with associations to sex and *ABCB1* haplotypes. Presented at The American Society for Clinical Pharmacology and Therapeutics Annual Meeting, Indianapolis, IN, March 5–9, 2013.

**193. Long-term blood pressure goal achievement in liver transplant patients within an underserved community.** *Justin Harris, Pharm.D.<sup>1</sup>, Christina Ruggia-Check, Pharm.D., Yardlee S. Kauffman, Pharm.D., MPH<sup>3</sup>, Thomas Delate, Ph.D., MS<sup>4</sup>, David Johnson, Pharm.D.*; (1) Temple University Hospital, Philadelphia, PA (2) Pharmacy Department, Kaiser Permanente Colorado, Aurora, CO (3) Kaiser Permanente Colorado, Aurora, CO

**PURPOSE:** Cardiovascular disease is the leading cause of death after liver transplant in those with a functioning allograft. Hypertension, dyslipidemia, and hyperglycemia contribute to cardiovascular disease and may worsen after liver transplant. This is due to a variety of factors, including the use of immunosuppressants. Additionally, as patients in medically underserved areas have higher risk of developing cardiovascular disease, liver transplant recipients in these areas may have compounded risk. No studies to date have investigated the incidence of achieving cardiovascular risk goals in liver recipients transplanted in medically underserved areas.

**METHODS:** This retrospective cohort study was designed to investigate the incidence of cardiovascular disease risk goal achievement in liver transplant patients between January 2009 and April 2011 transplanted at an institution primarily treating underserved patients. The primary endpoint was median blood pressure  $\leq 130/80$  mmHg between 12 and 18 months post-transplant.

**RESULTS:** A total of 46 patients received liver transplants between January 2009 and April 2011. Of the patients included for analysis, 23.1% met the primary endpoint. The mean blood pressure between 12 and 18 months post-transplant was 128/82 mmHg ( $\pm 16/9$  mmHg). A median low density lipoprotein (LDL)  $\leq 100$  mg/dL was achieved in 91.7% of patients during the primary observational period. Finally, a median fasting plasma glucose (FPG)  $\leq 130$  mg/dL was seen in 60.6% of eligible patients.

**CONCLUSION:** Few patients receiving liver transplant at a center within a medically underserved area meet the current blood pressure goals for post-liver transplant. Though within goal, mean systolic blood pressure increased overall during the study period.

**194. A closer look at outcomes in kidney transplant recipients discharged early post-transplant.** *Thinh Luong, N/A, Kimi Ueda, Pharm.D.*; Department of Transplantation, California Pacific Medical Center, San Francisco, CA

**PURPOSE:** Post-transplant education for kidney transplant recipients (KTR) is crucial to maximize adherence and reduce complications and is required by the Centers for Medicare and



Medicaid Services. KTR who are discharged early post-transplant receive fewer education sessions than those discharged later. With increased pressure to discharge patients earlier, the purpose of this study is to evaluate outcomes of KTR depending on the post-operative day (POD) of discharge.

**METHODS:** This single-center, retrospective study analyzed outcomes in 128 living donor KTR. Only KTR discharged POD 3-5 were included in this analysis. Demographics and background information were collected. Outcomes analyzed included biopsy proven acute rejection (BPAR), rehospitalizations, serum creatinine, and patient and graft survival.

**RESULTS:** Demographics and background information for KTR discharged on POD 3, 4 and 5 groups respectively included: mean age (years) 39.5, 48.6 and 52.6; Percent non-English speaking 25.8%, 17.5% and 22.5%; post-high school education 54.8%, 57.9% and 57.5%; and diabetes mellitus 9.7%, 21.1% and 35%. Serum creatinine (mg/dL) at 1, 3, 6 and 12 months were: 1.31, 1.29, 1.23 and 1.25 for POD 3; 1.35, 1.29, 1.23 and 1.21 for POD 4; and 1.27, 1.23, 1.15 and 1.14 for POD 5, respectively. Rehospitalization rates were 29%, 31.6% and 25% for POD 3, 4 and 5 respectively and BPAR rates were 3.2%, 8.8% and 2.5%. Overall, there was one death with graft function in the POD 3 group.

**CONCLUSION:** There was no difference in BPAR, rehospitalizations, patient or graft survival among KTR discharged on POD 3, 4 or 5. KTR discharged on POD 5 tended to be older and more had diabetes as their cause of kidney disease. Despite this, serum creatinine was numerically lower than KTR discharged earlier at all timepoints. In select patients, discharging KTR on POD 3 is feasible without an increase in post-transplant complications.

**195E. Single center experience with long-term prospective BK viremia monitoring in renal transplantation.** Jennifer Trofe-Clark, Pharm.D., BCPS<sup>1</sup>, Deirdre Sawinski, M.D.<sup>1</sup>, Tracy M. Sparkes, Pharm.D.<sup>2</sup>, Simin Goral, M.D.<sup>1</sup>, Melissa Bleicher, M.D.<sup>1</sup>, Roy D. Bloom, M.D.<sup>1</sup>; (1) Renal Electrolyte and Hypertension Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA (2) Department of Pharmacy, Hospital of the University of Pennsylvania, Philadelphia, PA

**PURPOSE:** Prospective screening for BK viremia (BKV) in renal transplant recipients (RTR) may detect early BKV and prevent BK nephropathy (BKVN). Utility of long term BKV screening is unknown. The purpose of this study was to determine the incidence and time to BKV with use of protocolized screening.

**METHODS:** In Jan 2008, we implemented quantitative BKV plasma screening for all RTR patients (pts) at 3, 6, 12 months (mos) then yearly. Detectable BKV was defined as  $\geq 2.6$  log copies/mL. Biopsies were performed for graft dysfunction and all BKVN episodes were biopsy-proven. RTR received induction with rabbit anti-thymocyte globulin (majority of pts), or basiliximab (low-immunologic risk pts) and maintenance w/tacrolimus (TAC), mycophenolate mofetil (MMF) and steroids. MMF was discontinued upon BKV detection, followed by TAC decrease if BKV persisted. Retrospective analysis was performed for any RTR transplanted Jan 2008-December 2011 who had  $\geq 1$  BKV load drawn per protocol until June 2012.

**RESULTS:** 622/691 (90%) pts had BKV protocol screening: (473 values at 3 months, 448 at 6 months, 394 at 12 months, 171 at 24 months, 92 at 36 months, 10 at 48 months). At least one detectable BKV occurred in 106 (17%) pts (Table). A pt with first BKV detected at 24 months had a negative screen at 12 months. Two pts first detected at 36 months had negative screens at 3 and 24 months respectively. BKVN occurred in 8 pts (1%).

Time of First BKV Detection at Protocol Time-Point (months)

3	51 (48%)
6	34 (32%)
12	18 (17%)
24	1 (0.9%)
36	2 (2%)
48	None

**CONCLUSION:** BKV was most often detected at 3 months screen and BKVN rates remained low. New onset BKV at  $\geq 24$  months was rare, questioning utility of screening beyond 12-24 months unless renal dysfunction is present.

Published in Trofe-Clark J, Sawinski D, Sparkes T, Goral S, Bleicher M, Bloom R. Single Center Experience with Long-Term Prospective BK Monitoring in Renal Transplantation. American Journal of Transplantation 2013; 13 (suppl 5): Abstract C1360 (page 432).

**196. Assessment of rabbit antithymocyte globulin dosing and clinical outcomes in kidney transplantation.** Heather Snyder, Pharm.D.<sup>1</sup>,

Amy Krauss, Pharm.D., BCPS<sup>2</sup>, Vinaya Rao, M.D.<sup>3</sup>, Dagny Ulrich, Ph.D.<sup>4</sup>, Benjamin Duhart, Jr., M.S., Pharm.D.<sup>1</sup>; (1) Department of Pharmacy, University of Tennessee Health Science Center/Methodist University Hospital, Memphis, TN (2) Department of Pharmacy, Methodist University Hospital, Memphis, TN (3) Department of Transplant Nephrology, University of Tennessee Health Science Center/Methodist University Hospital Transplant Institute, Memphis, TN (4) Department of Pharmacy, University of Tennessee Health Science Center, Memphis, TN

**PURPOSE:** Optimal dosing of rabbit antithymocyte globulin (rATG) remains undefined and varies between transplant centers. Previously the Methodist University Hospital Transplant Institute (MUHTI) based rATG dosing on kidney graft function (GF) following transplantation, but now utilizes risk stratification (RS) to guide dosing. The study aim was to evaluate outcomes of the RS dosing protocol in kidney transplant recipients as compared to the GF protocol.

**METHODS:** A retrospective chart review was done to identify adult patients who underwent single-organ kidney transplantation at the MUHTI and received rATG induction using the GF or RS protocol. The following 1 year outcomes were compared between groups: mean cumulative rATG induction dose, SCr and eGFR, patient and graft survival, episodes of biopsy-proven acute rejection, and infection with BK Polyoma virus and/or cytomegalovirus. Chi-square test was used to analyze categorical variables and student's t-test was used for continuous variables. A Kaplan-Meier analysis was used to compare patient and graft survival.

**RESULTS:** Of the 100 patients studied, 50 were dosed under the GF protocol and 50 were dosed using the RS protocol. The mean cumulative rATG dose in the GF group was  $7.4 \pm 2$  mg/kg compared to  $5.4 \pm 1$  mg/kg in the RS group ( $p < 0.05$ ). At 1 year renal function was significantly better in the RS group versus the GF group ( $p < 0.05$ ) and patient and graft survival were similar between groups ( $p > 0.05$ ). There was a higher incidence of acute rejection in the RS group (14%) versus the GF group (8%); however, this difference was not statistically significant. The incidence of infection with BK Polyoma virus and cytomegalovirus were similar between groups ( $p > 0.05$ ).

**CONCLUSION:** The RS dosing protocol for rATG improved renal outcomes without compromising patient or graft survival and led to a decrease in the mean cumulative rATG dose in kidney transplant recipients.

**197. Roe's solution for cold preservation of the harvested pediatric donor heart.** Astrelia Sison, Pharm.D.<sup>1</sup>, Marc Halushka, M.D.<sup>2</sup>,

Claude Beaty, M.D.<sup>2</sup>, Timothy George, M.D.<sup>2</sup>, Janet Scheel, M.D.<sup>3</sup>, Luca Vricella, M.D.<sup>2</sup>, Kenneth Shermock, Pharm.D., Ph.D.<sup>2</sup>, Leann McNamara, Pharm.D.<sup>2</sup>, Christopher R. Ensor, Pharm.D.<sup>4</sup>; (1) Childrens Hospital of Philadelphia (2) Johns Hopkins University (3) National Childrens Medical Center (4) Department of Pharmacy & Therapeutics, University of Pittsburgh Medical Center, Pittsburgh, PA

**PURPOSE:** Ischemic necrosis (IN) may be associated with primary graft dysfunction (PGD). Roe's solution (RS) is used for preservation at our pediatric heart transplant (HT) program but hasn't been evaluated in humans. We examined the effect of RS on outcomes in pediatric HT.

**METHODS:** A retrospective, single-center, cohort study of pediatric donor hearts preserved with RS was conducted. A single cardiovascular pathologist blinded for biopsy date reviewed all

biopsies (EMB) available at 2 and 4 weeks after HT and assigned IN grade on a 0–3 scale (none to severe). Primary outcomes included incidence and grade of IN. Secondary outcomes were comparison of IN grade, 1-year mortality, and PGD between RS, UW and Celsior (CS) in adults.

**RESULTS:** Fifty pediatric HT recipients preserved with RS had 77 EMB specimens available for scoring. 177 adults, 40 preserved with UW and 127 with CS were included. Over half of RS-preserved EMB had no evidence of IN at two and 4 weeks (IN grade 0, 60% & 56%); few had severe injury (IN grade 3, 6% & 4%). Median IN grade were 0 (IQR=0–1) at 2 and 4 weeks, and significantly less than UW (0.5, 1,  $p=0.04$ ) or CS (1.1,  $p<0.01$ ). Mean and maximum IN grade was significantly less with RS versus UW or CS ( $p<0.01$ ). Increasing IN grade (OR 1.54, 95%CI 1.04–2.15,  $p=0.03$ ) and CS use (OR 4.91, 95%CI 1.65–14.6,  $p<0.01$ ) were associated with PGD by univariate logistic regression. 1-year survival and PGD were not different between groups by multivariate Cox regression.

**CONCLUSION:** RS performs well for preservation of pediatric allografts and is associated with less IN compared to adult allografts preserved with UW or CS. This assessment is limited by differences in allograft age. We have confirmed the association between increasing IN grade and PGD found in our previous publication.

**198. Interferon-gamma gene polymorphism +874 A/T is associated with an increased risk of cytomegalovirus infection among Hispanic renal transplant recipients.** Don Vu, Pharm.D., Ph.D.<sup>1</sup>, Tariq Shah, M.D.<sup>2</sup>, Ian V. Hutchinson, Ph.D., DSc<sup>3</sup>, Robert Naraghi, M.D.<sup>2</sup>, David I. Min, Pharm.D.<sup>4</sup>; (1)National Institute of Transplantation and Western University of Health Sciences, Los Angeles, CA (2)National Institute of Transplantation and St. Vincent Medical Center, Los Angeles, CA (3)USC School of Pharmacy, Los Angeles, CA (4)College of Pharmacy and National Institute of Transplantation, Western University of Health Sciences, Los Angeles, CA

**PURPOSE:** Cytomegalovirus (CMV) infection is one of the most common viral infections among renal transplant recipients (RTR). Cytokines such as tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-10 (IL10), and interleukin-2 (IL2) have been shown to possess antiviral properties and their polymorphisms are associated with disease outcome. We assessed the impact of IL10, IL2, and TNF- $\alpha$  gene polymorphisms on the risk of CMV infection.

**METHODS:** IL10 -1082 A>G, -592 A>C; TNF- $\alpha$  -308 A>G; and IFN- $\gamma$  +874 A>T gene polymorphisms were studied in 247 RTRs (52 RTRs with CMV infection and 195 without CMV infection), using DNA-based polymerase chain reaction with sequence-specific primers and restriction.

**RESULTS:** Median time to CMV infection was 6 months with a mean peak CMV viral load of 7925 copies/mL. Patients with donor-positive/recipient-negative [D<sup>+</sup>/R<sup>-</sup>] serostatus were found to be associated with a high risk of CMV infection ( $p=0.001$ ). IFN- $\gamma$  +874 A allele was associated with susceptibility to CMV infection ( $p=0.007$ ). RTRs with IFN- $\gamma$  +874 AA genotype had a 3.4-folds increased risk of developing CMV infection (95% CI = 1.24–9.34,  $p=0.01$ ). Multifactorial Cox regression analysis demonstrated that the IFN- $\gamma$  +874 A allele was an independent risk factor for CMV infection (OR = 2.01,  $p=0.012$ ). The polymorphisms of TNF- $\alpha$  and IL-10 were not associated with CMV infection. Individuals with IFN- $\gamma$  +874 TT genotype exhibited higher risk of allograft loss.

**CONCLUSION:** IFN- $\gamma$  +874 A allele was shown to be a risk factor in CMV susceptibility, whereas the high producer IFN- $\gamma$ +874 TT genotype appears to be a marker for protection against CMV infection.

**199. Genetic variations in a Sestrin2/Sestrin3/mTOR axis and development of new-onset diabetes after transplantation in hispanic kidney transplant recipients.** Don Vu, Pharm.D., Ph.D.<sup>1</sup>, Robert Naraghi, M.D.<sup>2</sup>, Ian V. Hutchinson, Ph.D., DSc<sup>3</sup>, Tariq Shah, M.D.<sup>2</sup>, David I. Min, Pharm.D.<sup>4</sup>; (1)National Institute of Transplantation and Western University of Health Sciences, Los

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**PURPOSE:** Genetic variations in *Sestrin2/Sestrin3/mTOR* axis may cause obesity-associated metabolic syndrome, including lipid accumulation and insulin resistance, and then increase the individual's risk of diabetes. Accordingly, we explore the association between single nucleotide polymorphisms (SNPs) of these genes and new onset diabetes after transplantation in our Hispanic kidney transplant recipients.

**METHODS:** We genotyped 8 potential functional polymorphisms in *Sestrin2*, *Sestrin3* and *mTOR* genes using the Taqman method in a study of 129 Hispanic RTRs with no evidence of pre-existing diabetes who developed NODAT and 186 controls with no history of diabetes. The Cox proportional hazard model was used to examine risks for NODAT. Nongenetic and genetic characteristics were included in the multivariate risk model.

**RESULTS:** We observed significant associations between NODAT and mTOR rs2295080 (OR = 1.6, 95% CI = 1.03–2.49,  $p=0.03$ ), Sestrin2 rs580800 (OR = 0.58, 95% CI = 0.37–0.99,  $p=0.01$ ), and Sestrin3 rs684856 (OR = 0.52, 95% CI = 0.31–0.89,  $p=0.01$ ). There was an interaction between the mTOR rs2295080 and Sestrin3 rs684856 and risk of NODAT ( $p_{\text{interaction}}=0.046$ ). Of the nongenetic factors, use of tacrolimus, older age, and acute rejection were associated with increased risk for NODAT.

**CONCLUSION:** Polymorphism in the *Sestrin2/Sestrin3/mTOR* gene may confer certain protection or predisposition for NODAT.

**200. Relationship between interleukin-2 polymorphism and BK virus infection after kidney transplantation.** 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., DSc<sup>3</sup>, David I. Min, Pharm.D.<sup>4</sup>; (1)National Institute of Transplantation and Western University of Health Sciences, Los Angeles, CA (2)National Institute of Transplantation and St. Vincent Medical Center, Los Angeles, CA (3)USC School of Pharmacy, Los Angeles, CA (4)College of Pharmacy and National Institute of Transplantation, Western University of Health Sciences, Los Angeles, CA

**PURPOSE:** BK virus (BKV) can cause BKV nephropathy, that affects up to 10% of renal transplant recipients (RTRs), causing allograft dysfunction and graft loss. Cytokines such as tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-10 (IL10), and interleukin-2 (IL2) have been shown to possess antiviral properties and their polymorphisms are associated with disease outcome. We assessed the impact of IL10, IL2, and TNF- $\alpha$  gene polymorphisms on the risk of BKV infection.

**METHODS:** IL2-330 G>T; IL10 -1082 A>G; and TNF- $\alpha$  -308 A>G gene polymorphisms were studied in 233 RTRs (58 RTRs with BKV and 175 without BKV), using DNA-based polymerase chain reaction with sequence-specific primers and restriction. We then examined the functionality of these promoter genetic variants by luciferase assay and EMSA.

**RESULTS:** IL2-330 TT was associated with an increased risk of BKV infection (OR = 2.9, 95% CI = 1.2–6.5,  $p=0.01$ ) while IL2-330 GG genotype was associated with a reduced risk of BKV infection (OR = 0.34, 95% CI = 0.13–0.87,  $p=0.01$ ). In luciferase reporter assay, IL2-330 G allele tended to enhance the transcriptional activity of IL2 with an approximate 0.6-fold over T allele. Furthermore, EMSA tests showed that stimulated peripheral blood mononuclear cells (PBMCs) in culture with peptide pools encompassing BKV led to a significant increase in IL2 response. There was no significant association between the allelic as well as genotypic frequencies of IL10 -1082 A>G and TNF- $\alpha$  -308 A>G gene polymorphisms with BKV infection.

**CONCLUSIONS:** These results suggested that IL2 -330 TT/T was associated with an increased risk, but IL-330 GG/G was associated with reduced risk of BKV infection. This SNP, which effectively influenced the expression of IL2, may be a new biomarker of early diagnosis of BKV infection.

### 201. Analysis of risk factors affecting medication knowledge after transplantation.

Chelsea Sammons, Pharm.D., Christina T. Doligalski, Pharm.D., BCPS; Tampa General Hospital, Tampa, FL

**PURPOSE:** Medication knowledge following transplantation is vital to successful outcomes. Objectives of this study were to determine if certain characteristics affect medication knowledge, and if knowledge correlates with outcomes.

**METHODS:** This single-center, retrospective study used a 20-question assessment tool evaluating medication knowledge and level of comfort following transplantation to analyze demographics associated with lower scores and 60-day readmission rates.

**RESULTS:** From 10/2012 to 4/2013, 117 transplant recipients proceeded to discharge; 50.4% were renal, with 24.5% cardiothoracic and 19% liver. Most were male (64.1%) and Caucasian (72.6%) (avg. age = 54). Lung and kidney-pancreas recipients, African-Americans, Hispanics, and patients without a high school degree had lower assessment tool scores; increased length of stay and need for ICU care also negatively affected medication knowledge. However, low scores were not associated with higher 30- and 60-day readmission rates. Increased perceived medication knowledge was associated with higher scores. Questions evaluating side effects were most commonly missed; those evaluating drug interactions and administration were consistently answered correctly.

**CONCLUSION:** Several patient factors were associated with lower than average assessment tool scores, highlighting populations which may require additional, or individualization of, transplant medication education. Perception of knowledge correlating with higher scores demonstrates patient awareness of their learning. A larger population is likely needed to determine the impact of lower assessment tool scores on clinical outcomes.

## Women's Health

### 202. Rates of post-partum screening for diabetes in patients with gestational diabetes.

Arezo Noormohammadi, Pharm.D., Alicia B. Forinash, Pharm.D., BCPS, BCACP, Abigail M. Yancey, Pharm.D., BCPS; St. Louis College of Pharmacy, Saint Louis, MO

**PURPOSE:** Determine the frequency of post-partum (PP) diabetes screening in women with gestational diabetes (GDM) at the Maternal Fetal Care Center (MFCC) or referring obstetrician's office.

**METHODS:** Retrospective data collection was performed through a 2 year retrospective chart review of patients with GDM utilizing ICD-9 codes. Demographic and clinical data/information were collected. The primary outcome was proportion of completed 75 g, 2-hour oral glucose tolerance test (OGTT) 6–12 weeks PP. Secondary outcomes included proportions of other diabetes screening tests ordered, tests performed outside 6–12 weeks post-partum, completed diabetes tests, PP diabetes diagnosis, and PP glucose intolerance diagnosis. If PP diabetes screen was not done at MFCC, outside providers (if available) were contacted to obtain the needed information. Demographic and obstetric parameters were evaluated to identify potential differences between completers and non-completers.

**RESULTS:** Of the 107 patients eligible for the study, 75 (70.09%) had a PP diabetes screening test ordered. No difference in baseline characteristics was seen between completers and non-completers or between those who had a test ordered and those who did not. Diagnosis of diabetes (3.13%) and impaired glucose tolerance (18.75%) was low.

Test	Ordered n	Ordered	Completed n (%)
		6–12 weeks PP n (%)	
75 g OGTT	64	56 (52.34%)	32 (29.91%)
A1c	3	1 (0.93%)	1 (0.93%)
2 hours post prandial	7	7 (6.54%)	6 (5.61%)
Random plasma glucose	1	1 (0.93%)	1 (0.93%)

**CONCLUSIONS:** Although ordering of PP screening for diabetes was high, with the majority of physicians appropriately ordering the 2 hours OGTT, a low percentage of patients actu-

ally completed the test (30%). There appeared to be no difference in baseline demographics between those that completed the screening and those that did not. Further studies evaluating potential barriers to completing PP diabetes screening are needed.

## CLINICAL PHARMACY FORUM

### ADR/Drug Interactions

### 203E. Identifying high risk patients for pain management strategies aimed at reducing postsurgical opioid-related adverse events.

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**PURPOSE:** This study's goals were to identify ORADE risk factors, derive a risk score to identify high-risk patients, and evaluate the potential benefits to patients and hospital systems of targeting high-risk patients for alternative pain management strategies aimed at reducing ORADE risk.

**METHODS:** This retrospective study utilized data on inpatient surgeries within the Memorial Hermann Hospital System. Patients ≥ 18 years who received opioids following gastro-intestinal (GI) or orthopedic surgeries between 01/01/2010 and 12/31/2010 were included. Logistic regression was used to identify ORADE risk factors and to develop gender, procedure, and gender by procedure specific risk scores. Receiver-operating characteristics analysis was used to identify the risk score model that most accurately predicted ORADEs. The threshold score for differentiating high and low-risk patients was the score with the highest sum of sensitivity and specificity.

**RESULTS:** 4888 patients (mean age: 54.0 years; 64.5% female) were included: Overall, 551 (11.3%) patients experienced ORADEs: GI ORADEs were most common (7.1%), followed by respiratory (3.6%) and genitourinary (1.7%) ORADEs. The best risk score model, a composite of gender by procedure specific models, had an AUC of 0.726. 22% of high-risk patients experienced ORADEs versus 6.9% of low-risk patients. High-risk patients had longer LOS (mean=7.2 days versus 4.1 days for low-risk patients, p<0.0001) a higher 30-day readmission rate (12.3% versus 9.1%, p=0.0006), and greater hospitalization costs (mean=\$21,292 versus \$14,849, p<0.0001). Based on these results, alternative pain management strategies intended to prevent ORADEs among high-risk patients have the potential to reduce LOS by 74–294 days per 1,000 surgical patients, assuming a decrease in ORADE incidence ranging from 25% to 100%, with accompanying cost savings of \$255,811–\$1,023,243.

**CONCLUSION:** Opioids and their related adverse events threaten patient safety, lead to prolonged hospital stays, and increase economic burden. Targeting high-risk patients for non-opioid pain management strategies, including locally acting, non-systemic medications and surgical interventions, may reduce opioid requirements. Presented at the National Patient Safety Foundation Patient Safety Congress, New Orleans, LA May 8–10, 2013.

## Adult Medicine

### 204. Taking control of controlled substance prescribing in an academic family practice center.

Cari Brackett, BS, Pharm.D.<sup>1</sup>, Becky Wilkins, BS<sup>2</sup>, Nicholas Kahl, RN, MSN<sup>3</sup>, William Buoni, M.D.<sup>2</sup>; (1) Division of Pharmacy Practice and Administration, Ohio State University College of Pharmacy, Columbus, OH (2) The Ohio State University Wexner Medical Center, Columbus, OH (3) Rardin Family Practice Center, The Ohio State University Wexner Medical Center, Columbus, OH

**PURPOSE:** To describe the 3-year process of refining controlled substance prescribing in a large academic family practice.



**METHODS:** Over a 3 years period, an academic family practice center developed and implemented a system of controlled substance use contracts, toxicology screening, and cross-verification with the Ohio OARRS database that revolutionized prescribing habits. The process and outcomes will be described in detail in order that other practices might transfer it to their own centers.

**RESULTS:** Systematic toxicology screening yielded results that were very unexpected and that clearly demonstrated the unreliability of long-term impressions. Controlled substance prescribing for chronic conditions diminished markedly. Strict compliance with patient controlled substance contracts gives prescribers confidence and minimizes negotiations with patients in the face of questionable behavior. Chronic pain patients who did not meet the new criteria have been referred to pain management centers or have left the practice. Prescribers express diminished anxiety about working with chronic controlled substance patients in the practice.

**CONCLUSION:** Development and implementation of controlled substance patient contracts, toxicology screening, database cross-checking, and referral to specialized pain clinics has dramatically altered prescribing habits and patient behavior. In light of nationwide escalation of controlled substance diversion and misuse, these efforts contribute to the health of practitioners and patients alike.

#### 205. Medication management to improve post acute care transfer.

*Erin Neal, Pharm.D., BCPS, Amy Myers, Pharm.D., BCPS, Patricia B. Miller, Pharm.D.; Vanderbilt University Medical Center, Nashville, TN*

**PURPOSE:** Patients discharged from Vanderbilt University Hospital (VUH) to post-acute care (PAC) facilities typically have multiple co-morbidities, are older, and experience 30-day re-hospitalization rates up to 25%. Improve post acute care transfer (IMPACT) aims to improve outcomes and quality of care across acute and PAC facilities. Pharmacists are creating medication management plans as part of the IMPACT transition bundle.

**METHODS:** Pharmacists create medication management plans for all Medicare patients discharged from VUH to partner skilled nursing facilities (SNF). The medication management plan includes the pre-hospital medication list, changes made to the regimen with rationale, and monitoring recommendations. Pharmacists review the regimen for appropriateness and recommend discontinuation of potentially inappropriate medications or initiation of additional therapy according to evidence-based guidelines and core measures. Pharmacists also provide a prospective monitoring plan particularly for high-risk medications such as diuretics, insulin, and anticoagulation. Pharmacists ensure that there are stop dates for short courses of therapy like antibiotics, thromboembolism prophylaxis, and post-surgical pain medications. The medication management plan is a component of a standardized discharge bundle compiled by nurse transition advocates and sent with the patient to the SNF. Nurse transition advocates also attempt to provide a "warm hand-off" and verbally highlight any important medications issues to a SNF representative.

**RESULTS:** Three pharmacists have provided this service for all Medicare patients discharged to partner SNFs since April 2013. Medication management plans have been completed for over 100 patients. The SNF reports that the medication management plans have helped them scrutinize multiple contradictory medication lists, and highlight important clinical issues.

**CONCLUSION:** This project highlights pharmacists' role in improving care transitions. Data is being collected to demonstrate pharmacists' impact on transitions of care to post acute care facilities.

#### 206. Reduction in missed doses of warfarin through use of an order reminder in the EPIC electronic medical record. *Maura Wychowski, Pharm.D., BCPS; Department of Pharmacy, Rochester General Hospital, Rochester, NY*

**PURPOSE:** Evaluate the implementation of a warfarin order reminder in the medication administration record (MAR) of the electronic medical record (EMR) on inpatient warfarin management specifically related to consistency of dosing.

**METHODS:** This retrospective study quantified the number of unintentional missed warfarin doses before and after the implementation of a warfarin order reminder in the MAR. Data was collected at baseline and quarterly for three data points. Information collected from the medical record included length of stay, total number of days of warfarin therapy, and number of unintentional missed doses. Held warfarin doses were excluded if specifically intended by the provider (e.g., procedure, bleeding, or supratherapeutic INR [international normalized ratio]).

**RESULTS:** A total of 400 patients were reviewed for consistent warfarin dosing during their inpatient stay. The number of warfarin doses/1000 patient days was significantly higher in the three quarters post implementation when compared to baseline ( $762 \pm 229$ ,  $855 \pm 247$ ,  $970 \pm 261$ , and  $1020 \pm 323$ ;  $p < 0.01$ ). At baseline, 26% of patients had 1 or more missed doses (one missed dose, 16%; two missed doses, 7%; three missed doses, 3%). After implementation, unintentional missed warfarin doses were reduced to one missed dose in 2% of patients ( $p < 0.0001$ ). This was maintained in the second and third quarter at 2% and 0%, respectively.

**CONCLUSION:** The addition of a warfarin order reminder in the MAR to prompt providers to order warfarin each day has significantly decreased the number of unintentional missed doses and optimized anticoagulation therapy in the EMR.

### Ambulatory Care

#### 207. Factors influencing enrollment in the Medication Therapy Management Clinic (MTMC) at an academic ambulatory care clinic. *Mansi Shah, Pharm.D., BCACP<sup>1</sup>, Jessica Tilton, Pharm.D., BCACP<sup>2</sup>, Shiyun Kim, Pharm.D., CDE<sup>2</sup>; (1) Pharmacy Practice, University of Illinois at Chicago, Chicago, IL (2) University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** In 2001, the University of Illinois Hospital and Health Sciences System (UI Health) established a pharmacist-run, referral based MTMC. Referrals are obtained from any UI Health provider or by self referral. Although there is a high volume of referrals, a large percentage of patients do not enroll. This study was designed to determine the various factors that influence patient enrollment in MTMC.

**METHODS:** This study was a retrospective chart review of demographic and patient variable data during years 2010 and 2011. Disabilities, distance from MTMC, mode of transportation, past medical history, and appointment dates were extracted from the medical records. Data was analyzed using descriptive statistics and logistic regression analysis.

**RESULTS:** A total of 103 referrals were made; however, only 17% of patients remain enrolled in MTMC. The baseline demographics included a mean age of 63 years, 68% female, 70% African American, and 81% English speaking. Patients lived an average of eight miles from MTMC; most utilized public or government supplemented transport services. 24% of patients reported some type of disability; most commonly utilizing a walker or wheelchair. On average, patients were prescribed 13 medications with hypertension (70%), diabetes (56%), and hyperlipidemia (48%) being the most common chronic disease states. The reason for referral included medication management, education, medication reconciliation, and disease state management. Five patients were unable to be contacted to schedule an initial appointment. Additionally, 18 patients failed their scheduled initial appointment. Logistic regression analysis demonstrated distance traveled for clinic visit, age, and history of hypertension affected the probability of patients showing for their appointments ( $\chi^2 = 19.7$ ,  $p < 0.001$ ).

**CONCLUSION:** This study demonstrated that distance from MTMC is the most common barrier in patient enrollment; therefore, strategies to improve patient access are necessary.

#### 208. Promoting Safe use of medications: providing medication education to seniors receiving Meals on Wheels. *Kristina Ward, BS, PharmD, BCPS, Lisa Cohen, PharmD, CDE; Department of Pharmacy Practice, University of Rhode Island College of Pharmacy, Kingston, RI*

**PURPOSE:** Meals on Wheels (MOW) services seniors and those with disabilities, populations at high-risk for preventable harm from medications, allowing them to remain independent. Collaboration with MOW may help pharmacists position themselves to enhance patient education and reduce medication misadventures. We hypothesized that pharmacist provided medication education and counseling to MOW participants decreases medication-related preventable harm.

**METHODS:** At baseline and 6-months, participants were instructed to bring all their medications and complementary products. Questionnaires regarding health conditions, medication-taking practices, and quality-of-life were administered at each visit. Medications and dietary supplements were reviewed with each participant; pill counts were completed for all chronic medications. Morisky scale was used to estimate medication adherence; use of Beer's List medications, drug-drug interactions, and drug-supplement interactions were assessed to indicate the presence of preventable harm.

**RESULTS:** Twenty-eight subjects consented and 26 completed the initial visit; 20 subjects completed the study in its entirety. No statistically significant differences were found for mean occurrence of drug-drug interactions (baseline  $0.52 \pm 0.92$  vs.  $0.13 \pm 0.24$  at 6 months), drug-supplement interactions (baseline  $0.16 \pm 0.37$  vs. none reported at 6 months), or preventable harm (baseline  $0.40 \pm 0.71$  vs.  $0.44 \pm 0.73$  at 6-months). Mean number of Beer's list medications was  $0.48 \pm 0.77$  at baseline vs.  $0.31 \pm 0.60$  at 6 months. Medication adherence rates increased from  $71.4 \pm 42.5\%$  at baseline to  $94.3 \pm 161\%$  at 6 months ( $p=0.52$ ). Morisky scale decreased from  $0.95 \pm 0.83$  at baseline to  $0.75 \pm 0.91$  at 6 months ( $p=0.26$ ). At the initial visit 85% of MOW subjects agreed or strongly agreed that they trusted a pharmacist and at the 6-month visit, 93% of subjects trusted a pharmacist.

**CONCLUSION:** Although not statistically significant, pharmacist intervention with MOW participants appeared to improve medication adherence rates but had limited effect on medication-related preventable harm; larger studies are needed to confirm these findings.

**209. Evaluation of a pharmacist's impact in a university-based wellness clinic: a pilot study.** Angela H. Pegram, PharmD, BCPS, CDE, Sabrina W. Cole, PharmD, BCPS; Wingate University School of Pharmacy, Wingate, NC

**PURPOSE:** To combat the rising cost of health care, Wingate University established a mandatory Wellness program administered by a pharmacy faculty member to encourage yearly health maintenance and medication compliance among its self-insured subscribers. The purpose is to evaluate the impact of the annual intervention and counseling by a pharmacist in the Wellness Clinic.

**METHODS:** A retrospective chart review was conducted to identify all participants with chronic diseases who participated in the Wellness program during the 2009–2010 academic year and completed a follow-up screening appointment in 2011. Prescription-refill data were obtained from the University pharmacy benefits plan to calculate the medication possession ratio (MPR), giving a percentage of adherence with prescribed medication therapy from the baseline to follow-up visits. Patients with an 80% MPR were deemed compliant with therapy. Changes in blood pressure, composite lipid panel, body mass index, blood glucose concentrations, medical costs, prescription costs, and total health care costs were also evaluated.

**RESULTS:** Of the 91 patients included in the study, 51% ( $n=46$ ) were at least 80% compliant with their medication therapy for chronic diseases assessed at the follow-up visit. Gender and number of prescribed medications were not associated with differences in adherence ( $p=0.17$  and  $0.34$ , respectively). No significant differences were seen in blood pressure, lipid panel, body mass index, or blood glucose. At the follow-up visit, 53% ( $n=48$ ) of patients had a decrease in overall healthcare costs.

**CONCLUSION:** The impact of clinical pharmacists in the ambulatory care setting has been well documented. This pilot study supports that intervention and counseling by a pharmacist as a

component of a Wellness program improves medication adherence in chronic diseases and decreases overall healthcare costs for the University.

**210. Implementing clinical pharmacy services within a multidisciplinary bariatric surgery team.** Taya M. Staples, Pharm.D., BCPS, Sara Griesbach, Pharm.D., BCPS, BCACP; Marshfield Clinic, Marshfield, WI

**PURPOSE:** Patients undergoing bariatric surgery frequently require drug therapy adjustments due to changes in the anatomy and physiology of their gastrointestinal tract postoperatively. Utilizing a pharmacist to assess drug therapy, identify potential drug therapy opportunities, and communicate recommendations to primary care providers can improve patient care and decrease the potential for medication errors throughout the bariatric surgery process.

**METHODS:** Marshfield Clinic Bariatric Services offers a multidisciplinary approach to surgical weight loss and recognized the need to incorporate a clinical pharmacist. The primary responsibility of the clinical pharmacist is to provide comprehensive medication review pre-operatively for select bariatric patients [e.g., complex medication histories, taking multiple extended-release formulations, and/or taking other drugs which should be avoided post-bariatric surgery (e.g., NSAIDs)] and document findings in the electronic medical record. A medication compendium was developed to record detailed pharmacokinetic information relating to drugs commonly prescribed in the bariatric patient population.

**RESULTS:** From February 2011 to June 2013, 117 patients were referred to the clinical pharmacist pre-operatively. The mean number of pharmacist recommendations was 3.6 per patient. The most common interventions identified by clinical pharmacist included change in dosage form, drug/disease interaction, and provider education. Recommendations for medication changes were communicated with the bariatric team and entered into the patient's electronic medical record prior to surgery. Medical record notes are viewable by the bariatric team and other healthcare providers. The newly developed medication compendium contains 260 entries.

**CONCLUSION:** Utilizing a pharmacist to help manage bariatric surgery patients' medications helps to ensure medications are utilized appropriately after bariatric surgery to optimize efficacy and promote safety. Pharmacists can apply clinical knowledge and pharmacokinetic parameters to identify if drug absorption may be altered post-surgery.

**211. Highlighting the work of the ACCP ambulatory care PRN in 2012–2013.** Catherine A. Bourg, PharmD, BCPS, BCACP<sup>1</sup>, Stefanie Nigro, PharmD, BCACP, BC-ADM<sup>2</sup>, Marissa E. Quinones, PharmD, CDE<sup>3</sup>, Maria M. Thurston, PharmD, BCPS<sup>4</sup>, Emily McCoy Armstrong, PharmD, BCACP<sup>5</sup>, Brian K. Irons, PharmD, FCCP, BCACP, BCPS, BC-ADM<sup>6</sup>; (1) University of Georgia College of Pharmacy, Athens, GA (2) University of Connecticut – School of Pharmacy, Storrs, CT (3) Parkland, Dallas, TX (4) Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, GA (5) Auburn University Harrison School of Pharmacy Mobile Campus, Mobile, AL (6) TTUHSC School of Pharmacy, Lubbock, TX

**PURPOSE:** To highlight the Ambulatory Care PRN of ACCP  
**METHODS:** The Ambulatory Care PRN has over 1350 members that practice in a variety of ambulatory care settings. Our PRN provides support to its members through professional development, research/scholarship, networking opportunities, and service on various committees.

**RESULTS:** The Education Committee has been busy developing two focus sessions for the upcoming Annual Meeting in Albuquerque, New Mexico: one in collaboration with the Pain & Palliative Care PRN and another focusing on the Patient-Centered Medical Home. Also in development is a webinar for student and resident PRN members. The Research & Scholarship Committee provides scholarships to the ACCP Focused Investigator Training (FIT) Program, grant opportunities, and coordinates Walk Rounds for

the Annual Meeting poster session. They are also working on developing a strategy to create Virtual Walk Rounds for the ACCP Virtual Poster Symposium. The PRN Executive Committee has been working on the new Innovation Grant, which will be available for the Fall to support professional ventures to expand and improve pharmacy practice, not directly related to research activities. The Newsletter Committee recently published their 2013 newsletter and provided updates to its members on topics ranging from innovative pharmacy practice models to new drugs. The PRN also highlighted one of our members, Melissa Lipari, PharmD, BCACP, for her contributions to the pharmacy profession and the PRN. The Communication Committee continues to work on monitoring the list serve and gathering information for the poster session.

**CONCLUSION:** The Ambulatory Care PRN continues to seek opportunities for growth in the number and quality of our members. There are multiple ways to become and remain involved in your PRN.

**212. Evaluating a pharmacist-managed 24-hour ambulatory blood pressure monitoring service in the primary care setting.** Kristina Susic, Doctor of Pharmacy<sup>1</sup>, Peter Koval, Doctor of Pharmacy<sup>2</sup>; (1) Family Medicine, Moses H. Cone Hospital, Greensboro, NC (2) Family Medicine, Moses Cone Family Medicine, Greensboro, NC

**PURPOSE:** Hypertension is a major risk factor for heart disease, stroke, congestive heart failure, and kidney disease. While many therapeutic agents are available for the treatment of hypertension, many patients fail to reach adequate blood pressure control despite being adherent to prescribed medications. While various hypertension guidelines acknowledge potential benefits of 24-hour ambulatory blood pressure monitoring, widespread use of monitoring is still limited.

**METHODS:** A pharmacist-managed 24-hour ambulatory blood pressure monitoring program was implemented using the *SunTech Oscar2* monitor and accompanying *AccuWinPro* software. Eligible patients were referred by their primary care provider, were  $\geq 18$  years old with uncontrolled hypertension based on  $\geq 2$  office readings, were adherent to pharmacologic therapy ( $\geq 2$  medications) at therapeutic doses for  $\geq 4$  weeks. Review of current and past anti-hypertensive use, medication adherence, and procedure for wearing the monitor were discussed with patients. Patients wore the monitor for 24 hours, after which the blood pressure data was analyzed. Interventions were made as appropriate per protocol, including adding additional medications, changing administration times, titrating doses, or simplifying regimens using combination products.

**RESULTS:** Based on the 24-hour blood pressure data, nine patients (64%) were found to have uncontrolled hypertension, three (21%) of which had an abnormal or blunted diurnal pattern. Five patients (36%) had blood pressures averages at goal, suggesting a component of white coat hypertension. Of those nine patients with inadequate blood pressure control, seven achieved blood pressure goal after pharmacist intervention, two remained above goal.

**CONCLUSION:** Pharmacist managed 24-hour ambulatory blood pressure monitoring provides physicians with a service that aids patients in achieving better blood pressure control.

**213. Upper extremity deep vein thrombosis (UEDVT) in a sickle cell subset population: a retrospective cohort evaluation at a university teaching hospital antithrombosis clinic.** Rebecca H. Stone, PharmD, Adam P. Bress, Pharm.D., Edith A. Nutescu, PharmD, Nancy L. Shapiro, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** To compare risk factors and treatment strategies in UEDVT patients with and without sickle cell disease.

**METHODS:** Retrospective cohort evaluation of confirmed UEDVT patients managed at the University of Illinois at Chicago (UIC) Antithrombosis Clinic between January 1, 1996 and October 1, 2011. Patients were identified via chart screening or ICD9 code for UEDVT (451.89, 453.82) in the electronic medical record. Primary outcomes collected were VTE risk factors and

treatment strategies. A standardized data collection sheet was utilized and descriptive statistics were performed with SAS software.

**RESULTS:** A total of 229 patients were included, 163 (71.1%) were African American, and 24 (10.5%) had sickle cell disease. Sickle cell patients were younger than controls, 34 vs. 51 years ( $p < 0.0001$ ). Fewer sickle cell patients were diagnosed with malignancy, 13% vs. 33% ( $p = 0.04$ ). The most common risk factor for all UEDVT patients was central venous catheter use (78%), followed by age greater than 40 (74%), and immobility in last 30 days (51%). Of sickle cell patients, 75% had a CVC versus 54% ( $p = 0.046$ ), 63% received DVT prophylaxis vs. 32% ( $p = 0.0032$ ), and 79% received LMWH for acute treatment of UEDVT vs. 37% ( $p < 0.001$ ). Sickle cell patients had a lower percent of INRs in therapeutic range, 25% vs. 37.5% ( $p = 0.006$ ), and more were lost to follow up, 67% vs. 45% ( $p = 0.05$ ). Recurrent VTE occurred more often in sickle cell patients, 42% vs 19% ( $p = 0.01$ ). During acute and long term treatment, there was no significant difference in any or major bleeding.

**CONCLUSION:** Patients with UEDVT and sickle cell disease had differences in baseline characteristics and increased CVC use, while other major VTE risk factors did not appear to differ. Sickle cell patients more frequently received prophylaxis and LMWH for acute treatment, had a lower percent of therapeutic INRs, and a higher frequency of recurrent VTE.

**214. Pharmacist integration in pre-visit planning in the medical home.** Megan Mormann, Pharm.D<sup>1</sup>, James D. Hoehns, Pharm.D.BCPS, FCCP<sup>2</sup>; (1) Northeast Iowa Family Practice Center & Waverly Health Center, Waterloo, IA (2) University of Iowa College of Pharmacy and Northeast Iowa Family Practice Center, Waterloo, IA

**PURPOSE:** The patient centered medical home (PCMH) model provides new opportunities for pharmacist involvement in patient care. A key aspect of the PCMH is to optimize medication use. Although some pharmacists participate in patient care at medical homes, such practices are not widespread, and there is much interest in developing new pharmacist care models in ambulatory care. The objective of the study was to evaluate a new model of pharmacist care in the PCMH at Northeast Iowa Family Practice Center (NEIFPC).

**METHODS:** Pharmacy staff prospectively reviewed electronic patient medical records the day prior to their physician appointment. Pharmacists identified potential drug related problems and recorded them in the chart to be printed on the pre-visit huddle form. Pharmacists then attended the pre-visit patient care huddles to provide further clarification on recommendations.

**RESULTS:** Overall, 431 patient charts were reviewed prior to their physician appointments. Chart reviews were conducted in  $\leq 5$  minutes for 64% of patients. Drug therapy problems were frequently identified, occurring in 60% of chart reviews. The most common drug therapy problems identified pertained to laboratory monitoring and a need for additional drug therapy. Although there was only partial capture of physician acceptance rates of pharmacist recommendations, acceptance rates were similar between pharmacists (61%) and students (58%).

**CONCLUSION:** Prospective pharmacist review of a patient's medical record is seldom done in ambulatory physician clinics. We developed a method to facilitate pharmacist documentation of potential drug therapy problems and recommendations within an existing electronic medical record and incorporated them as part of the pre-visit "team huddle". Most reviews were performed in  $\leq 5$  minutes per patient. This suggests a feasible process whereby a small number of pharmacists could provide this service to a busy physician practice. We believe this is a pharmacist care model which could readily be adapted to other medical homes.

**215E. Management of medication-related problems at transitions of care by medical home pharmacists for a safety net population.** Grace Kim, PharmD, Mimi Lou, MS, Steven Chen, PharmD, FASHP, FCSHP; School of Pharmacy, University of Southern California, Los Angeles, CA



**PURPOSE:** The post-discharge period is a vulnerable time for patients, and medication-related problems (MRPs) often contribute to readmissions. We identified post-discharge MRPs among patients within a large urban safety net health organization and explored the impact of medical home pharmacists on reducing MRPs and readmission risk.

**METHODS:** We completed a retrospective chart review for 111 patients to identify post-discharge MRPs and performed a multivariate logistic regression to identify risk factors for 90-day readmission. We also developed two processes to integrate pharmacists into post-discharge care provided at five safety net medical homes.

**RESULTS:** The retrospective review identified that most patients' discharge medication lists contained at least one MRP. Most patients who had a single hospital admission during the 12-month evaluation period received outpatient post-discharge follow-up, compared to fewer than half the patients with multiple admissions. Having a greater number of MRPs (OR 1.563, 95% CI 1.048–2.330, p-value 0.0284) and not receiving outpatient post-discharge care (OR 0.130, 95% CI 0.041–0.415, p-value 0.0006) were highly associated with 90-day readmission. We also established two processes to refer post-discharge patients to an appointment with a medical home pharmacist for timely medication reconciliation and counseling, one of which is generalized to all sites while the other is a multidisciplinary process specific to a single clinic.

**CONCLUSION:** This study addresses current gaps in post-discharge care and evaluates the impact of medical home pharmacists on improving care transitions for safety net patients. Our findings are consistent with those of previous studies: post-discharge MRPs are common and associated with readmissions, post-discharge follow-up is associated with reduced early readmissions, and pharmacists are able to identify and resolve MRPs for post-discharge patients.

Presented at Western States Conference, San Diego, CA, May 14, 2013.

**216. Implementation of a clinical pharmacist-directed hospital discharge service to improve transitions in care.** Anita Sharma, Pharm.D., Chrystian R.Pereira, Pharm.D.; University of Minnesota College of Pharmacy, Minneapolis, MN

**PURPOSE:** Establishing a systematic approach for clinical pharmacists to manage hospital discharge patients in the ambulatory care setting. Clinical pharmacy services worked collaboratively with members of the primary care team to identify, prevent, and resolve drug therapy problems in post hospitalized patients.

**METHODS:** All patients discharged from a hospital between January 2013 and May 2013 were offered a clinical pharmacist visit before their follow up visit with their medical provider. The clinic's call center or Care Coordinators would follow a script and process to sign patients up over the phone. During each visit, a clinical pharmacist reviewed the patient's medications and then identified/resolved drug therapy problems, which were categorized into four groups: indication, effectiveness, safety, and convenience.

**RESULTS:** A total of 50 hospital discharge patients were scheduled and seen by a clinical pharmacist in the five month period. Twenty-three patients were scheduled as a follow up from the emergency room, while 27 patients were seen after being discharged from the hospital. A total of 81 drug therapy problems were identified by the clinical pharmacists. Eighty two percent of patients presented with one or more drug therapy problems. There were nine patients who did not have any drug therapy problems, many of which were ED discharges. The leading three drug therapy problems were "untreated condition," "does not understand instructions," and "needs additional monitoring."

**CONCLUSION:** Implementing a systematic clinical pharmacist intervention for post hospital discharge patients resulted in the identification of various drug therapy problems and worked towards improving overall patient care.

**217. Outcomes of ambulatory medication reconciliation in a geriatric patient-centered medical home.** Victoria Liu, Pharm.D.<sup>1</sup>, Bibban Bant Deol, M.D.<sup>2</sup>, Ann Balarezo, CNP<sup>3</sup>, David Trupiano,

Pharm.D.<sup>1</sup>, Candice L. Garwood, PharmD<sup>4</sup>; (1) Department of Pharmacy Services, Detroit Medical Center Harper University Hospital, Detroit, MI (2) Department of Internal Medicine/Geriatrics, Wayne State University School of Medicine, Detroit (3) Rosa Parks Wellness Institute for Senior Health, Detroit Medical Center Geriatric Center of Excellence, Detroit, MI (4) Department of Pharmacy Practice, Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI

**PURPOSE:** Medication reconciliation is important at transitions of care because lapses in safety and quality can lead to poor health outcomes, adverse events, and medication errors. The Rosa Parks Wellness Institute for Senior Health (RP-WISH) is a designated Patient-Centered Medical Home (PCMH) where the pharmacy team conducts post-discharge medication reconciliation to optimize transitions of care, ensure accurate medication profiles, and improve health outcomes. The purpose of this study is to describe pharmacist interventions and evaluate healthcare outcomes in outpatients receiving post hospital discharge telephone medication reconciliation.

**METHODS:** We assessed completed medication reconciliation follow up phone calls after discharge conducted by a member of the pharmacy team. Thirty day re-hospitalization and hospital utilization rates were compared with those who did not receive a phone follow up. Medication related problems (MRPs) identified during reconciliation were quantified, classified, and assigned a severity rating. Additionally, the interventions made during the phone call were recorded and categorized.

**RESULTS:** A total of 288 MRPs were identified for the 93 completed medication reconciliation phone calls and 83% of calls identified  $\geq 1$  MRP. The most common types of MRP were a documentation discrepancy (58%) and nonadherence (18.1%). Five percent were classified as medication errors and 10% were severity rating (ii). Approximately six percent required immediate medication change. Patients receiving a reconciliation call had lower 30 day readmission rates (8.9% vs. 13.8%; p=0.03) and lower 30 day hospital utilization rates (31.5% vs. 43.1%; p=0.05). Patient's without reconciliation calls were more likely to be readmitted (OR=2.26, CI=1.12–4.57) and for hospital utilization (OR=1.66, CI=1.02–2.70) within 30 days post index discharge.

**CONCLUSION:** We found that a pharmacist-run post-discharge medication reconciliation call program plays a role in patient safety and reducing hospital readmissions and utilization.

**218. The impact of pharmacist-physician collaborative diabetes care in a medically underserved population.** Jennifer L. Rosselli, Pharm.D.<sup>1</sup>, Christina Ley, Pharm.D., J. Christopher Lynch, Pharm.D.<sup>1</sup>; (1) Southern Illinois University Edwardsville School of Pharmacy, Edwardsville, IL

**PURPOSE:** The purpose of this study was to determine the effect of pharmacist-physician collaboration on diabetes care and outcomes.

**METHODS:** Clinical markers and adherence to American Diabetes Association (ADA) patient care recommendations were evaluated through a retrospective chart review. Data of patients co-managed by a pharmacist (study group) and those solely managed by a primary care provider (control group) were analyzed. The pharmacist-physician collaborative service 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 or underinsured patients. The pharmacist was authorized to initiate, modify, or discontinue drug therapy related to diabetes, blood pressure, and lipid management. Primary outcomes were A1C, blood pressure, and low-density lipoprotein cholesterol (LDL-C). Secondary outcomes included: frequency of A1c and urine albumin excretion testing, appropriate use of ADA-recommended medications, receipt of microvascular screening examinations and vaccinations against influenza and pneumococcal infections.

**RESULTS:** During the 2.5-year follow-up, A1C decreased 1.1% in the study group and 0.2% in the control group (p<0.001). Diastolic blood pressure and LDL cholesterol of study group patients

significantly decreased 3.2 mmHg and 13.8 mg/dL, respectively ( $p < 0.001$ ). Larger reductions in primary endpoints were observed in study group patients having at least three encounters with a pharmacist. Other significant differences in the study group included more frequent laboratory monitoring, appropriate medication use, and currency of annual exams and immunizations in the study group.

**CONCLUSION:** Pharmacist-physician collaborative care improved A1c, diastolic blood pressure, cholesterol, and adherence to ADA patient care recommendations.

## Cardiovascular

### 219. Impact of grapefruit juice on the antiplatelet activity of loading and maintenance doses of clopidogrel in healthy volunteers.

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**PURPOSE:** Grapefruit juice (GFJ) impacts the metabolism of a number of drugs via inhibition of metabolic enzymes. This study evaluated the impact of GFJ on the antiplatelet activity of a loading dose (LD) and 7 days of maintenance dose (MD) clopidogrel.

**METHODS:** Healthy volunteers participated in two separate treatment protocols. The first protocol included a 300 mg LD clopidogrel and the second protocol included MD clopidogrel 75 mg given for 7 consecutive days. In both protocols, subjects were randomized to take clopidogrel with GFJ or with tap water (TW). At 6 hours after the LD and after the last MD of clopidogrel, a P2Y<sub>12</sub> reaction unit (PRU) value was determined using the VerifyNow<sup>®</sup> P2Y<sub>12</sub> assay. A PRU value  $> 235$  was defined as high on-treatment platelet reactivity or hyporesponsive to clopidogrel.

**RESULTS:** Fourteen subjects completed the LD protocol and 17 subjects completed the MD protocol. Following administration of the LD, the mean PRU with GFJ and TW was 235.2 (95% CI 210.4–260.0) and 177.4 (95% CI 141.6–213.2), respectively ( $p = 0.001$ ). Following administration of the LD, the number of subjects with a PRU  $> 235$  with GFJ and TW was 9 (64%) and 3 (21%), respectively ( $p = 0.031$ ). In the MD protocol, the mean PRU with GFJ and TW was 212.4 (95% CI 175.8–249.0) and 186.1 (149.6–222.7), respectively ( $p = 0.059$ ). In the MD protocol, the proportion of patients with a PRU  $> 235$  with GFJ and TW was 9 (53%) and 4 (23%), respectively ( $p = 0.031$ ).

**CONCLUSION:** Compared to TW, GFJ significantly increased the proportion of patients with high on-treatment platelet reactivity following both LD and 7 days of MD clopidogrel. More study is needed to determine the clinical significance of these findings and whether patients should be advised to avoid GFJ while taking clopidogrel.

### 220. Comparing the impact of two omega-3 fatty acid products on the lipid profile.

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**BACKGROUND:** Elevated levels of triglycerides ( $> 150$  mg/dL) and the ApoB/ApoA1 ratio ( $> 1.0$ ) are associated with a higher incidence of coronary artery disease (CAD). Some evidence indicates the ApoB/ApoA1 ratio is a better predictor of CAD risk than LDL cholesterol. Low levels of HDL ( $< 40$  mg/dL) including the more cardioprotective subfraction HDL-2b ( $< 10$  mg/dL) also increase CAD risk.

**PURPOSE:** To assess the impact of an over-the-counter (krill oil) and a prescription omega-3 fatty acid preparation on the lipid profile.

**METHODS:** Patients ( $n = 155$ ) in a private cardiologist's clinic had two total lipid panels drawn on different dates within a one year period. To investigate the effects of time in each group, data were analyzed retrospectively using General Linear Model-Repeated Measures Analysis of Variance (ANOVA). Other parameters included history of CAD and whether or not a patient had taken a statin. Counts of subjects with lipid parameters changing in a clinically favorable direction were compared via two-way Chi Square analysis.

**RESULTS:** Both omega-3 products were associated with a significant ( $p < 0.05$ ) decrease in triglycerides, and a significant increase in total HDL, including the HDL-2b subfraction ( $p < 0.05$ ). Neither product was associated with a significant reduction in the ApoB/ApoA1 ratio ( $p > 0.05$ ), but there was a trend for the ratio to decrease ( $p = 0.061$ ) in more patients taking the prescription omega-3 product. No significant differences ( $p > 0.05$ ) were noted in patients taking a statin or having a history of CAD.

**CONCLUSION:** Both omega-3 products positively impacted several lipid parameters, including the more cardioprotective HDL-2b subfraction. Many previous studies involving omega-3 fatty acid products did not address the ApoB/ApoA1 ratio or the HDL-2b subfraction in their results. Prescription omega-3 fatty acids may be the better recommendation for patients with an elevated ApoB/ApoA1 ratio. Both omega-3 products are useful regardless of prior statin use or history of CAD.

## Clinical Administration

### 221E. Growth of a pharmacist-led critical care practice-based research network: the critical care pharmacotherapy trials network.

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**PURPOSE:** The Critical Care Pharmacotherapy Trials Network (CCPTN) is a pharmacist-led critical care practice-based research network with study sites across the United States. This report is intended to describe the growth and contributions of the CCPTN since its inception in 2007 and demonstrate the value of successful collaboration. We hypothesized there is a significant association between the number of patients enrolled and CCPTN study number.

**METHODS:** Key data from each of the four completed CCPTN studies were compiled with descriptive statistics utilized. Additionally, univariate regression modeling was utilized to evaluate for a relationship between the number of patients enrolled and CCPTN study number. A  $p$ -value of 0.05 was considered statistically significant.

**RESULTS:** Four cross-sectional studies were completed via the CCPTN from 2007 through 2011. The first three studies included data from a 24-hour period, whereas the fourth study included data from a 72-hour period. The median number of study sites and intensive care units contributing data to the trials was 28 and 58, respectively. The initial study enrolled 414 patients, whereas the most recently completed study enrolled 998 patients. Patient enrollment increased in each study, with a median increase of 192 patients. There was a significant relationship between patient enrollment and study number, with an exponential equation best fitting the data (model equation  $y = 291.8e^{0.297x}$ ,  $R^2 = 0.979$ ,  $p = 0.011$ ). Eleven abstracts including data collected via the CCPTN have been presented at national meetings, ten of which were presented at the Society of Critical Care Medicine Annual Congress. Two peer-reviewed manuscripts have been published.

**CONCLUSION:** Studies from the CCPTN have grown in size and scope since the Network's inception. There is a strong relationship between the number of enrolled patients and CCPTN study number, indicating exponential growth and viability of this

Network as a structure to facilitate critical care pharmacotherapy research.

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**222. Dexmedetomidine high cost expense reduction.** *TaMica Brown, BS., CPhT, Sarah Adriance, PharmD, BCPS, Anthony Gerlach, PharmD, BCPS, FCCM; Pharmacy, The Ohio State University Wexner Medical Center*

**PURPOSE:** Dexmedetomidine (DEX) is an alpha-2-receptor agonist restricted at our institution for use in the intensive care unit and in the operating room (OR). During fiscal year 2012, DEX was the eleventh most expensive medication accounting for an expenditure of over \$540,000. We sought to decrease DEX cost without compromising patient care.

**METHODS:** A committee was formed to evaluate DEX use and consisted of staff pharmacists, clinical pharmacists and technicians. We set out to focus first on OR wastage and target use in the ICU as a second step in the project as approximately 70% of DEX use is in the OR. We collected data on all patients who received DEX in the OR during October 2012 including mcg administered. A change to our standard OR concentration was implemented on January 23, 2013. We changed to 100 mcg/50 mL from 200 mcg/100 mL. DEX cost before and after the change was determined and compared using students t-test.

**RESULTS:** In October 2012, 47 patients received DEX in the OR. The mean amount of DEX administered was 89.5 mcg and the mean duration was 2.7 hours. Seventy-five percent of patient received less than 100 mcg of DEX. After changing the standard DEX concentration the mean pharmacy dispensing cost decreased significantly from \$71,018 ± 20,482 the four months prior to the change to \$42,494 ± 8706 for the four months afterwards.

**CONCLUSION:** After determining use of DEX throughout our institution we were able to significantly decrease DEX expenditures. Currently we are implementing changes to DEX usage in the ICU.

**223. Evaluation of patient safety culture in a community safety-net hospital.** *Charlene A. Hope, PharmD, BCPS; Norwegian American Hospital, Chicago, IL*

**PURPOSE:** This study evaluates the current status of patient safety culture in the pharmacy department of a community safety-net hospital. It will also serve to identify strengths and areas for patient safety culture improvement.

**METHODS:** The Agency for Healthcare Research and Quality *Pharmacy Survey on Patient Safety Culture* emphasizes patient and medication safety and quality-assurance issues. The survey includes 36 items measuring 11 composites. In addition to the composites, the pharmacy survey includes three items about the frequency of documenting different types of mistakes, three items about respondent background characteristics, an overall rating question, and a section for open-ended comments. Paper surveys were generated and distributed to pharmacy leadership, pharmacists and pharmacy technicians in both the inpatient and outpatient pharmacy departments. Respondents were given two weeks to complete the survey. A response rate goal of >50 % was established. Survey responses were compiled and analyzed utilizing a Microsoft Excel-based software program.

**RESULTS:** A total of 21 surveys were received with a response rate of 88%. Forty-five percent of respondents were pharmacy leadership and pharmacist and 50% were pharmacy technicians. The overall rating on Patient Safety was ranked as good by 47% (n=10) of respondents; followed by very good 32% (n=7). The highest ranked patient safety culture composites were response to mistakes (85%), communication about medications across shifts (84%) and communication openness (80%). The lowest ranked were staffing, work pressure and pace (33%); patient counseling (51%) and physical space and environment (62%).

**CONCLUSION:** While the department ranked our patient safety culture as good, there are definitely opportunities for improvement. The pharmacy department's daily huddle at shift change has contributed to our highest ranked patient safety composites.

The pharmacy leadership team will share results with staff to solicit input on how we can improve on the lowest ranked composites. Plans are in place to re-survey staff again next year.

## Community Pharmacy Practice

**224. Project ECHO: a novel model for clinical pharmacists in a multidisciplinary Telehealth care network for rural and underserved communities.** *Paulina Deming, PharmD<sup>1</sup>, Joe Anderson, PharmD<sup>1</sup>, Melanie Dodd, PharmD<sup>1</sup>, BernadetteJohnson, Pharm.D.<sup>1</sup>, Mark Holdsworth, PharmD<sup>1</sup>, Renée-ClaudeMercier, Pharm.D.<sup>2</sup>, Gretchen Ray, PharmD<sup>1</sup>, Karla Thornton, MD, MPH<sup>3</sup>, Sanjeev Arora, MD<sup>3</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) University of New Mexico, Albuquerque, NM (3) School of Medicine, University of New Mexico, Albuquerque, NM*

**PURPOSE:** The Extension for Community Healthcare Outcomes (ECHO) Model was developed by the University of New Mexico Health Sciences Center as a platform for academic medical centers to deliver complex specialty medical care to under-served populations. Using state-of-the-art multi-point telehealth technology, co-managed patient care, supported and iterative practice, and chronic disease best practices, ECHO trains and supports primary care clinicians to develop knowledge and self-efficacy to treat complex diseases. Given the financial and systemic barriers to quality healthcare for rural and urban under-served patients with chronic disease, broader access to chronic disease care requires use of new models.

**METHODS:** Pharmacists can be integral members of the healthcare team but, like other healthcare professionals, often practice in veritable silos of expertise. Unlike other clinical pharmacy models, ECHO pharmacists provide concurrent consultation, serving as a unifying link among a multidisciplinary consultation of specialists and the patient's own clinician with the aim of optimizing pharmacotherapy, a cornerstone of best practices. In ECHO, pharmacists collaborate in the hepatitis C, HIV, chronic pain, complex care, dementia, and diabetes and cardiovascular care clinics. Unlike other referral services, ECHO's panel-discussion format allows a more comprehensive examination of the patient by eliminating the usual consultation performed by each specialist independently. Community clinicians participate in weekly teleECHO clinics, called "knowledge networks," by joining a one-to-many videoconference and present their cases by sharing patient medical histories and laboratory results. University specialists, including pharmacy, provide advice and clinical mentoring to clinicians. In 2007, ECHO won the Changemakers award, an international designation sponsored by the Robert Wood Johnson and Ashoka Foundations for innovative practices. The model is currently being replicated nationally and internationally.

**CONCLUSION:** As healthcare delivery evolves, so do the roles of clinical pharmacists and involvement in ECHO affords new opportunities to enhance patient care with clinical outreach to rural and under-served communities.

## Critical Care

**225. Implementation and evaluation of a new sedation, analgesia, and delirium order set in a large community hospital.** *Jonathan D. Edwards, Pharm D<sup>1</sup>, Adam Sawyer, Pharm D<sup>2</sup>, Katie Sims, Pharm.D.<sup>2</sup>, Edward Eiland, III, Pharm.D., MBA<sup>3</sup>; (1) Department of Pharmacy, Huntsville Hospital, Huntsville, AL (2) Huntsville Hospital, Huntsville, AL (3) Department of Pharmacy, Huntsville Hospital System, Huntsville, AL*

**PURPOSE:** To implement and evaluate the impact of a new sedation, analgesia, and delirium order set based on the Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adult Patients in the Intensive Care Unit (PAD Guidelines) recently published by the Society of Critical Care Medicine (SCCM).

**METHODS:** An interdisciplinary Delirium Task Force was formed to identify ways to prevent ICU delirium and improve patient outcomes. Focus areas identified included implementation



of the Confusion Assessment Method for the ICU (CAM-ICU) monitoring, discouraging use of pro-delirious medications, early physical therapy intervention, sedation vacations, and spontaneous breathing trials. This is an ongoing quality improvement process in an effort to optimize prevention, identification, and treatment of delirium in adult ICU patients.

**RESULTS:** After the implementation of this anti-delirium process, an evaluation was conducted to determine its impact. Post-implementation, the use of non-benzodiazepines in ventilated patients increased, CAM-ICU assessment was initiated, sedation vacations and spontaneous breathing trials were conducted daily, and early patient mobilization was initiated. As a result, average ventilator hours decreased by 17.6%, average ventilator associated events were decreased by 8 events per 1,000 ventilator days, and hospital length of stay was reduced by 1.1 days. During the study period, it was determined that the delirium portion of the order set was being under utilization. Therefore, a process improvement initiative is currently underway to improve workflow for CAM-ICU documentation, prescriber notification, and development of a delirium treatment protocol.

**CONCLUSION:** The implementation of a new sedation, analgesia, and delirium order set increased awareness and documentation of delirium, initiated non-pharmacologic and pharmacologic interventions for the treatment of delirium, decreased total ventilator hours, decreased ventilator events, and reduced hospital length of stay. An interdisciplinary approach was required to successfully implement the recommendations detailed in the SCCM PAD Guidelines to achieve these results.

## Education/Training

**226. Development of a regional teaching certificate program for pharmacy residents practicing in institutional settings.** *Harminder Sikand, Pharm.D., FCSHP, FASHP<sup>1</sup>*, Jonathan Lacro, Pharm D., BCPS, BCPP, FASHP<sup>2</sup>, Marcie Lepkowsky, Pharm D<sup>3</sup>, Natalie Hall, Pharm.D., BCOP<sup>4</sup>, Jennigrace Bautista, Pharm D<sup>5</sup>, GrantLum, Pharm.D<sup>6</sup>, Gale Romanowski, Pharm D<sup>7</sup>, Jennifer Floyd, Pharm D., BCPS<sup>8</sup>, Nahed Bahlawan, Pharm D<sup>9</sup>; (1) Scripps Mercy Hospital, San Diego, CA (2) Pharmacy, VA San Diego Healthcare System (3) UC San Diego Health System (4) Naval Medical Center-San Diego (5) Kaiser Permanente (6) Sharp Chula Vista Medical Center, Chula Vista, CA (7) Rady Children's (8) Palomar Pomerado Health (9) Naval Hospital Camp Pendleton

**PURPOSE:** To develop a teaching certificate program for pharmacy residents through a collaborative effort among all the residency directors in San Diego County.

**METHODS:** Nine San Diego County organizations offer residency programs for 55 postgraduate year one and two (PGY1, PGY2) residents annually. Residency program directors in San Diego collaborated in the design and implementation of a program aimed at improving resident teaching skills. We conducted a literature review of existing programs to seek components that would align with our goals and fit into a yearlong program. Our program required the creation of a teaching philosophy, attending didactic lectures and workshops, and providing teaching to pharmacists and healthcare professionals. Each resident was required to provide a minimum number of teaching activities such as a formal large group presentation and small group facilitation and teaching. Each teaching activity was evaluated by the attendees using a specific evaluation form. The program was initiated in 2010 as a mandatory requirement for PGY1 residents and elective for PGY2 residents. Participants were surveyed at the completion of the program to assess satisfaction and their comfort with teaching.

**RESULTS:** During the initial two years, 85% of the residents received a certificate of completion and 53% anonymously returned an end of the year survey. Responders who agreed or strongly agreed that "the educational components of the program were excellent," "program significantly enhanced my knowledge of teaching and precepting," "program has made me an effective teacher/preceptor," "program significantly enhanced my confidence/comfort level in teaching and precepting," and "I would

strongly encourage future residents to participate in the program" were 61%, 66%, 69%, 64% and 71%, respectively.

**CONCLUSIONS:** The San Diego countywide Teaching Certificate Program resulted in self-reported increased knowledge and effectiveness of teaching and precepting and an increase in confidence among the residents. The teaching program continues today as a collaborative approach.

**227. From pilot to practice: feasibility & impact of a layered learning practice model experience in cardiology.** *Bethany A. Kallich, PharmD, BCPS<sup>1</sup>*, Jonathan D. Cicci, PharmD, BCPS<sup>2</sup>, Shailly Shah, PharmD, Brent N. Reed, PharmD, BCPS<sup>1</sup>; (1) Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC (2) Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC

**PURPOSE:** Layered-learning practice models (LLPM) comprised of pharmacists, residents, and students have been proposed as a strategy for providing comprehensive clinical pharmacy services while also enhancing professional education. The purpose of this pilot was to evaluate feasibility and impact of an LLPM in cardiology.

**METHODS:** This pilot was conducted across three cardiology teams during February 2013; coverage consisted of a PGY1 and PGY2 resident (cardiology), PGY2 resident (critical care), and clinical pharmacy specialist. A technician performed medication histories on new admissions. Team members participated in interdisciplinary rounds; verified orders; and performed medication reconciliation, discharge counseling, and clinical documentation. Data collection included interventions made, discrepancies discovered during reconciliation, and time required for the LLPM, including patient care and educational activities.

**RESULTS:** During this 18-day pilot, the average daily census for the three teams was 10.6 ( $\pm 3.2$ ), 13.2 ( $\pm 4.0$ ), and 9.6 ( $\pm 1.5$ ) patients. Admission medication reconciliation was performed on 8.1 patients/day, and 512 discrepancies (3.5/patient) were found. Discharge medication reconciliation was performed on 6.0 patients/day. Collectively, 763 recommendations were made (42.4/day), and 720 (94.4%) were accepted; 55 (7.6%), 96 (13.3%), and 45 (6.3%) of interventions were those recognized in peer-reviewed literature as conferring improvements in mortality, cardiovascular events, and hospitalizations, respectively. Average time spent participating in the LLPM was 10.8 ( $\pm 1.6$ ), 11.4 ( $\pm 1.0$ ), 11.0 ( $\pm 2.1$ ), and 9.9 ( $\pm 2.1$ ) hours daily for the PGY1, PGY2 (cardiology), PGY2 (critical care), and clinical specialist, respectively.

**CONCLUSION:** This pilot made it possible to perform in-depth assessment of medication therapy at admission, discharge and throughout hospitalization, although time required for these and educational activities was significant. Based on the quantity of interventions, and potential benefit in this patient population, an LLPM appears to be an effective and potentially feasible strategy for providing comprehensive clinical pharmacy services. Future studies should evaluate how these impact patient and educational outcomes.

## Emergency Medicine

**228. Efficacy and safety of intravenous N-acetylcysteine in obese versus non-obese patients with acetaminophen toxicity.** John J. Radosovich, PharmD, BCPS, *Asad E. Patanwala, PharmD, BCPS*, Brian L. Erstad, PharmD, FASHP, FCCM, FCCP, BCPS; The University of Arizona College of Pharmacy, Tucson, AZ

**PURPOSE:** There is limited information regarding the use of intravenous (IV) N-acetylcysteine (NAC) for acetaminophen (APAP) poisoning in the obese. It is possible that some patients who are obese do not receive optimal dosing leading to poor outcomes. Also, obese patients may be more susceptible to APAP induced liver injury, thereby diminishing the efficacy of IV NAC. The purpose of this study was to evaluate the efficacy and safety of IV NAC in obese versus non-obese adults for the management of APAP toxicity.

**METHODS:** This was a retrospective cohort study conducted in a tertiary care, academic medical center. Adult patients treated with IV NAC for presumed APAP toxicity between June 2005 and August 2012 were included. Patients were categorized into two groups based on body mass index (BMI): 1) obese (BMI 30.0 kg/m<sup>2</sup> or more) versus 2) non-obese (BMI 18.5–24.9 kg/m<sup>2</sup>). The primary outcome measure was the proportion of patients who developed hepatotoxicity (AST or ALT >1000 IU/L). The occurrence of adverse drug effects were also evaluated.

**RESULTS:** A total of 80 patients were included in the final cohort (40 in each group). The median BMI for the obese and non-obese groups was 34.5 kg/m<sup>2</sup> (IQR 31.4–40.2) and 22.4 kg/m<sup>2</sup> (IQR 21.2–23.9), respectively (p<0.001). Other than more Caucasian patients in the non-obese group, there were no other baseline differences between groups with regard to demographics, liver function tests, or coagulation studies. Obese patients received a median IV NAC dose of 291.5 mg/kg (IQR 270.8–300.7) compared to 300 mg/kg (IQR 287.8–301.9) in the non-obese group (p=0.07). Hepatotoxicity occurred in 27.5% of obese patients and 37.5% of non-obese patients (p=0.34). No adverse drug effects were noted in either group.

**CONCLUSION:** Obese and non-obese patients being treated with IV NAC for APAP toxicity experienced similar efficacy and safety.

**229. Hospital pharmacy preparedness for mass casualty events.** Nadia Awad, Pharm.D., Craig Cocchio, Pharm.D., BCPS; Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, Piscataway, NJ

**PURPOSE:** To assess the preparedness of hospital pharmacies in New Jersey in the provision of pharmaceutical services in mass casualty scenarios.

**METHODS:** An electronic cross sectional survey was developed and distributed via hyperlink to hospital pharmacy representatives in New Jersey. The survey tool assessed the general knowledge of available resources, and attitudes towards the preparedness of the pharmacy department.

**RESULTS:** Of 60 invitations distributed, a total of 18 (30%) surveys were completed. Most respondents practiced at community-based hospitals (12, 66.6%) with no trauma center designation (11, 61.1%) that served greater than 500 licensed beds at their institution (5, 27.7%). Six (33.3%) respondents indicated between 75,000 and 100,000 patients visit their emergency departments annually. While 17 (94.4%) sites reported an institutional disaster preparedness protocol exists, only 10 (55.5%) indicated that there is a specific plan for the pharmacy department. Most respondents (10, 55.5%) were unsure of the adequacy of the quantity of analgesic medication, rapid sequence intubation agents, vasopressors, antiemetics, respiratory medications, ophthalmic medications, oral antimicrobials, and chemical weapon specific antidotes. Five (27.7%) agreed the pharmacy disaster plan included processes to ensure care for patients already hospitalized and 4 (22.2%) agreed the quantity of medication was adequate to treat patients and hospital employees if necessary. Medication stock and quantities were determined based on national or international guidelines at 3 (16.6%) institutions surveyed.

**CONCLUSION:** This survey demonstrates that despite individualized institutional protocols for disaster preparedness, there is a lack of general consensus regarding hospital pharmacy preparedness for mass casualty scenarios. Standardized recommendations from government and/or professional pharmacy organizations should be developed to guide the preparation of hospital pharmacy departments for mass casualty scenarios.

**230. Medication error interventions in psychiatric patients boarded in the emergency department.** Hussain Bakhsh, PharmD<sup>1</sup>, Stephen Perona, PharmD<sup>2</sup>, Whitney Shields, PharmD<sup>2</sup>, Sara Salek, MD<sup>3</sup>, Arthur Sanders, MD<sup>4</sup>, Asad Patanwala, PharmD<sup>5</sup>; (1)The University of Arizona (2)Pharmacy, Northwest Medical Center, Tucson, AZ (3)Psychiatry, Veterans Affairs Palo Alto Health Care System (4)Emergency Medicine, The University of Arizona, Tucson, AZ (5)Pharmacy Practice and Science, The University of Arizona

**PURPOSE:** Psychiatric patients often remain in the emergency department (ED) for extended durations prior to hospital admission or transfer to another facility. This is termed patient boarding and may increase the risk for medication errors. The purpose of this study was to characterize medication error interventions by an emergency pharmacist in these patients and identify factors associated with the need for intervention.

**METHODS:** This was a prospective observational study conducted in a community ED between December 21st, 2012 and May 31st, 2013. During this time period an emergency pharmacist evaluated all psychiatric patients boarded in the ED for drug therapy optimization. A pharmacist investigator observed and recorded all medication error interventions made by the emergency pharmacist. The observation periods were based on the convenience of the observer and emergency pharmacist. The target sample for observation was 100 patients. Data collected included patient demographics and detailed information regarding each intervention. Descriptive analysis was performed for all data. Logistic regression analyses were performed to identify factors associated with the need for intervention.

**RESULTS:** There were a total of 288 interventions in the 100 patients observed in the study. Mean patient age was 43 ± 20 years, 56% were female, and all patients were Caucasian. Of the patients in the study, 65% required one or more interventions. Most interventions were regarding the initiation of home medications (89%) and the overall physician acceptance rate was high (92%). Increasing number of home medications (OR 1.28, 95% CI 1.12–1.47; p<0.001), and age [per 10 year increment] (OR 1.42, 95% CI 1.11–1.81; p=0.005) were associated with the occurrence of a medication error intervention.

**CONCLUSIONS:** Psychiatric patients boarded in the ED frequently require medication error interventions to restart their chronic medications. The need for intervention increases with age and the number of home medications.

**231. Impact of implementation of clinical pharmacy service in the emergency department (ED) in a tertiary academic hospital in Qatar.** Hani Abdelaziz, PharmD, AhmedAbdel Moneim, B.Pharm, MohamedAbdelmoneim, B.Pharm, AshrafEl Malik, B.Pharm, SaraFouad, B.Pharm, MohamedSaad B., Pharm BCPS, Rasha Alanany, PharmD, HaleemaAl-Tamimi, B.Pharm; Hamad General Hospital, Hamad Medical Corporation, Doha, Qatar

**PURPOSE:** The implementation of Clinical Pharmacy (CP) services is relatively new to the emergency department. This field is characterized by having a highly dynamic nature and therefore is a high-risk zone for inappropriate medication use and errors of all sorts. The purpose of this study was to perform a descriptive analysis of pharmacists' interventions in the ED at HGH to show the impact of implementation of CP service in Emergency Department (ED).

**METHODS:** This is a retrospective study. The Interventions electronic system was used to track the interventions associated with clinical pharmacy service for patients in short stay units at ED. Data was collected over a 7-months period (Since October 2012 to April 2013). Emergency medicine pharmacists documented the total number of interventions done, including detailed data pertaining to interventions. For each intervention, the following data were documented: date, time, medication of question, type of intervention, reason for intervention, and the acceptance rate. Three independent Clinical Pharmacists then reviewed each intervention and commented on or re-classified them.

**RESULTS:** A total of 980 interventions were documented. Intervention categories included providing information to physicians (17.6%), discontinue un-necessary or inappropriate medication (12.6%), dose adjustment or calculations (12.3%), Addition of therapeutic agents (8.3%), formulary selection (2.3%), frequency optimization (4.1%) and patient education (3.1%). The main reasons for discontinuing medication were inappropriate or absence of indication, adverse drug reaction, duplication and contraindication. The acceptance rate for the interventions were 630 (64.2%). The most common drugs that needed intervention were: Rabeprazole, Warfarin, Ipratropium, Ceftriaxone, Amlodipine, Enoxaparin, Ranitidine, Tramadol and Aspirin.

**CONCLUSION:** This study shows a great impact of Emergency Medicine Clinical Pharmacists at HGH. Our model can be used by other hospitals considering the implementation of Emergency Department clinical pharmacy services.

## Family Medicine

**232. Defining family medicine residency program directors' utilization of and attitudes towards clinical pharmacists as faculty members.** Jennie Broders, PharmD, BCPS<sup>1</sup>, Jody Lounsbury, PharmD, BCPS<sup>2</sup>, Stephen Wilson, MD, MPH<sup>3</sup>; (1)UPMC St. Margaret Family Medicine Residency Program, UPMC St. Margaret, Pittsburgh, PA (2)Department of Pharmaceutical Care & Health Systems, University of Minnesota College of Pharmacy (3)UPMC St. Margaret Family Medicine Residency Program

**PURPOSE:** An interprofessional approach to care and education is a cornerstone of family medicine. Pharmacists are a well-documented and valued member of this team. Pharmacotherapy core curricula guidelines for family medicine residents focus on basic pharmacotherapy principles, such as individualized patient goals, cost-effective practice and unbiased drug information, but also practically linked the application of this knowledge to required core competencies. Pharmacy education and training have evolved to meet this clinical and scholastic need of the healthcare environment. However, clinical pharmacist incorporation into family medicine residency (FMR) programs as educators and providers has remained stagnant over the last 20 years. The Council of Academic Family Medicine (CAFM) was formed from the four major family medicine organizations as a mechanism to facilitate scholarly activity. The CAFM Education Research Alliance (CERA) was born from this association and administers an annual survey of FMR program directors to gain information about its constituents. Professionals of these organizations are encouraged to submit questions to this CERA survey to increase quality and frequency of research among members.

**METHODS:** The aim of our survey application is to describe the current landscape of clinical pharmacists as family medicine resident educators from the perspective of FMR directors. The objectives of our survey are: 1. Assess the prevalence of formalized pharmacotherapy curricula in FMR programs 2. Assess the prevalence of clinical pharmacists as the educators within FMR programs 3. Determine the perceived utility, outside of a formalized pharmacotherapy curriculum, of clinical pharmacists as faculty members of FMR programs 4. Describe attitudes of FMR program directors towards a pharmacy faculty position 5. Categorize barriers and influences to clinical pharmacist incorporation within FMR faculty 6. Compare our results with the findings of previously published data and add further breadth to the literature on clinical pharmacists as faculty members of FMR programs.

**233E. Pharmacist intervention to reduce hypoglycemia in older patients with diabetes mellitus.** Emily Hays, PharmD<sup>1</sup>, Karen Gunning, Pharm.D.<sup>2</sup>, Carrie McAdam-Marx, RPh MS, PhD<sup>3</sup>, Karly Pippitt, MD<sup>4</sup>; (1)Department of Pharmacy, University of Utah Hospitals and Clinics, Salt Lake City, UT (2)University of Utah College of Pharmacy and School of Medicine, Salt Lake City, UT (3)Department of Pharmacotherapy & Pharmacotherapy Outcomes Research Center, University of Utah College of Pharmacy, Salt Lake City, UT (4)University of Utah School of Medicine – Department of Family & Preventive Medicine, Salt Lake City, UT

**PURPOSE:** This study developed a process to systematically target older patients at higher risk of hypoglycemia by: 1) providing medication therapy interventions in order to reduce the risk of hypoglycemia in older patients with diabetes mellitus while maintaining A1C control within a patient-specific target range, 2) describing pharmacist interventions for medication therapy changes, and 3) identifying patient characteristics associated with recommendations to alter medication therapy.

**METHODS:** A pharmacist reviewed the medical records of 38 patients with diabetes mellitus who were  $\geq 65$  years, had an A1C  $\leq 7\%$ , and were taking a sulfonylurea or insulin. The pharmacist

contacted all patients to determine their current medication therapy, rate of hypoglycemia, average blood glucose, and patient-specific target A1C. A collaborative drug therapy management agreement was then utilized to initiate drug therapy changes. Baseline characteristics, intervention description, and changes from baseline in medication therapy, A1C, average blood glucose, and rate of hypoglycemia were documented.

**RESULTS:** Medication therapy interventions were provided for 19 of the 38 patients. Interventions included: decreasing the dose of insulin or sulfonylurea (47%), discontinuing insulin or sulfonylurea (32%), and discontinuing insulin or sulfonylurea and initiating alternative medication (21%). Medication therapy interventions were not provided for 19 of the 38 patients due to the following: no lows in the last 3 months (n=11), low risk of hypoglycemia per clinical judgment (n=5), oncology drug trial (n=1), sulfonylurea dose already reduced (n=1), and falsely low A1C (n=1). The average A1C increased from baseline in both groups, but the increase was not clinically significant. Both groups also saw a decrease in number of hypoglycemia episodes per month.

**CONCLUSIONS:** Pharmacist intervention provided a reduction in the number of hypoglycemia symptoms while maintaining adequate blood glucose control in older patients with well controlled diabetes.

Presented at Presented at the Society of Teachers of Family Medicine Annual Spring Meeting, Baltimore, MD, May 1–5, 2013

## 234. The “Clinical Pharmacy Priority (CP2) Score” to prioritize patients for comprehensive medication review in family medicine.

Joseph Vande Griend, PharmD<sup>1</sup>, Joseph Saseen, Pharm.D.<sup>1</sup>, Debra Bislip, MD<sup>2</sup>, Colleen Conry, MD<sup>2</sup>, Caroline Emsermann, MS<sup>2</sup>, Wilson Pace, MD<sup>2</sup>; (1)University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences (2)University of Colorado School of Medicine

**PURPOSE:** A decision tool that would facilitate the prioritization of patients for comprehensive medication review (CMR) by a clinical pharmacist in family medicine would enhance efficiency. This research describes and evaluates the “Clinical Pharmacy Priority (CP2) Score.” We hypothesize that patients with high CP2 scores are more likely to receive a medication recommendation after CMR than patients with lower CP2 scores.

**METHODS:** The CP2 score (range: 0–21) was developed collaboratively by the research team. The score is derived from eleven patient-specific factors (e.g. number of medications, age, co-morbidities) and is extracted from the EMR weekly to identify patients with high scores that are prioritized for CMR by a clinical pharmacist. To evaluate the utility of the CP2 score, CMR was performed prospectively on patients with appointments between October 1, 2012 and December 31, 2012 at two University of Colorado Family Medicine Clinics.

**RESULTS:** CMR was performed on 1,107 patients. Of these, 101 patients were identified as having received a medication recommendation after CMR. The likelihood of a patient receiving medication recommendation after CMR increased with increasing CP2 score. For patients with a CP2 score of 0–2, 2/588 (0.3%) charts reviewed received a medication recommendation. The proportion who received a medication recommendation increased to 37/358, or 10.3% for scores of 3–7, to 40/119, or 33.6% for scores of 8–10, and 22/42, or 52.4% for scores of 11 or higher ( $\chi^2=236$ , DF=3,  $p<0.0001$ ).

**CONCLUSION:** These pilot data show that patients with higher CP2 scores are more likely to receive a medication recommendation after clinical pharmacist-provided CMR than patients with lower CP2 scores. The CP2 score could be utilized in family medicine and other ambulatory care practices to help clinical pharmacists prospectively identify patients who are likely to need CMR.

## 235. Developing a pharmacy-faculty led pharmacotherapy rotation for medical residents at a rural family medicine residency program.

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**PURPOSE:** To assess and implement a pharmacy faculty-led pharmacotherapy rotation emphasizing evidence-based medicine (EBM) into a rural family medicine residency program

**METHODS:** A baseline EBM assessment was conducted in 2011 during a noon-conference session. Survey participants were first (R1), second (R2), and third (R3) year residents in an unopposed family medicine residency program serving a rural population. The survey instrument consisted of 16 items, including 8 biostatistics application questions which required interpretation of clinical trial results. Confidence in biostatistics and article interpretation was assessed using a 10-point scale.

**RESULTS:** were assessed overall, and divided per resident year. A pharmacotherapy rotation syllabus with an EBM emphasis was drafted and approved by the faculty for implementation during the 2012–2013 year. Results 19/30 (63.3%) residents participated in the baseline assessment, including 9 R1, 5 R2, and 5 R3 responses. The overall mean score on the biostatistics application questions was 25.5%. Moderate confidence was reported in regards to both knowledge of biostatistics and application of clinical trial results (mean 5.5 and 5.5 on a 10 point scale respectively). Mean scores (R1 22.2%, R2 35%, R3 47.5%) and reported confidence (R1 4.67 and 5, R2 6 and 6, R3 6.7 and 6.1) increased as residents progressed in training. A mandatory pharmacotherapy rotation was implemented for ten R2 residents from July 2012–June 2013. Pharmacy faculty from a variety of backgrounds (ambulatory care, internal medicine, critical care, psychiatry) served as preceptors. Rotation activities included rounds, clinic, guideline reviews and topic discussions, journal article evaluations, and presentations given by the resident using the PICO format.

**CONCLUSION:** Knowledge and application of common biostatistical skills could be enhanced in a family medicine residency program through utilization of pharmacy faculty from a local school of pharmacy. Impact and long-term feasibility of the rotation model will require further on-going assessment.

**236E. Pharmacist initiated transitions of care program: effect on hospital readmission and adherence to follow-up PCP appointments.** Amanda Wojtusik, PharmD<sup>1</sup>, Jennie Broders, PharmD, BCPS<sup>2</sup>; (1) Department of Medical Education, UPMC St. Margaret, Pittsburgh, PA (2) UPMC St. Margaret Family Medicine Residency Program, UPMC St. Margaret, Pittsburgh, PA

**PURPOSE:** Medication discrepancies following hospital discharge can result in costly hospital readmissions. In an effort to minimize these medication discrepancies, UPMC St. Margaret began a Transitions of Care Initiative in March 2012. Outpatient pharmacists contacted patients via telephone within 4 days following hospital discharge. During each telephone encounter pharmacists reinforced discharge plans, reconciled post-hospitalization medications, updated medication records, and emphasized the need for prompt follow-up with a primary care physician (PCP). Our objective was to formally evaluate the Transitions of Care Initiative and its impact on 30-day readmission and PCP follow-up.

**METHODS:** This retrospective chart review included all adults (>18 years of age) discharged from the UPMC St. Margaret inpatient family health center (FHC) service between March 2012 and December 2012. Patients were excluded if they had not followed with a PCP from one of the three UPMC St. Margaret FHCs within the previous two years. Patients were also excluded if they died during the index hospitalization, were transferred to another hospital, were discharged to a medical living facility, or were discharged to a hospice service. Patients who received a post-discharge telephone call were identified using the inpatient and outpatient electronic health records (EHRs). Thirty-day readmission rates and PCP follow-up were compared between patients who received a post-discharge telephone call and patients who did not.

**RESULTS:** Of patients who received a telephone call, 53.3% followed-up with a PCP within 7 days after discharge compared to 50.6% of patients who did not receive a telephone call (p=0.39). The 30-day readmission rate for patients who received a tele-

phone call was 12.0% compared to 20.7% in patients who did not receive a telephone call (p=0.05).

**CONCLUSION:** Although there is room for improvement, the UPMC St. Margaret FHC Transitions of Care Initiative is an effective model for care coordination following hospital discharge.

Presented at Presented at the Annual Spring Conference of the Society for Teachers of Family Medicine, Baltimore, MD, May 1–5, 2013.

## Gastroenterology

**237. Corticosteroid avoidance in patients with crohn's disease who are newly initiated to therapy with an anti-TNF agent versus azathioprine.** Sunanda Kane, MD, MSPH, FACG<sup>1</sup>, Tanna Hassig, PharmD, BCPS<sup>2</sup>, Phyllis Malpas, MA, RN, CGRN<sup>2</sup>, KellyAnne Pennington, BSN, RN, CCRN<sup>2</sup>, Teak Smith, RN, BSN<sup>2</sup>, Rachel Velvet Hicks, RN<sup>2</sup>, Merriman Dowdle, MS, PA-C<sup>2</sup>, Srihari Jaganathan, MS<sup>3</sup>, Sara Horst, MD, MPH<sup>4</sup>, David A. Schwartz, MD<sup>4</sup>; (1) Mayo Clinic, Rochester, MN (2) Medical University of South Carolina, Charleston, SC (3) UCB Pharma, Smyrna, GA (4) Vanderbilt University Medical Center, Nashville, TN

**PURPOSE:** Corticosteroids (CS) are often used in patients with Crohn's disease (CD) to treat disease flares. Long-term CS use, however, can be associated with complications (eg, osteoporosis and diabetes) and tapering CS can decrease the risk of these complications. Anti-tumor necrosis factor- $\alpha$  (TNF) agents and azathioprine (AZA) are CS-sparing agents. We evaluated the rate of CS avoidance in CD patients newly initiated to therapy with either an anti-TNF agent or AZA.

**METHODS:** A retrospective analysis of US patient claims data (January 2008–January 2011) assessing patients aged  $\geq 18$  years with a CD diagnosis, newly initiating an anti-TNF agent or AZA (index date), who received a CS prescription within the 6-month pre-index period was conducted. CS avoidance (no new CS prescription) within 6 and 12 months of initiation to an anti-TNF agent (certolizumab pegol [CZP], infliximab [IFX], or adalimumab [ADA]), or AZA was evaluated.

**RESULTS:** Overall, 2241 patients were newly initiated to an anti-TNF agent (64%) or AZA (36%) and received a CS within 6-months pre-initiation. When anti-TNF agents were collectively compared with AZA, patients initiated to an anti-TNF agent avoided further CS use at a significantly greater rate than patients receiving AZA at 6 months (52% vs 34%; p<0.0001) and 12 months (42% vs 27%; p<0.0001). Individually, CZP, IFX, and ADA showed significantly higher rates of CS avoidance compared with AZA (49%, 53%, and 52% vs 34% at 6 months, respectively; and 41%, 43%, and 42% vs 27% at 12 months, respectively; p<0.001–0.0260).

**CONCLUSION:** In this study, anti-TNF agents were associated with less CS use and exposure over 1 year compared with AZA. Clinical pharmacists can play an important role in minimizing exposure to CS through communication, patient education, and drug monitoring. Additionally, clinical pharmacists can help to identify appropriate long-term immunosuppressive therapy in CD, tailored to individual patient needs.

**238. Corticosteroid taper in Crohn's disease patients (PRECISE 2 trial): An important role for pharmacists.** Tanna Hassig, PharmD, BCPS<sup>1</sup>, Cem Kayhan, MD<sup>2</sup>, Bosny Pierre-Louis, DrPH<sup>2</sup>, Phyllis Malpas, MA, RN, CGRN<sup>1</sup>, KellyAnne Pennington, BSN, RN, CCRN<sup>1</sup>, Teak Smith, RN, BSN<sup>1</sup>, Rachel Velvet Hicks, RN<sup>1</sup>, Merriman Dowdle, MS, PA-C<sup>1</sup>; (1) Medical University of South Carolina, Charleston, SC (2) UCB Pharma, Raleigh, NC

**PURPOSE:** Long-term corticosteroid (CS) therapy increases the risk of complications, including osteoporosis and diabetes. Tapering CS is a quality indicator and an area where pharmacists can impact patient care. Use of anti-tumor necrosis factor- $\alpha$  therapies (anti-TNFs) can reduce CS reliance. We evaluated the efficacy of the anti-TNF certolizumab pegol (CZP) as a CS-sparing agent in Crohn's disease (CD).

**METHODS:** PRECiSE 2<sup>1</sup> is a 26-week randomized, double-blind, placebo-controlled trial. Adults (N=668) with active CD (CD Activity Index [CDAI] 220–450) who responded to an open-label loading dose of CZP 400 mg at Weeks 0, 2, and 4 were randomized to continuous therapy with CZP 400 mg or placebo every 4 weeks through Week 24. Responders ( $\geq 100$ -point reduction in CDAI from baseline 8–12 weeks from first CZP injection) were eligible to taper CS. CS-free clinical remission (CDAI  $\leq 150$  and discontinuation of all oral CS) was evaluated at Week 26 (last observation carried forward).

**RESULTS:** Among responders to the CZP loading regimen, 34% (74/215) were treated with CS at baseline; of these, 70% (52/74) were eligible to taper CS. Among eligible patients, 87% (45/52) initiated a CS taper. 31% (14/45) of patients taking CS at baseline that initiated a taper were in CS-free clinical remission at Week 26. Among patients who tapered CS, 11% (5/45) of patients taking CZP vs 10% (4/41) taking placebo subsequently required an increased CS dose between weeks 8 and 12 but did not exceed the Week 0 CS dose.

**CONCLUSION:** Approximately one third of patients taking CS at baseline that initiated a taper achieved CS-free clinical remission and tapered CS with CZP therapy. Clinical pharmacists who care for CD patients on anti-TNF therapy can play a role in minimizing exposure to CS through communication, education, and drug monitoring for individual patient needs.

**REFERENCE:** 1. Schreiber S, et al. *N Engl J Med* 2007;357:239–25.

## Geriatrics

**239. The impact of a pharmacy resident geriatric clinic.** *Cassandra White, Pharm.D.*<sup>1</sup>, *Alisa Hughes-Stricklett, Pharm.D., BCPS*<sup>2</sup>; (1)Pharmacy Service 119, VA Maine Healthcare System, Augusta, ME (2)VA Maine Healthcare System, Augusta, ME

**PURPOSE:** This clinic was developed to extend clinical pharmacy services to the ambulatory geriatric population with the goals of addressing polypharmacy, improving safety and appropriateness of therapy, and ensuring the patient's understanding of his or her medications.

**METHODS:** The pharmacy resident conducted a thorough medication chart review and then met with the patient during their regularly scheduled geriatric clinic appointment. Recommendations, patient reported problems, and medication reconciliation discrepancies were then communicated to the provider. Recommendations included: assessment of renal function, therapeutic drug monitoring, excessive dose or duration, duplicate therapy, decreased regimen complexity, and formulary interchange. The impact of each recommendation on polypharmacy was documented.

**RESULTS:** From January 2013 to May 2013, chart reviews were performed for 64 patients and 60 were interviewed for medication reconciliation and education. Patients were elderly with an average age of 82.5 (62–97) years, and multiple chronic disease states (57.8% had at least 3 of following: hypertension, hyperlipidemia, diabetes, mental health, or dementia). Before meeting with the pharmacy resident, patients had an average 12.5 (3–31) prescriptions and after, had an average 10.4 (4–31) prescriptions. Overall, 150 of 166 recommendations were accepted and 143 medications were discontinued.

**CONCLUSION:** This geriatric clinic model offered clinical pharmacy services to a patient population at higher risk of adverse events associated with polypharmacy. The model allows for identification of high-impact pharmacotherapy recommendations, includes the patient in the pharmacist-provider plan, and preserves the central patient-physician relationship. Pharmacist services in the geriatric clinic had a significant influence on reducing polypharmacy, improving patient care and education, and would be easily adaptable to other practice settings.

**240. Clinical characteristics and predictors of exacerbation in cognitively impaired nursing home residents with chronic obstructive pulmonary disease (COPD).** *Barbara Zarowitz, Pharm.D.*<sup>1</sup>, *Ter-*

*rence O'Shea, Pharm.D.*<sup>2</sup>, *Carrie Allen, Pharm.D.*<sup>3</sup>; (1)Omnicare, Inc., Livonia, MI (2)Division of Clinical Services, Omnicare, Inc., Englewood, OH (3)West Division, Omnicare, Inc., San Antonio, TX

**PURPOSE:** It has been established that 22% of cognitively and functionally impaired nursing home (NH) residents with COPD experience  $\geq 2$  exacerbations of COPD/year. We sought to identify predictors of COPD exacerbation.

**METHODS:** Retrospective analysis of linked and de-identified pharmacy claims and Minimum Data Set (MDS) 2.0 records, from 10-1-2009 through 9-30-2010. Cognitive impairment (CI) was defined as Cognitive Performance Scale (CPS) scores of 3–6.

**RESULTS:** A total of 12,116/22,309 (54.3 %) NH residents with COPD had moderate to very severe CI. In the 7,159 residents with MDS and pharmacy claims data, 42.4% received short-acting bronchodilators (SABA) (35.9% routine, 24.7% routine/PRN therapy); 34.2% received long-acting inhaled agents (LABD) and 46.4% received no COPD medications. Residents with  $\geq 2$  COPD exacerbations had more concomitant systemic illness, used more SABA (74% vs. 31%,  $p=0.001$ ) and short-acting antimuscarinic agents (30.6% vs. 11.2%,  $p=0.001$ ), had more shortness of breath (SOB) ( $p=0.001$ ), oxygen therapy ( $p=0.001$ ), hospital stays ( $p=0.001$ ), and emergency department (ED) visits ( $p=0.001$ ) than those with  $< 2$  exacerbations. Residents who used  $\geq 1.5$  SABA doses/day had less anxiety (27.8% vs. 33.1%,  $p=0.046$ ), used more oxygen therapy ( $p=0.001$ ), and experienced more COPD exacerbations (13.4% vs. 9.4%,  $p=0.001$ ) than those who used  $< 1.5$  SABA doses/day.

**CONCLUSION:** Predictors of frequent COPD exacerbations in NH residents included multiple comorbidities, shortness of breath, and use of oxygen and short-acting bronchodilators.

## Health Services Research

**241. The effectiveness of pharmacist-involved collaborative care model in the management of patients with diabetes: a million dollar initiative in Asia.** *Joyce Lee, PharmD, BCPS, BCACP*<sup>1</sup>, *YuKo, Ph.D.*<sup>1</sup>, *Melanie Siaw, BSc (Pharm)(Hons)*<sup>1</sup>, *Daniel Malone, RPh PhD*<sup>2</sup>; (1)Department of Pharmacy, Faculty of Science at National University of Singapore, Singapore (2)Department of Pharmacy Practice and Science, The University of Arizona, Tucson, AZ

**PURPOSE:** Diabetes is an increasing epidemic worldwide. As Asia remains the world's most populous region, more than 60% of these patients are expected to come from Asia. Evidence has shown that healthcare can be delivered more effectively and efficiently through a multidisciplinary team approach, in which providers are supported by experts from different disciplines, and as a result are better equipped with the necessary resources and knowledge to manage their patients with chronic diseases. In October 2007, a collaborative care model involving clinical pharmacists in caring for patients with uncontrolled diabetes was successfully piloted in Asia, specifically Singapore for the first time. Today, the collaborative care model has been implemented in six healthcare institutions in Singapore. However, the effectiveness of such a model has only been evaluated retrospectively in one institution and its external validity is yet to be elucidated. This study aims to determine the effectiveness of a new model of care in Asia in which clinical pharmacists are active participants in caring for patients with uncontrolled diabetes through robust study design which is yet to be found in Asia.

**METHODS:** This is a prospective, randomized, multi-center, controlled study supported by a million dollar Health Services Research Grant from the Ministry of Health, Singapore. Eligible patients with uncontrolled DM and additional pharmaceutical challenges such as polypharmacy or those who require closer monitoring are currently being recruited and randomized into pharmacist-involved collaborative care or the usual care without pharmacist involvement.

**RESULTS:** This study has received IRB approval, and is currently in progress.

Types of Outcomes Evaluated	Descriptions
Clinical	Glycated hemoglobin (HbA1c), systolic blood pressure (SBP), low density lipoprotein (LDL), and fasting triglyceride (TG) levels Incidence of minor and major hypoglycemia Appropriateness of medication use
Humanistic	Health-related quality of life Medication adherence
Economic	Cost effectiveness

## Hematology/Anticoagulation

**242. The incidence of venous thromboembolism in overweight and obese adult patients following administration of standard dose vs. dose-adjusted subcutaneous heparin.** Jennifer Bushwitz, PharmD<sup>1</sup>, Abigail Dee Antigua, PharmD<sup>2</sup>, Joseph Schreiner, PharmD<sup>3</sup>, Karly L. Tommolino, PharmD<sup>2</sup>; (1) Department of Pharmacy, University of Florida Health Shands Hospital, Gainesville, FL (2) University of Florida Health Shands Hospital, Gainesville, FL (3) University of Florida College of Pharmacy, Gainesville, FL

**PURPOSE:** The objective of this study was to determine the incidence of venous thromboembolism in obese and overweight ICU patients receiving unfractionated heparin (UFH) 5000 units every 8 hours compared to UFH 7500 units every 8 hours for prophylaxis.

**METHODS:** A retrospective cohort study was conducted in critically ill adult patients between May 20, 2011 and July 30, 2012. Patients that met the following criteria were included in this study: use of only 1 pharmacological VTE prophylaxis regimen for greater than 72 hours, weight >100 kg or BMI >30 kg/m<sup>2</sup>, ICU stay >48 hours.

**RESULTS:** Of the 358 patients included in the study, 335 patients received UFH 5000 units SC every 8 hours and 23 patients received UFH 7500 units subcutaneously every 8 hours. Patients who received 7500 units had a longer length of stay (median 17 vs. 11 days, P=0.004), longer ICU length of stay (median 11 vs. 7 days, p<0.001), higher weight (median 140 kg vs. 100 kg, p<0.001), higher BMI (median 44 kg/m<sup>2</sup> vs. 34 kg/m<sup>2</sup>, p<0.001), and longer median duration of VTE prophylaxis in the ICU (median 15 vs. 10 days, p=0.08). Eleven patients experienced the primary outcome of a VTE event for an overall event rate of 3.07%.

**CONCLUSION:** Among the 358 overweight or obese adults evaluated, there was a low overall incidence of VTE events. Few patients were included in the UFH 7500 units group; therefore, the study was unable to show a difference in VTE events between the two groups. Larger randomized controlled trials are needed to establish the most appropriate dose of UFH for VTE prophylaxis in critically ill overweight and obese patients.

## Infectious Diseases

**243. Impact of antimicrobial stewardship on tigecycline utilization.** Erin Scruggs, PharmD<sup>1</sup>, Neil Labak, PharmD<sup>2</sup>; (1) Department of Pharmacy, Carolinas Medical Center-Northeast, Concord, NC (2) Carolinas Medical Center-Northeast, Concord, NC

**PURPOSE:** Based on the FDA safety communication release in 2010, tigecycline utilization was reviewed daily by the antimicrobial stewardship team (AST) to ensure appropriate use. The underlying purpose was to deter inappropriate usage and reduce unnecessary drug expenditure

**METHODS:** Patients on tigecycline were prospectively reviewed on a daily basis by the AST to assess appropriateness of use from December 2010 through March 2013. Education was provided to physicians in verbal and written format at baseline, as well as throughout this program on the risks associated with its use. Physicians were contacted for situations where inappropriate use was determined or when other therapeutic options were more beneficial for the patient. Drug utilization and cost were compiled on a quarterly basis. All information was collected prospectively.

**RESULTS:** Defined daily doses per 1,000 adjusted patient days declined by 97.6% from 10.68 in quarter one of 2009 to 0.26 in quarter one of 2013. Drug expenditure decreased by 96.2% from \$51,530 in quarter one of 2009 to \$1,968 in quarter one of 2013. The primary indications for therapy were for complicated intra-abdominal infections and complicated skin and skin structure infections. In many cases, tigecycline was used off-label. Physicians responded positively to the education and recommendations for alternative antimicrobial selection provided by the AST.

**CONCLUSION:** Prior to the implementation of an antimicrobial stewardship program, tigecycline usage was high. Education, monitoring and alternative antibiotic selection provided by the AST helped to significantly deter inappropriate tigecycline utilization as well as reduce irrational drug expenditure over a three year period. To date, tigecycline use has remained below 0.5 defined daily doses per 1,000 adjusted patient days.

**244. Prospective evaluation of Epic Antibiotic Report and Safety Surveillor to improve efficiency and identification of clinical pharmacy interventions.** Leanna Liu, Pharm.D.<sup>1</sup>, Christine Hamby, Pharm.D.<sup>1</sup>, Maura Wychowski, Pharm.D., BCPS<sup>1</sup>, Mary Lourdes Brundige, Pharm.D.<sup>1</sup>, Mary Butler, Pharm.D.<sup>1</sup>, Alexandra Yamshchikov, MD<sup>2</sup>, Maryrose Laguio-Vila, MD<sup>2</sup>; (1) Department of Pharmacy, Rochester General Hospital, Rochester, NY (2) Infectious Disease Unit, Rochester General Hospital, Rochester, NY

**PURPOSE:** Prospective evaluation of two data-mining methodologies for identifying interventions by hospital-based clinical pharmacists.

**METHODS:** Intervention opportunities were identified during two 10-day periods using a report derived from the facility's electronic medical record (Epic Antibiotic report, EAR). Safety Surveillor (SS) data mining software was added during the second period. Primary outcomes were intervention rates, chart review efficiency, and acceptance rates for antibiotic and non-antibiotic interventions. Secondary outcomes were clinical significance and skill level of interventions, determined using established criteria.

**RESULTS:** Three clinical pharmacists made 643 interventions spanning 2,080 patient-days. EAR identified more interventions compared to SS (79%, [95% CI, 72–84%] vs. 37%, [95% CI, 30–44%]), and nearly all (95%) interventions identified through SS were concurrently identified by EAR. Antibiotic (353 ± 154 vs. 366 ± 137/1,000 antibiotic patient-days; p=0.71) and non-antibiotic (141 ± 83 vs. 178 ± 135/1,000 patient-days; p=0.20) intervention rates were similar across study periods. Efficiency of chart review was maintained between EAR and EAR/SS periods (90.1% vs. 95.5%; p=0.19). Provider acceptance rates were similar in both periods (EAR 90.3% vs. EAR/SS 89.2%; p=0.69). Although absolute number and proportion of advanced-skill antibiotic interventions were similar between the two study periods (65/152, 43% vs. 74/163, 45%; p=0.65) these recommendations were more readily accepted by providers when identified in EAR/SS period (86% vs. 97%; p=0.02). Intervention opportunities identified by SS alone required advanced clinical skills, and more clinically significant interventions were made during EAR/SS period compared to EAR alone (42% vs. 58%; p=0.01).

**CONCLUSION:** Although reports derived from the electronic medical record, such as the EAR, may represent the most comprehensive methodology to identify interventions, the addition of integrated data-mining software, such as SS, may help maximize the skill level and clinical significance of the recommendations. Our findings suggest that each tool has unique strengths and limitations that may compliment diverse needs across clinical contexts and institutions.

## Managed Care

**245. Economic analysis of a primary care clinical pharmacy service on post-fracture care in postmenopausal women.** Adriane N Irwin, MS, PharmD<sup>1</sup>, Rachel MF Heilmann, PharmD<sup>2</sup>, Sarah J Billups, PharmD<sup>1</sup>; (1) Kaiser Permanente Colorado, Aurora, CO (2) Kaiser Permanente Colorado, Denver, CO



**PURPOSE:** A previously completed study of women aged 67 or older with a documented fracture showed that a Clinical Pharmacy Osteoporosis Management Service (CPOMS) was associated with a significantly greater proportion of women completing bone mineral density (BMD) testing or initiating drug therapy when compared to a similar intervention provided by a nurse (65% vs 46%, respectively;  $p < 0.001$ ). The purpose of this study was to compare the cost inputs associated with each intervention and quantify any cost avoidance due to hip fracture prevention.

**METHODS:** This economic analysis was conducted from the healthcare payer's perspective. Intervention costs included healthcare provider time, BMD tests, and anti-osteoporosis medications. Data from the original study was used to construct a deterministic decision-tree analysis model to compare 12 month costs that included predicted hip fractures.

**RESULTS:** A total of 827 and 302 women were managed by CPOMS and the comparator group in the original study, respectively. The cost of provider time for the CPOMS and comparator group interventions was \$27.16 and \$24.03 per patient evaluated, respectively. However, for those patients achieving the endpoint of completing BMD testing or initiating drug therapy, the cost was \$100.75 and \$138.19 per patient, respectively. Based on the decision-tree analysis model, 12 month costs of osteoporosis care for CPOMS patients was \$413,753.05 versus \$506,701.21 for patients in the comparator service.

**CONCLUSION:** The CPOMS resulted in a higher cost per patient evaluated, but a lower cost for patients completing BMD testing or initiating drug therapy. When including costs associated with predicted hip fractures, CPOMS was less expensive than the comparator group because more patients completed treatment recommendations. From the healthcare payer's perspective, the CPOMS intervention appears to have a lower cost per patient achieving treatment outcomes while also leading to future cost savings

## Medication Safety

**246E. Use of the MR ROSS (Medication Reconciliation – Review of Systems Subject) tool at the initial visit in an outpatient geriatric clinic.** *Scott Vouri, PharmD, BCPS, CGP<sup>1</sup>, Zachary A. Marcum, PharmD, BCPS<sup>2</sup>; (1) Division of Pharmacy Practice, St. Louis College of Pharmacy, Saint Louis, MO (2) University of Pittsburgh, Pittsburgh, PA*

**PURPOSE:** Obtaining a complete medication list may be difficult in older adults for a variety of reasons. A specific challenge is identifying errors of omission where medications are not continued because the medical staff does not have a complete list. To address this problem, a pictorial tool called Medication Reconciliation – Review of Systems Subject (MR ROSS) was created to assess potential missed medications in a 'review of systems' fashion. Our objective is to determine if the use of the MR ROSS tool is an effective method to identify errors of omission at an initial visit in an outpatient geriatric clinic.

**METHODS:** After the medication evaluation was completed at the initial visit at a Program of All-inclusive Care for the Elderly (PACE), MR ROSS was used to collect additional medication information to identify errors of omission. Using MR ROSS, the clinical pharmacist asked the patient, "Are you taking anything for [system]?" This line of questioning was continued for every noted area. Data from January 2012 to December 2012 were collected via retrospective chart review.

**RESULTS:** Of the 40 new patients, thirty-one patients (77.5%) had  $\geq 1$  error of omission identified by MR ROSS. Of these patients, an average of 4.0 additional medications per patient was identified. Patients with a Mini Mental Status Exam score of  $\geq 24$  were more likely to have an error of omission detected using MR ROSS ( $p = 0.009$ ). Of the 123 additional medications identified using MR ROSS, 73.2% and 69.9% were non-prescription and as needed medications, respectively. Of the medications found using MR ROSS, 57%, 17%, and 8.6% were oral medications, topical medications, and oral inhalers, respectively.

**CONCLUSION:** The use of the MR ROSS tool was a feasible and effective method to identify errors of omission at an initial visit in an outpatient geriatric clinic.

Presented at Missouri Society of Health-Systems Pharmacists – Spring Meeting, St. Charles, MO, April 11-13, 2013.

**247. Use of an interactive magnesium allergy listing in the electronic medical record to prevent magnesium-induced myasthenia crisis.** *Margaret Verrico, BS, Pharm<sup>1</sup>, Richard Simmons, MD<sup>2</sup>, David Lacomis, MD<sup>2</sup>; (1) Department of Pharmacy/School of Pharmacy, University of Pittsburgh Medical Center, Pittsburgh, PA (2) University of Pittsburgh Medical Center, Pittsburgh, PA*

**PURPOSE:** An effort was initiated to prevent the administration of intravenous magnesium to myasthenia gravis (MG) patients. A myasthenia gravis (MG) patient in a University of Pittsburgh Medical Center (UPMC) Presbyterian (PUH) intensive care unit (ICU) was automatically ordered intravenous (IV) magnesium sulfate based on its inclusion within a PUH ICU admission order set. A neurologist and a pharmacist intervened. Magnesium is a neuromuscular junction blocker that may precipitate myasthenic crisis and respiratory arrest in MG patients. An intervention was requested to prevent automatic IV magnesium orders for MG patients.

**METHODS:** An interactive electronic medical record allergy alert was used to warn prescribers and pharmacists of a potential medication-related concern when orders for IV magnesium were generated from the order set. Magnesium sulfate was entered into the allergy profile of MG patients as "proposed intolerances" with a reaction of "myasthenic crisis." The allergy fields of all known myasthenia patients were flagged. New incoming myasthenia patients were identified via a daily alert generated from an electronic search of inpatient medical records that list the term, "myasthenia," or list an ICD-9 code for MG. The records of such patients were similarly flagged upon confirming a MG diagnosis.

**RESULTS:** At the time of this report, 459 MG patient records have been flagged. Similar allergy flags for aminoglycoside and quinolone administration have been implemented to safeguard MG patients, as well. Other UPMC Health System hospitals have also implemented this process. This intervention has continued since March of 2009 with no new IV magnesium, aminoglycoside or quinolone-induced myasthenic crisis events reported in known/identified MG patients with allergy flags.

**CONCLUSION:** The use of an interactive allergy alert successfully prevented magnesium-induced myasthenic crisis in MG patients.

**248. Evaluation of azithromycin use in high-risk patients: response to the FDA drug risk communication.** *Zhe Han, PharmD, Natasha N. Pettit, PharmD, Benjamin D. Brielmaier, PharmD; University of Chicago Medicine, Chicago, IL*

**PURPOSE:** The Food and Drug Administration (FDA) issued a drug risk communication in March 2013 highlighting the potential of azithromycin to cause fatal cardiac arrhythmias. We retrospectively reviewed institutional use to characterize the patient population receiving azithromycin, including risk factors for QTc prolongation, and adherence to institutional recommendations for initiation and monitoring.

**METHODS:** Institutional guidelines for monitoring of drug-induced QTc prolongation were implemented in 2011, which included evaluation of patient risk factors for QTc prolongation and recommendations on frequency of monitoring and electrolyte replacement. Daily EKGs are recommended for high-risk medications associated with QTc prolongation according to institutional guidelines, including azithromycin, in patients whose baseline QTc is 440 msec or greater and not on continuous telemetry monitoring. Adult inpatients initiated on intravenous or oral azithromycin between November 2012 and February 2013 were included.

**RESULTS:** A total of 50 patients were reviewed. Azithromycin was most frequently initiated for pneumonia (64%), followed by exacerbation of chronic obstructive pulmonary disease (26%) and

acute chest syndrome (6%). Eighty-six percent of patients had at least one FDA-identified risk factor. The most common risk factors included concurrent use of other QTc prolonging medications (58%), age (46%), underlying cardiac disease (28%) and baseline QTc prolongation (24%). Of 27 patients receiving azithromycin therapy without continuous telemetry monitoring, 18 patients (67%) had baseline QTc obtained and repeat EKGs were obtained only in five of these patients after azithromycin initiation. The remaining nine patients had no baseline and repeat EKGs obtained. Compliance rate with institution QTc monitoring guideline was 22% among patients initiated on azithromycin. **CONCLUSION:** Azithromycin was frequently initiated in high-risk patients and inadequately monitored. Institutions should seek to optimize data reporting within the electronic medical record to identify patients at high-risk for QTc prolongation at the time of order-entry in order to enhance medication safety.

**249. Pharmacist versus physician conducted medication reconciliation on an internal medicine service at an urban teaching hospital.** *Michael J. Gonyeau, BS, Pharm PharmD, BCPS, FCCP<sup>1</sup>, EmilyHeath, B.S., Pharm.D.<sup>2</sup>, (1) Northeastern University School of Pharmacy, Boston, MA (2) Sarasota, FL*

**PURPOSE:** Previously published studies have shown positive impact of pharmacists on identifying discrepancies in the medication reconciliation (MedRec) process upon hospital admission. Specific medications are more prone to error, providing an opportunity where pharmacists may be influential on patient care during healthcare transitions.

**METHODS:** A prospective study was conducted in patients  $\geq 18$  to compare pharmacist (or pharmacy student) vs. physician performed MedRec on general medicine inpatient service at a 760 bed tertiary care hospital during a 3 month period in 2012. Pharmacist MedRec entailed patient interview, contacting outpatient pharmacies/PCP offices and review of electronic medical record (EMR) compared to physician standard of care including patient interview and EMR review. Discrepancies were discussed with admitting physicians and regimens clarified/alterd. Discrepancy types included Rx-drug omission, non-Rx drug omission, incorrect dose, incorrect frequency, patient non-adherence: dose change, patient non-adherence: frequency, and patient non-adherence: self-discontinuation. A severity of error grade was assigned to each discrepancy based on NCC MERP categorization method for medication errors.

**RESULTS:** A total of 306 patients were enrolled in the study (age:  $59.43 \pm 18.63$ , 42% male) and 1580 discrepancies identified ( $5.16 \pm 17.46$ /patient), with a trend toward increasing discrepancies observed in patients with 6–10 medications. The most common discrepancies identified were patient non-adherence: self-discontinued (n=597; 37.78%) and prescription drug omission (n=593; 37.53%). The most common severity score category assigned was F (n=609; 38.54%). Most discrepancies were identified in the drug class "Rx-other" (n=699; 44.24%). Cardiovascular agents accounted for 295 (18.67%) discrepancies. Medications most likely to reveal discrepancies included aspirin and albuterol, while medications with the fewest discrepancies included non-prescription gastrointestinal agents and non-prescription non-opioid analgesics.

**CONCLUSION:** Pharmacy-directed medication reconciliation may have a substantial impact on the clarity of outpatient medication regimens, adherence, and quality of care in hospitalized patients. Many of the discrepancies identified could result in significant morbidity and mortality.

**250. Creation and implementation of a web-based home-grown pharmacy intervention system using Microsoft SharePoint®.** *Adam B. Woolley, Pharm.D., BCPS<sup>1</sup>, Maria Scarlatos, BS<sup>1</sup>, Shawn Saunders, PharmD<sup>2</sup>, (1) School of Pharmacy, Northeastern University, Boston, MA (2) VA Boston Healthcare System, West Roxbury, MA*

**PURPOSE:** To develop a pharmacy intervention database in compliance with strict security standards that is easy to create,

use, manage and update without unnecessary resource expenditures.

**METHODS:** A committee was formed to evaluate several third party web-based intervention programs and determine which best fit the needs of the pharmacy department. After weighing several factors, the decision was ultimately made to build a home-grown web-based intervention database, utilizing Microsoft SharePoint®. A small task force developed the intervention database, and training was provided to the pharmacy department regarding how to use the system.

**RESULTS:** Intervention fields were created and customized for institution-specific optimization. View options were restricted to protect employee privacy, and the database was set up on the intranet to meet institutional standards for protected health information (PHI). The system has the ability to trigger customized emails to specific members of the pharmacy department in order to assist with hand-offs. The intervention database also generates reports through utilization of an Excel® Pivot Table.

**CONCLUSION:** Microsoft SharePoint® allows the pharmacy department to utilize an intervention tracking service at no additional expense. The system can be replicated because this software is already widely available at all VA medical centers as well as many other institutions. The system is easy to create and use, is sustainable, and can be customized to service goals in real-time. Further assessment of the intervention database is needed to evaluate pharmacist perception of the system as well as to analyze documented interventions.

**251. Innovative use of prescription cancellation data to improve patient safety and efficiency within a mail order pharmacy.** *Carrie Nolan, PharmD, George Dooling, PharmD, Gia Leonetti, PharmD Candidate, Michael Sutherland, PharmD; VA SW CMOP, Tucson, AZ*

**PURPOSE:** Prescription cancellation by pharmacists at the Department of Veterans Affairs Southwest Consolidated Mail Outpatient Pharmacy (VA SW CMOP) can cause delays in service to veterans and duplicate work for both the CMOP and VA medical centers (VAMCs). In this study, prescription cancellation data was aggregated in a structured format and reported to VAMCs in order to bring prescriber attention to preventable problems with prescriptions and increase the efficiency of the mail order system by reducing the number of prescription cancellations.

**METHODS:** Every month VAMCs serviced by the SW CMOP received a site progress chart showing the total number of monthly cancels over time, a progress chart with the top three reasons for site cancellation, and a cancellation rate chart comparing the different VAMCs. Decrease in average prescription cancellation rate was analyzed using a t-test.

**RESULTS:** Over a one year period (January 2012 to December 2012), the average number of prescription cancellations among all VAMCs fell from 48.8 cancels per 10,000 fills to 37.5 cancels per 10,000 fills. This represents a 23% decrease in the overall cancellation rate to VAMCs (p=0.006).

**CONCLUSION:** By providing benchmark data to the VAMCs for analysis, CMOP is able to play a more active role in promoting patient safety and improving the efficiency of mail order service.

**252. Assessing the accuracy and quality of medication history collection: effect of implementation of electronic health record.** *Kena Lanham, PharmD, BCPS<sup>1</sup>, Lindsay Saum, PharmD, BCPS, CGP<sup>2</sup>, David Reeves, PharmD, BCOP, Colleen Scherer, PharmD, MPA, BCPS, Beth Johnston, PharmD, BCPS<sup>1</sup>, Anthony Antonopoulos, RPh MBA, Suellen Sorensen, PharmD, BCPS<sup>1</sup>; (1) Department of Pharmacy, Saint Vincent Hospital, Indianapolis, IN (2) Department of Pharmacy Practice, Butler University, Indianapolis, IN*

**PURPOSE:** We hypothesized that pharmacy staff auditing of previously recorded admission medication histories will identify significant and potential medication errors, and that implementation

of an electronic medical record [EMR] will not improve the quantity of discrepancies or the quality of admission medication histories, despite showing Joint Commission and Heart Failure Core Measure compliance.

**METHODS:** At our institution, medication reconciliation is completed at the time of admission through collaboration with prescribers and nursing staff. A pharmacy medication reconciliation team is utilized on the cardiac step down unit and employs pharmacy technicians to obtain an accurate and complete medication history. This history is verified by a pharmacist, compared to the initial medication history and inpatient medication orders. Identified discrepancies are reconciled with a licensed prescriber. A retrospective evaluation assessed the discrepancies identified by the pharmacy team medication history audits, as well as audits completed by clinical pharmacists on other hospital units, and compared the quantity of discrepancies before and after EMR implementation.

**RESULTS:** With support provided by the pharmacy team, medication reconciliation completion was 82% pre-EMR implementation and increased to 91% immediately post-EMR implementation; Core Measure compliance has remained above 90%. The average number of medication omissions per patient upon admission medication reconciliation was 0.55 pre-EMR implementation and increased to 2.32 post-EMR implementation. The average number of incorrect drugs/patient upon admission medication reconciliation 0.16 (pre) and 0.61 (post); and incorrect doses/patient was 0.32 (pre) and increased to 0.63 (post).

**CONCLUSION:** Despite showing medication reconciliation and core measure compliance with the implementation of EMR, our data shows discrepancies between the medication lists collected as a routine part of admission and those lists collected via the pharmacy team audit. In fact, more errors were identified after EMR implementation. The pharmacy team's activities should be continued and even expanded in order to prevent future discrepancies.

**253. The positive impact of a med Rec ED pharmacist on medication management in patients admitted to a hospitalists' service.** *Anthony Intintoli, MD, FACP, FHM<sup>1</sup>*, Anna Dushenkov, Pharm D, BCPS<sup>2</sup>, Sanu Koshy-Varghese, Pharm D<sup>3</sup>, William Hendricks, RPh<sup>4</sup>, Jack Mateyunas, RPh<sup>5</sup>; (1)Huntington Hospital NSLIJ HS (2)Pharmacy, Huntington Hospital NS LIJ HS (3)Emergency Department/Pharmacy, Huntington Hospital NSLIJ HS (4)Pharmacy, Huntington Hospital NSLIJ HS (5)Huntington Hospital NS LIJ HS

**PURPOSE:** TJC recognizes medication reconciliation, known as "med rec", as a critical step in medication therapy management that affects patient outcomes through continuum of care. Eighty five percent of admission errors originate from inaccurate medication histories that could lead to the increased risk of preventable ADEs (pADEs). We hypothesized that teaming a full time ED pharmacist dedicated exclusively to med rec (EMRP) with the hospitalists' admitting service can substantially reduce pADEs thereby improving patient care.

**METHODS:** This was a six month (October 2012 – April 2013) observational case study. An EMRP performed medication reconciliations on patients admitted to hospitalists' service during the peak hours of ED volume. Patients admitted by hospitalists but not seen by the EMRP over the same period of time served as the control group. The impact was assessed for: medication history accuracy, delays in medication administration due to med rec discrepancies, cost avoidance associated with pADEs, and admitting hospitalist's time savings.

**RESULTS:** The EMRP performed an average of 1,600 interventions per month. Ninety percent reduction in medication history inaccuracies and 97% decrease in delays in medication administration were achieved within the first two months. Seventy three interventions were identified as high potential to cause patient's harm with an estimated cost avoidance of \$860,816/year. The EMRP has saved up to 2.25 hours of admitting hospitalist's time per shift.

**CONCLUSION:** The implementation of a dedicated EMRP has substantially decreased medication history inaccuracies and

streamlined the medication therapy management. There was also a considerable time savings for the hospitalists' admitting service that might allow to increase the admitting hospitalists' productivity and efficiency, and contribute to ED throughout. These accomplishments can ultimately translate into improved institution's performance and reduced liability.

## Other

**254. A collaborative effort to develop clinical pharmacy services and Advanced Pharmacy Practice Experience (APPE) student exchange programs in Ethiopia and China.** *Golden Peters, Pharm.D., BCPS<sup>1</sup>*, Shin-YuLee, Pharm.D<sup>2</sup>, KennethSchafermeyer, Ph.D.<sup>3</sup>; (1)Saint Louis College of Pharmacy, Saint Louis, MO (2)Pharmacy Practice Division, Saint Louis College of Pharmacy, Saint Louis, MO (3)Pharmacy Administration, Saint Louis College of Pharmacy, Saint Louis, MO

**PURPOSE:** An initial visit was conducted to Mekelle, Ethiopia and Shanghai, China to discuss potential opportunities for collaboration between the St. Louis College of Pharmacy (STLCOP) and Mekelle University College of Health Sciences (CHS) School of Pharmacy (SOP) and Fudan University School of Pharmacy (SOP).

**METHODS:** One STLCOP faculty member each visited Mekelle University CHS SOP and Fudan University SOP in Spring of 2013. Discussions with current clinical pharmacists and faculty members centered around ways for further clinical pharmacy development, and parameters for implementing APPE student exchange programs.

**RESULTS:** Major outcomes identified as shared points of interest include: establishing a faculty exchange/sharing program, Advanced Pharmacy Practice Experience (APPE) rotation sites for students and a distance learning/educational series between STLCOP and the two schools of pharmacy. Basic clinical pharmacy services have been established with the associated hospitals near the SOPs. Services currently involve daily hospital rounds involving pharmacists and students. Cultural activities at Fudan University help round out APPE student experiences which include observing practices of traditional Chinese medicine (herbal medicine, coining, cupping, acupuncture) at hospital based integrative medicine clinic.

**CONCLUSION:** This is a prime example of how US clinical pharmacy skills can be greatly utilized to advance global health initiatives. Based upon the relationships between these international pharmacy schools, there are plans for STLCOP APPE students and faculty members to return to Mekelle and Fudan University to further develop the relationships by increasing integration of interdisciplinary care teams in more specialized medical units. This will enhance both the quality of patient care provided and the educational experience for nursing, medical, and pharmacy students, and medical residents. One major limitation associated with this discussion is that only one School of Pharmacy was visited in each country, and may not be fully representative of the other Schools of Pharmacy in those countries.

**255. A clinical decision support system facilitates appropriate prescribing and monitoring of epoetin alfa in the inpatient setting.**

*Danny McNatty, Pharm.D., MHA, BCPS*, Ephu Yip, Pharm.D., Denise Erickson, Pharm.D., BCPS; Banner Health, Phoenix, AZ

**PURPOSE:** A clinical decision support system (CDSS) that restricts orders for epoetin alfa (EPO) to appropriate indications and encourages patient monitoring will align use of this agent with evidence-based practice.

**METHODS:** A CDSS consistent with guideline and manufacturer recommendations for use of epoetin alfa was recently implemented. A pre-post analysis of patients who received EPO at one of three facilities between August 1, 2011 – October 31, 2011 (pre-CDSS) and August 1, 2012 – October 31, 2012 (post-CDSS) was performed. Indication for EPO, hemoglobin, ferritin, and orders for iron supplementation were collected for each patient. Indication for use, administration when contraindicated for



hemoglobin greater than 11 g/dL, orders for iron studies, and orders for iron supplementation were compared between the pre- and post-CDSS groups.

**RESULTS:** A total of 388 patients in the pre-CDSS period and 313 patients in the post-CDSS period received EPO. Patients in the post-CDSS group were significantly less likely to receive EPO when contraindicated for hemoglobin greater than 11 g/dL (0% versus 14%;  $p < 0.001$ ). Patients in the post-CDSS group were significantly more likely to have iron studies ordered (56% versus 25%;  $p < 0.001$ ). The rate of iron supplementation when iron studies revealed a low ferritin was similar between groups (54% versus 52%,  $p = 0.8$ ). Total doses administered fell by 20% in the post-CDSS period, resulting in a combined drug acquisition cost reduction of 19% (\$19,672) for the three facilities.

**CONCLUSION:** The implementation of a CDSS for EPO increased orders for iron studies, reduced doses received when contraindicated for Hgb  $> 11$  g/dL, and lowered total use of this agent. The CDSS had no effect on orders for iron supplementation.

**256. Residency program implementation through a community-based research program.** Leigh Ann Ross, PharmD, BCPS<sup>1</sup>, Lauren S. Bloodworth, PharmD, BCPS<sup>1</sup>, Justin J. Sherman, M.C.S., Pharm.D.<sup>2</sup>, Laurie Warrington, PharmD, BC-ACP<sup>1</sup>, Ashley W. Ellis, Pharm.D., BCACP<sup>3</sup>; (1) University of Mississippi School of Pharmacy, Jackson, MS (2) The University of Mississippi School of Pharmacy, Jackson, MS (3) University of Mississippi, University, TN

**PURPOSE:** To describe an innovative approach to the development of a new Post-Graduate Year 1 (PGY-1) Residency Program.

**METHODS:** The University of Mississippi School of Pharmacy (UM SOP) implemented a Community-Based Research Program in 2008. The first project which laid the foundation for the CBRP was the Delta Pharmacy Patient Care Management Project (Delta Project). The Delta Project focuses on the implementation of Medication Therapy Management services in community pharmacies, Federal and private provider clinics, and an employer-based setting in the underserved 18-county Mississippi Delta region. One goal of this project is to increase access to care. In addition to beginning new pharmacy services, the research team outlined a specific objective to increase the number of residency-trained providers for the community setting. In 2009, with financial support from this project and a partner community pharmacy, the UM SOP implemented a PGY-1 Community Pharmacy Residency Program CPRP.

**RESULTS:** The CPRP was supported in the initial year through a regional organization with funding from Health Resources and Services Administration (HRSA) and accepted the first resident in July 2009. The CPRP is structured with longitudinal experiences in community pharmacy practice, patient-centered medical home, academics, research, practice management, and community-based research. This initial funding allowed for implementation of the program and demonstrated to School of Pharmacy administration the impact of a residency program in this underserved area. With these results, the School of Pharmacy approved an additional residency position in 2010, and the program received full accreditation for a six-year cycle in 2011.

**CONCLUSIONS:** Pharmacy may benefit from exploring innovative funding mechanisms for residency programs as the demand for additional residency positions increases. As grant opportunities arise, incorporating this objective into project proposals for education or research purposes may provide additional opportunities to expand residency positions.

## Pharmacoeconomics/Outcomes

**257. Erythropoietin stimulating agent use during transitions in care.** Jeff Hurren, PharmD<sup>1</sup>, Michael Palmer, RPh<sup>2</sup>, Anthony Elias, PharmD<sup>3</sup>, Michelle Dehoorne-Smith, PharmD<sup>2</sup>; (1) Department of Pharmacy Services, St John Hospital & Medical Center, Detroit, MI (2) St John Hospital & Medical Center, Detroit, MI (3) University of Michigan, Ann Arbor, MI

**PURPOSE:** Erythropoietin stimulating agents (ESA) have garnered increasing attention in the past few years due to an increase in safety concerns. At the same time, these agents continue to comprise a large portion of inpatient pharmacy budgets. Therefore, some have questioned their value in terms of both safety and efficacy, relative to their cost. The purpose of this study was to evaluate the effect of an institutional policy which modified ESA use, including data on both patient outcomes and financial impact. The policy changed the preferred ESA at St John Hospital & Medical Center from erythropoietin to darbepoetin. A number of other changes also took effect, including a delay-to-administration for some patient groups. For those chronically receiving ESAs as an outpatient, administration would commence on day 7 of the admission. There is a provision for earlier administration in some situations.

**METHODS:** A retrospective chart review was undertaken, utilizing pre-conversion and post-conversion data. Patients were identified via the pharmacy dispensing database. Patient information was retrieved from the electronic medical record and included hemoglobin at admission and discharge, transfusion rate, as well as other clinical information. Financial data collected included ESA purchase history during the study period.

**RESULTS:** A total of 289 patients were included over a 7-month period. Patients were similar at baseline, with the exception of length of stay ( $p = 0.008$ ) which was expected to be longer in the darbepoetin group. The proportion of doses given on day  $\geq 7$  of admission increased from 19% to 44% ( $p < 0.001$ ) during the study period. No differences were noted in change in hemoglobin or transfusion rate during the admission (NSS, for both). The decrease in ESA purchases was \$16,393 per month, corresponding to roughly \$197,000 per year.

**CONCLUSIONS:** The policy has had a positive effect on hospital finances, without decreasing quality of patient care.

**258E. Impact of regular molecular monitoring on tyrosine kinase inhibitor therapy adherence in chronic myelogenous leukemia in the chronic phase.** Annie Guérin, MSc<sup>1</sup>, Lei Chen, MD, PhD<sup>2</sup>, Eric Q. Wu, PhD<sup>1</sup>, Katherine Dea, MSc<sup>1</sup>, Stuart L. Goldberg, MD<sup>3</sup>; (1) Analysis Group Inc., Boston, MA (2) Oncology US CD & MA, Novartis Pharmaceuticals Corporation, East Hanover, NJ (3) Division of Leukemia, John Theurer Cancer Center at Hackensack University Medical Center, Hackensack, NJ

**PURPOSE:** The National Comprehensive Cancer Network and the European LeukemiaNet recommend molecular monitoring every 3 months by quantitative polymerase chain reaction (qPCR) of BCR-ABL mRNA transcripts using the International Scale. They also recommend evaluation of treatment adherence in patients not responding to treatment. This study assessed treatment adherence associated with frequency of molecular monitoring in Philadelphia chromosome-positive (Ph+) chronic-phase chronic myelogenous leukemia (CML-CP) patients receiving first-line tyrosine kinase inhibitor (TKI) therapies in the community setting.

**METHODS:** Two U.S. administrative claims databases were combined (01/2000–06/2012) to identify adult CML patients initiated on TKIs. Patients were followed for 12 months from their first TKI prescription and categorized into 3 cohorts based on frequency of qPCR tests (0, 1–2, 3–4). Using multivariate regression models adjusted for confounding factors, proportion of days covered (PDC) and medication possession ratio (MPR) were compared between cohorts. In a sensitivity analysis, regression models were also adjusted for the number of oncology outpatient visits not due to routine molecular monitoring.

**RESULTS:** Among 1,205 CML patients evaluated, 41.0% had no qPCR test, 31.9% had 1–2 tests, and 27.1% had 3–4 tests over the 12-month study period. Patients with 3–4 tests had significantly higher mean PDC (85.1 vs 76.6; adjusted difference [95% CI]: 8.8 [5.6, 12.0];  $p < 0.001$ ) and MPR (95.1 vs 86.0; adjusted difference: 9.8 [95% CI: 5.5, 14.0];  $p < 0.001$ ) compared to patients with no qPCR test. Results were consistent in the sensitivity analysis when also adjusting for the number of oncology outpatient visits. There were no statistically significant

differences between patients with 1–2 tests and those with no tests.

**CONCLUSION:** A possible explanation of the observed effect includes identification of nonresponders, which fosters targeted discussions about adherence. Regular qPCR testing per guidelines potentially improves patient adherence, promoting the delivery of quality care for Ph+ CML-CP patients on TKI therapies. Presented at 2013 American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2, 2013; abstract 7093.

**259E. Reducing total healthcare costs by shifting to outpatient (OP) settings of care for the management of gram + acute bacterial skin and skin structure infections (ABSSSI).** Alexandra Khachatryan, MPH<sup>1</sup>, Varun Ektare, MPH<sup>1</sup>, Mei Xue, MBA<sup>1</sup>, Michael W. Dunne, MD<sup>2</sup>, Kenneth E. Johnson, PharmD<sup>3</sup>, Jennifer M. Stephens, PharmD<sup>1</sup>; (1)Pharmerit International, Bethesda, MD (2)Durata Therapeutics, Inc., Branford, CT (3)Corporate Medical Affairs, Durata Therapeutics, Inc., Chicago, IL

**PURPOSE:** Rising healthcare costs and financial penalties have necessitated treatment strategies for ABSSSI that avoid hospital admissions and reduce length of stay (LOS), hospital acquired infections (HAIs), and readmissions. Providing parenteral antibiotic therapy in OP settings provides an opportunity to shift care outside the hospital to free hospital beds and reduce additional LOS from HAIs. This analysis estimated, from a US payer perspective, cost offsets of treating gram+ ABSSSIs with varied hospital LOS followed by OP care.

**METHODS:** Economic drivers of care were estimated using a literature-based economic model incorporating inpatient (IP) and OP components. The model incorporated equal efficacy, adverse events (AE), resource use, and costs from literature and public sources. Once and twice daily OP infusions to achieve a 14-day treatment were tested to determine cost offsets shifting IP days to OP days. Sensitivity analyses were performed. Costs were adjusted to 2012 US\$.

**RESULTS:** Total non-drug medical cost for ABSSSI ranged from \$8,790–\$15,968 for 3 and 7 days IP, respectively, while treatment entirely OP to avoid admission ranged from \$3,692–\$4,353. IP medical costs included IP bed-day (\$1853) and AE costs (\$343). OP care included either daily home care (\$194) or infusion center fee (\$154), PICC line with fluoroscopy (\$786), PICC complications (\$188), labs (\$102), and physician visit (\$222) for evaluation of ABSSSI. IP vs OP cost breakdown was: 3 days IP (\$5,902)/11 days OP (\$2,888–\$3,429); 7 days IP (\$13,314)/7 days OP (\$2,273–\$2,654). Sensitivity analyses revealed OP cost drivers to be IV days, infusion/OP care costs, and PICC costs versus LOS, bed-day cost, and IV days for IP drivers.

**CONCLUSIONS:** Shifting ABSSSI care to OP settings may result in cost savings up to 44%, with potential to prevent HAIs. Typical OP scenarios represent ~33% of total medical cost, with PICC accounting for 28–43% of OP burden. Value of new ABSSSI therapies will be driven by eliminating need for PICC line and ability to reduce/avoid hospital days.

Presented at Presented at the 18th Annual Meeting of International Society for Pharmacoeconomics and Outcomes Research, New Orleans, LA, May 18–22, 2013

**260. Cost trade-off analysis of bupivacaine liposome injectable suspension in a community hospital setting.** Jodie Pepin, PharmD<sup>1</sup>, Robert Wright, PharmD<sup>2</sup>; (1)Department of Pharmacy, Seton Medical Center Williamson, Round Rock, TX (2)Department of Pharmacy, Seton Medical Center Austin, Austin, TX

**PURPOSE:** Bupivacaine liposome injectable suspension (BL) was approved in October 2011 for the management of postsurgical pain. BL's duration of action lasts up to 72 hours, but BL is considerably more expensive than conventional bupivacaine. The primary purpose of this retrospective cohort study was to assess the potential cost tradeoffs associated with use of BL in a "real-world" community hospital setting. Secondly, we aimed to assess the clinical effectiveness and safety of BL compared to a historical comparator.

**METHODS:** The BL cohort (n=18) included adult patients (18–89 years) that received BL at a single community hospital between October and December 2012. A historical control cohort (n=365) was identified through query of electronic databases and included all patients (18–89 years) with similar DRG groupers to the BL cohort, but prior to introduction of BL at our institution (January to September 2012). Key outcomes assessed included total direct costs, length of stay, and elastomeric pump utilization. Opioid use and pain scores were collected for 72 hours post-operatively.

**RESULTS:** Total direct costs were similar between BL and control patients. Length of stay was slightly lower (6.4 versus 7.3 days) in BL patients versus control. The difference between actual and expected total costs for the same DRG by the same surgeons was approximately \$315 lower for BL patients compared to historical controls. Use of BL was also associated with a substantial reduction in the use of elastomeric pumps (0% versus 22%). PCA use was higher with BL compared to control (83 versus 77%). No patients in either cohort required naloxone for reversal of opioid-related adverse events

**CONCLUSION:** Use of BL in a community hospital setting was not associated with higher overall medical costs. Other costs, including use of elastomeric pumps, PCA use, and adverse events may be important when considering the cost effectiveness of novel therapies like BL.

## Pharmacogenomics/Pharmacogenetics

**261. Pharmacogenetically-based use of codeine in a children's hospital setting.** Kristine R. Crews, PharmD<sup>1</sup>, Cyrine E. Haidar, PharmD<sup>2</sup>, Gillian C. Bell, PharmD<sup>2</sup>, Ulrike M. Reiss, MD<sup>2</sup>, Kelly E. Caudle, Pharm.D., Ph.D<sup>2</sup>, James M. Hoffman, Pharm.D., M.S., BCPS<sup>2</sup>, Mary V. Relling, PharmD<sup>2</sup>; (1)Department of Pharmaceutical Sciences, St. Jude Children's Research Hospital, Memphis, TN (2)St. Jude Children's Research Hospital, Memphis, TN

**PURPOSE:** In 2012, the FDA issued a safety communication regarding codeine use in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnea. The communication cited reports of deaths in children who were ultrarapid metabolizers of CYP2D6, which catalyzes the conversion of codeine to morphine. In 2013, the FDA added a boxed warning to the label which includes a contraindication to codeine's use in children following tonsillectomy and/or adenoidectomy. Because codeine is an important analgesic at our hospital, we developed a therapeutic algorithm that implements pre-emptive CYP2D6 genotyping before codeine is prescribed, and restricts the use of codeine in children following tonsillectomy or adenoidectomy.

**METHODS:** Active clinical decision support was added to the electronic health record which is activated when codeine is ordered. An order for codeine is not permitted for patients following tonsillectomy or adenoidectomy. When ordering codeine for other indications, in patients not yet genotyped for CYP2D6, an on-screen alert is issued to remind the prescriber to order a CYP2D6 genotype. The alert provides alternate choices for therapy until a CYP2D6 result is returned. Recommended alternatives include non-opioid pain relievers, morphine, hydromorphone and the combination product of acetaminophen/hydrocodone. When CYP2D6 status is known, an on-screen alert is issued if codeine is prescribed to CYP2D6 ultrarapid metabolizers stating the increased risk of side effects; if codeine is prescribed to CYP2D6 poor metabolizers an alert indicates the increased risk of poor pain control. This pharmacogenetically-based therapeutic algorithm was approved by both the Pharmacogenetics Oversight and Pharmacy and Therapeutics Committees.

**RESULTS:** The use of codeine at St. Jude is now limited to patients with CYP2D6 extensive or intermediate metabolizer status.

**CONCLUSION:** Implementation of CYP2D6 pharmacogenetics, along with customized clinical decision support, allowed us to preserve codeine on the formulary, limiting its use to those most likely to tolerate it and to benefit from it.

**262. Development of a novel PGY2 pharmacogenomics and drug information residency in a personalized medicine program.** *Aniwa Owusu Obeng, Pharm.D.<sup>1</sup>, Kristin Weitzel, Pharm.D., CDE, FAPhA<sup>2</sup>, Julie Johnson, Pharm.D., BCPS, FCCP, FAHA<sup>2</sup>; (1)UF Health Personalized Medicine Program; Department of Pharmacotherapy and Translational Research, Center for Pharmacogenomics, University of Florida, Gainesville, FL (2)UF Health Personalized Medicine Program; Department of Pharmacotherapy and Translational Research, Center for Pharmacogenomics; University of Florida, Gainesville, FL*

**PURPOSE:** We describe a novel post-graduate year two (PGY2) Pharmacogenomics and Drug Information residency within an academic medical center-based Personalized Medicine Program (PMP).

**METHODS:** The UF Health PMP launched in June 2012 with a pilot CYP2C19–clopidogrel initiative in the cardiac catheterization laboratory. The first PGY2 Pharmacogenomics and Drug Information resident began in July 2012. Within the area of clinical implementation of pharmacogenomics initiatives, the resident coordinated literature evaluation for drug-gene pairs, served as a liaison between PMP and UF Health Pharmacy and Therapeutics committees, developed and assisted with implementation of clinical decision support tools within the EPIC electronic medical record, supported implementation of therapeutic changes in patients at risk for adverse events, and tracked quality improvement measures of PMP initiatives.

**RESULTS:** As of June 3, 2013, a total of 987 patients have been genotyped within the pilot clopidogrel–CYP2C19 initiative. In addition to assisting with development and implementation of this effort, the resident led evidence-driven revisions of the CYP2C19–clopidogrel protocol and review of other CYP2C19 substrates for potential clinical implementation. The resident was also instrumental in spearheading new drug-gene pair initiatives, including codeine use based on CYP2D6 genotype and genotype-guided thiopurine therapy. For the 2013–2014 residency year, the PMP program will continue to expand and has successfully filled two open PGY2 residency positions that have further been focused in the area of pharmacogenomics. The current resident has been recruited for employment as a clinical pharmacogenomics specialist in other large health-systems.

**CONCLUSION:** The resident has had a significant role in development and implementation of the UF Health PMP and has participated in an innovative training and practice environment. This residency training model has been mutually beneficial for the academic medical center, the residency program, and the PMP.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**263E. A study to evaluate the safety, tolerability, and pharmacokinetics of multiple weekly doses of intravenous dalbavancin in healthy subjects.** *Michael W. Dunne, MD<sup>1</sup>, Craig Sprenger, MD<sup>2</sup>, Susan Moriarty, MD<sup>1</sup>; (1)Durata Therapeutics, Inc., Branford, CT (2)PRACS, Fargo, ND*

**PURPOSE:** The long half-life and once-weekly dosing of dalbavancin, an investigational lipoglycopeptide, may provide an attractive option for the treatment of gram-positive infections that require prolonged durations of antimicrobial therapy. This study was an open-label, multiple-dose, safety, tolerability, and PK study of increasing dosing durations.

**METHODS:** The total sample size for this study was 18 asymptomatic, non-smoking adult volunteers divided into 3 dosing cohorts of 6 subjects each. All subjects received 1000 mg IV on Day 1. Cohort 1 received subsequent 500 mg IV doses on Days 8, 15 and 22; Cohort 2 received additional doses on Days 29 and 36; and Cohort 3 received additional doses on Days 43 and 50. Drug was administered intravenously over 30 minutes. Standard safety parameters were monitored throughout the study.

**RESULTS:** For the dalbavancin 500 mg IV dose given on the last day of dosing, the  $AUC_{0-\tau(ss)}$  ( $\mu\text{g}\cdot\text{h}/\text{mL}$ ) was 10202.82, 12992.79 and 12173.30 and the  $C_{max}$  was 160.00, 187.00 and 179.67 in Cohorts I, II and III respectively. The calculated elimination

curve reflected the beta ( $\beta$ )  $T_{1/2}$  of 99 to 109 hours.  $>$  Steady state was achieved by Day 8 with no observable accumulation. No serious AEs were reported over the course of this study. The most common treatment emergent AE reported was mild pain in the extremity without evidence of thrombophlebitis ( $n=2$  subjects). No subject withdrew or was discontinued from the study. No laboratory abnormality was attributed to dalbavancin.

**CONCLUSIONS:** Dalbavancin was well tolerated when administered IV as an initial dose of 1000 mg followed by 500 mg weekly doses for a total of up to 8 weeks.

Presented at 23rd Annual European Congress of Clinical Microbiology and Infectious Diseases, Berlin, Germany, April 27–30, 2013

## Psychiatry

**264. Impact of pharmacist educational in-service on psychotropic medication polypharmacy at a state supported living center.** *Abimbola Farinde, PharmD, MS, BCPP, CGP; Clear Lake Regional Medical Center, Webster, TX*

**PURPOSE:** Individuals with intellectual impairments, developmental delays who reside in state supported living centers, there is the potential to be placed many psychotropic medications to manage aggression, agitation, mood, or behavioral disturbances that may arise. The presence of polypharmacy can develop as a result of multiple providers prescribing without proper communication causing duplication of therapies. Clinical pharmacists have the unique opportunity to identify and resolve cases of psychotropic polypharmacy by providing continuing educational in-service on appropriate psychotropic medication prescribing. 1.Evaluate the prevalence of the prescribing psychotropic polypharmacy medications at state supported living center among psychiatrists resulting from clinical pharmacist educational in-service on the appropriateness of medication prescribing. 2.Prospectively review individualized patient charts of selected facility residents to assess frequency of psychotropic medication polypharmacy among psychiatrists pre and post clinical pharmacist educational in-service. 3.Determine the involvement of a clinical pharmacist on a psychotropic polypharmacy review committee is associated with the improvement of mental health care and utilization of psychotropic medications at state supported living facility.

**METHODS:** The involvement of a clinical pharmacist on a psychotropic polypharmacy committee will be utilized as the platform for evaluating the prevalence of polypharmacy prescribing among the facility's psychiatrists. This study will involve the prospective examination of psychotropic medication prescribing in the aftermath of a clinical pharmacist's educational in-service given to psychiatrists on the appropriateness of psychotropic medication prescribing. The study will follow prescribing patterns of psychiatrists over the span of 6 months and assess frequency of psychotropic polypharmacy as identified by the review of residents' medication regimens.

**RESULTS:** The results are pending analysis.

**CONCLUSION:** The study will report the number of psychotropic polypharmacy pre and post educational in-service. In addition, the study report the frequency of psychotropic medication polypharmacy and associated cost-saving that are identified during the six month observation phase.

## Pulmonary

**265. Saxagliptin as add-on to Metformin+ Sulfonylurea in patients with type 2 diabetes: outcomes stratified by baseline glycated hemoglobin and patient characteristics.** *Jodey Given, Ph.D.*

**PURPOSE:** To assess saxagliptin (SAXA) efficacy based on age, race, baseline glycated hemoglobin (A1C), or body mass index (BMI) in patients with type 2 diabetes inadequately controlled with metformin (MET)+sulfonylurea (SU).

**METHODS:** A post hoc analysis was performed with data stratified by patient age ( $<65$  year,  $\geq 65$  year), race (white vs Asian),



baseline A1C (<8%, 8%–<9%, ≥9%), and BMI; (<30 kg/m<sup>2</sup>, ≥30 kg/m<sup>2</sup>) from a placebo (PBO)-controlled 24 week, phase 3b trial in patients receiving MET+SU and randomized to SAXA 5 mg/d or PBO (NCT01128153).

**RESULTS:** Across categories of age (interaction p value=0.40), race (p=0.36), baseline A1C (p=0.12), and BMI (p=0.99), A1C (baseline A1C, 7.45%–9.53%) was reduced more with SAXA vs PBO (Table). Adverse events were comparable across treatment groups and categories and were reported by 58%–85% of patients. Symptomatic confirmed hypoglycemia (fingerstick glucose ≤50 mg/dL) was reported by 2 Asian patients receiving SAXA, with baseline A1C <8% and BMI <30 kg/m<sup>2</sup>.

**CONCLUSIONS:** When added to MET+SU, SAXA improves A1C across categories of age, race, baseline A1C, and BMI and is generally well tolerated.

Category	A1C, %		
	Adjusted Mean Change (SE) From Baseline at Week 24		Difference vs PBO (95% CI)
	SAXA+ MET +SU	PBO+ MET +SU	
			SAXA–PBO
Age			
<65 year	–0.78 (0.08)	–0.08 (0.09)	–0.71 (–1.00, –0.41)
≥65 year	–0.60 (0.16)	–0.09 (0.14)	–0.51 (–1.04, 0.03)
Race White	–0.48 (0.21)	0.08 (0.21)	–0.56 (–0.95, –0.18)
Asian	–0.99 (0.20)	–0.24 (0.19)	–0.75 (–1.09, –0.40)
Baseline A1C			
<8%	–0.58 (0.12)	0.02 (0.11)	–0.60 (–1.04, –0.15)
8%–<9%	–0.70 (0.12)	–0.15 (0.12)	–0.55 (–1.03, –0.08)
≥9%	–1.13 (0.15)	–0.10 (0.16)	–1.03 (–1.64, –0.42)
BMI <30 kg/m <sup>2</sup>	–0.73 (0.10)	–0.06 (0.10)	–0.67 (–1.01, –0.33)
≥30 kg/m <sup>2</sup>	–0.77 (0.12)	–0.10 (0.11)	–0.66 (–1.05, –0.27)

## Substance Abuse/Toxicology

**266. Clinical pharmacy services: interpreting toxicology laboratory results.** Anne DePriest, Pharm.D., BCPS, Julie Knight, Pharm.D., Brandi Puet, Pharm.D., Katie Miller, Pharm.D., David Black, Ph.D., D-ABFT; Aegis Sciences Corporation, Nashville, TN

**PURPOSE:** Drug testing for chronic pain patients has become a standard in recent years. However, practitioner understanding of test results has been demonstrably lacking in published studies. If test results are not properly interpreted then noncompliance, possible diversion, and substance abuse or misuse may be missed or misidentified. Such results may adversely impact healthcare costs and patient outcomes.

**METHODS:** A team of clinical pharmacists tracked 3,940 consults for toxicology result interpretation which originated from practitioners treating patients with chronic pain over a period of 17 months.

**RESULTS:** The top 10 topics were identified as follows: which licit or illicit medications could have caused an unexpected positive result (17.4%); reasons for detecting parent drug in urine in absence of tested metabolite(s) (10.4%); evaluation of unexpected or potential false negative results (8.6%); accuracy of the testing method used, whether mass spectrometry-based laboratory testing or immunoassay performed at the point-of-care (8.4%); potential unexpected positives due to metabolism of prescribed drugs (8.2%); period of detection (7.0%); interpretation of amphetamine or methamphetamine positives (6.4%); reference ranges for specimen type tested (5.5%); and potential false positive findings (5.3%). Discussion for these topics will be presented.

**CONCLUSION:** Pharmacists with knowledge of toxicology laboratory testing methods, drug pharmacokinetics, and drug disposition in various specimen types may offer interpretive assistance to practitioners conducting drug testing as part of routine compliance assessment. As abuse of prescription drugs has reached epidemic proportions and drug testing becomes necessary in both chronic pain management and primary care, pharmacists may offer a unique contribution to the implementation of these patient care services.

## Transplant/Immunology

**267. Safety and efficacy of outpatient administration of subcutaneous alemtuzumab in lung transplant recipients: a single center experience.** Mike Latran, PharmD<sup>1</sup>, Michael Duncan, MD<sup>2</sup>, Chadi Hage, MD<sup>2</sup>, David Roe, MD<sup>2</sup>; (1) Pharmacy, IU Health Methodist Hospital, Indianapolis, IN (2) IU Health Methodist Hospital

**PURPOSE:** Alemtuzumab (ALM) has been described as a treatment option for acute cellular rejection (ACR) and bronchiolitis obliterans syndrome (BOS) in lung transplant recipients. However, it may be associated with significant infusion related reactions when administered intravenously. Subcutaneous administration minimizes these adverse reactions. Induction with subcutaneous ALM (sALM) has been described but no data exists describing its use as a treatment option for ACR or BOS in the outpatient setting. The purpose of this study was to assess the safety and efficacy of outpatient sALM in lung transplant recipients.

**METHODS:** This was a retrospective single center study. All lung transplant recipients with biopsy proven ACR, presumed ACR, or BOS who received outpatient sALM 30 mg between 9/1/2011 and 3/31/2013 were included. Outcomes analyzed included number of admissions at 7 and 30 days post sALM, cause of admission, and the average biopsy scores (ABS) before and after treatment.

**RESULTS:** A total of 22 patients were included. Two (9.1%) patients were admitted at 7 days and 5 (22.7%) patients were admitted at 30 days. Fever was the cause of admission for both patients admitted at 7 days post sALM. Infectious related symptoms were the cause of admission for 3 out of 5 patients admitted at 30 days. No patients experienced significant administration reactions. No patients died at 30 days or during hospital admission. Table 1 shows that ABS significantly improved (n=12).

Table 1

Biopsy	Before	After	p-value
Grade A	1.88 (0.34)	0.42 (0.79)	0.0005
Grade B	0.75 (0.58)	0.5 (0.52)	0.2750
Grade A + B	2.63 (0.72)	0.92 (0.9)	0.0007

\*Data presented as mean (standard deviation)

**CONCLUSION:** Outpatient sALM administration was safe in patients treated for ACR or BOS in this cohort of lung transplant recipients. sALM was associated with a significant improvement in ABS in patients treated for ACR. sALM provided a unique and convenient treatment option.

## Women's Health

**268. Development and review of an interprofessional bone health program.** Sarah M. Westberg, Pharm.D., BCPS<sup>1</sup>, Sharon S. Allen, MD, Ph.D.<sup>2</sup>, Erin Kraemer, Pharm.D. pending 2014<sup>3</sup>; (1) University of Minnesota College of Pharmacy, Minneapolis, MN (2) University of Minnesota School of Medicine, Family Medicine and Community Health, Minneapolis, MN (3) University of Minnesota College of Pharmacy

**PURPOSE:** The purpose of this clinical service is to provide women with osteopenia or osteoporosis with thorough education regarding the disease state and the various treatment options. The patient's bone health is evaluated by the physician, and the pharmacist then presents this patient with the medications available. This inter-professional and patient-centered approach allows the patient to make a well informed, collaborative decision about her treatment supported by both her physician and pharmacist.

**METHODS:** Enrollment of patients into this clinical service has been ongoing for the past two years. Patients are eligible for the service if they are being seen at the University of Minnesota's Women's Health Specialists Clinic and if they have a new or existing diagnosis of osteopenia or osteoporosis. These patients are seen by the Family Medicine physician for an intake evaluation then referred to the pharmacist to establish a treatment plan through a collaborative practice agreement. The treatment option

agreed upon by the patient and pharmacist is communicated to the physician, along with justification of the choice when appropriate.

**RESULTS:** Since the initiation of this inter-professional service, the program has provided approximately 70 women with individualized treatment plans. Today, of these 70 women, 25 (36%) are postponing treatment, 16 (23%) are treated with Prolia, 12 (17%) are treated with a bisphosphonate, 11 (16%) are treated with Forteo, 5 (7%) are taking an intentional drug holiday, and 1 (~1%) is treated with raloxifene. Clinical outcomes in terms of treatment efficacy are not yet available, but patient retention in the program, and adherence to medications selected, if any, remains high.

**CONCLUSIONS:** This inter-professional clinical service is providing women with treatment plans that are not only agreed upon by the patient, physician, and pharmacist, but are tailored to meet the unique needs of individual women.

## Residents and Fellows Research in Progress

### Adult Medicine

**269. Factors associated with time in therapeutic INR range in patients with left ventricular assist devices anticoagulated with warfarin.** Lydia Newsom, PharmD<sup>1</sup>, Kathryn M. Momary, PharmD, BCPS<sup>2</sup>, Christopher Paciullo, PharmD<sup>3</sup>; (1)Department of Pharmaceutical Sciences, Emory University Hospital, Atlanta, GA (2)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA (3)Department of Pharmaceutical Services, Emory University Hospital, Atlanta, GA

**PURPOSE:** Left ventricular assist devices (LVADs) are becoming a more common therapeutic option for end stage heart failure. Modern LVADs such as the Heartmate II or Heartware devices require pharmacologic anticoagulation in combination with antiplatelet therapy to protect against device thrombosis or thromboembolism. However, these devices also induce a simultaneous coagulopathy, complicating anticoagulation management. The optimal anticoagulation of LVAD patients remains unclear and the literature provides little guidance for the use of warfarin in LVAD patients. The purpose of this study is to characterize patient specific factors associated time in therapeutic INR range (TTR) in patients with LVADs anticoagulated with warfarin. To our knowledge, no study to date has evaluated factors affecting warfarin therapy in this complex patient population.

**METHODS:** A retrospective chart review was performed for patients implanted with a Heartmate II or Heartware LVAD at Emory University Hospital between 1/1/2007 and 6/31/2012 and who received warfarin at discharge. Patients less than 18 years of age with a mechanical heart valve, documented bleeding disorder, end stage liver or kidney disease, or outpatient INR follow up of less than 70 days were excluded. Six months of INR data following warfarin initiation was collected and percent TTR was calculated. Patients were divided into two groups: TTR >60% and TTR ≤60%. Clinical characteristics and interacting medications were compared between groups using Chi-squared analysis and Student's t-test.

**RESULTS:** Preliminary findings (n=45) suggest that a history of left ventricular thrombus may be associated with an increased TTR (32% versus 4%, p=0.022). Similarly, a decreased platelet count ( $118 \pm 51.7$  versus  $156 \pm 66.8 \times 10^3$  cells, p=0.041) and increased alkaline phosphatase at the time of warfarin initiation was also associated with an increased TTR ( $57.0 \pm 37.5$  versus  $32.7 \pm 27.6$  units/L, p=0.017).

### Ambulatory Care

**270. Development and evaluation of clinical pharmacy technician roles in a safety net organization.** Janet Cho, Pharm.D., Steven Chen, PharmD, FASHP, FCSHP; School of Pharmacy, University of Southern California, Los Angeles, CA

**PURPOSE:** Health reform priorities emphasize efficiency and practice at the highest scope allowed for every member of the

healthcare team. Clinical pharmacists providing comprehensive medication management services in the ambulatory care setting are often encumbered by tasks that require little to no clinical skills or knowledge. Some of these tasks include filling medication boxes, scheduling follow up or laboratory appointments, and managing paperwork for medication assistance programs. If a non-clinician – such as pharmacy technician – were trained to perform such tasks, pharmacists would have more time to provide clinical services and resolve medication-related problems. The purpose of this project is to describe the development and evaluation of clinical pharmacy technician roles within a network of safety net clinics.

**METHODS:** Clinical pharmacy technicians were trained in clerical responsibilities, basic elements of medication reconciliation, and reinforcement of medication-related device use and monitoring, performed under the supervision of a clinical pharmacist. Workshops, in addition to continuous on-site training, were organized to facilitate proficiency in these duties. Technician performance was assessed by pharmacists via quarterly competency evaluations, and surveys were distributed to the technicians to measure job satisfaction.

**RESULTS:** After the integration of clinical pharmacy technicians into the clinical pharmacy team workflow, patient volume increase by approximately 40–50%. Competency evaluations demonstrated that technician competency met and/or exceeded pharmacist expectations. Technician surveys indicated high levels of job satisfaction, particularly with respect to a 'sense of accomplishment' and 'challenge of clinical responsibilities.'

**CONCLUSION:** The addition of clinical pharmacy technicians enabled pharmacists to schedule significantly more patients for individualized care and have more time to provide clinical services for patients and the healthcare team.

**271. Implementation of a clinical pharmacist-directed hospital discharge service to improve transitions in care.** Anita Sharma, Pharm.D., Chrystian R. Pereira, Pharm.D.; University of Minnesota College of Pharmacy, Minneapolis, MN

**PURPOSE:** Establishing a systematic approach for clinical pharmacists to manage hospital discharge patients in the ambulatory care setting. Clinical pharmacy services worked collaboratively with members of the primary care team to identify, prevent, and resolve drug therapy problems in post hospitalized patients.

**METHODS:** All patients discharged from a hospital between January 2013 and May 2013 were offered a clinical pharmacist visit before their follow up visit with their medical provider. The clinic's call center or Care Coordinators would follow a script and process to sign patients up over the phone. During each visit, a clinical pharmacist reviewed the patient's medications and then identified/ resolved drug therapy problems, which were categorized into four groups: indication, effectiveness, safety, and convenience.

**RESULTS:** A total of 50 hospital discharge patients were scheduled and seen by a clinical pharmacist in the five month period. Twenty-three patients were scheduled as a follow up from the emergency room, while 27 patients were seen after being discharged from the hospital. A total of 81 drug therapy problems were identified by the clinical pharmacists. Eighty two percent of patients presented with one or more drug therapy problems. There were nine patients who did not have any drug therapy problems, many of which were ED discharges. The leading three drug therapy problems were "untreated condition," "does not understand instructions," and "needs additional monitoring."

**CONCLUSION:** Implementing a systematic clinical pharmacist intervention for post hospital discharge patients resulted in the identification of various drug therapy problems and worked towards improving overall patient care.

**272. Does pharmacist-physician collaboration in medication therapy management (MTM) improve care?.** Patrick Cogan, Pharm.D.<sup>1</sup>, Katherine Vogel Anderson, Pharm.D., BCACP<sup>2</sup>, Danielle Pierini, Pharm.D.<sup>1</sup>, Eric Rosenberg, MD, MSPH, FACP<sup>3</sup>; (1)Department

of Pharmacotherapy and Translational Research, University of Florida College of Pharmacy, Gainesville, FL (2) Department of Pharmacotherapy and Translational Research, Division of General Internal Medicine, University of Florida College of Pharmacy and Medicine, Gainesville, FL (3) Division of General Internal Medicine, UF Department of Medicine, University of Florida College of Medicine, Gainesville, FL

**PURPOSE:** This study proposes to determine the influence of pharmacist-physician collaboration on patient care in an outpatient internal medicine medication therapy management clinic (the "IMTM Clinic"). Primary objectives are to determine whether pharmacist-physician collaboration improves achievement of treatment goals, patient satisfaction, and providers' adherence to process measures.

**METHODS:** Patients who meet inclusion criteria (age 18–90 years; three or more chronic conditions; 2–8 medications) are prospectively followed for 12 months. After an initial comprehensive medication review, patients are seen or telephoned by pharmacy service at months 3, 6, 9, and 12. Recommendations regarding therapy are made at each visit, and communicated via electronic medical record to the primary care provider. Patients fill out a satisfaction survey at the first and last study visit. Data regarding medications, recommendations made by pharmacy, and recommendations accepted or declined by physicians, will be compared pre- and post-enrollment in the IMTM clinic.

**RESULTS:** Data collection is ongoing. To date, 17 patients are enrolled. Sixty eight recommendations have been made; 17 recommendations (25%) were accepted for 11 patients. Of the seven patients who have been contacted for their 3 month follow-up, 2 did not return phone calls and 1 was not able to be reached. Of the remaining four patients, 12 recommendations were made at the 3 month follow-up, of which 3 (25%) were accepted.

**CONCLUSION:** Preliminary results indicate that pharmacy recommendations are accepted infrequently. Written communication may not be sufficient to convey drug therapy recommendations. Acceptance rates may improve with face-to-face interaction between the pharmacist and physician.

## Cardiovascular

**273. Use of video technology to improve pharmacist efficiency and patient comprehension of anticoagulation education.** Sarah Johannes Moore, PharmD<sup>1</sup>, Elizabeth A. Blair, PharmD<sup>2</sup>, David Steeb, PharmD<sup>3</sup>, Brent N. Reed, PharmD, BCPS<sup>4</sup>, J. Heyward Hull, PharmD, MS<sup>3</sup>, Brett Crisp, PharmD, MS<sup>1</sup>, Neelu Patil, PharmD, BCPS<sup>1</sup>, Jo E. Rodgers, PharmD, FCCP, BCPS (AQ Cardiology)<sup>5</sup>; (1) Department of Pharmacy, University of North Carolina Healthcare, Chapel Hill, NC (2) Division of Pharmacotherapy and Experimental Therapeutics, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC (3) University of North Carolina, Eshelman School of Pharmacy, Chapel Hill, NC (4) Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC (5) Division of Pharmacotherapy and Experimental Therapeutics, Eshelman School of Pharmacy, University of North Carolina

**PURPOSE:** The Joint Commission's National Patient Safety Goal 03.05.01 requires education of all patients being discharged on anticoagulant therapy. This study compared the impact of video technology versus face-to-face counseling on both pharmacist efficiency and patient comprehension of warfarin therapy.

**METHODS:** Forty adult patients requiring discharge education for warfarin therapy (n=20 new start, n=20 restart) were prospectively randomized to receive education by pre-recorded video (intervention) or face-to-face (control). Both groups received teach-back questions. Randomization was blocked to minimize assignment imbalance. Duration of pharmacist time spent with each patient was collected and the Oral Anticoagulation Knowledge (OAK) Test was administered at baseline, immediately following, and 7-days following education. The primary endpoint was the duration of pharmacist time spent with the patient. A secondary endpoint was patient comprehension at 7 days. Both endpoints will be adjusted for prior therapy status and predictors of

comprehension (e.g., education, socioeconomic status) using analysis of covariance Patient comprehension also will be adjusted for baseline. Based on only the endpoint pharmacist time, forty patients provided 85% power to detect a difference of 5 minutes, assuming a SD of 5 minutes (alpha 0.05).

**RESULTS:** Patient recruitment is ongoing with 12 new starts and 20 restarts enrolled. To date, for new starts, unadjusted duration of pharmacist time was reduced (mean  $\pm$  SD 14.6  $\pm$  5.7 minutes vs. 7  $\pm$  2.9 minutes) and restarts, (12.7  $\pm$  2.7 minutes vs. 4  $\pm$  1.9 minutes) in the control and intervention groups, respectively. OAK Test results (see table) demonstrate improved comprehension in all groups, but with differing baselines.

New Start (n=12)	Pre-recorded Video (% n=15)	Face-to-Face (% n=17)
Baseline	46 $\pm$ 20	59 $\pm$ 18
Immediately Post-Education	65 $\pm$ 17	66 $\pm$ 20
7-Day Follow Up	73 $\pm$ 20	80 $\pm$ 47
Restart (n=20)		
Baseline	64 $\pm$ 14	60 $\pm$ 25
Immediately Post-Education	75 $\pm$ 11	70 $\pm$ 26
7-Day Follow Up	81 $\pm$ 38	85 $\pm$ 48

**CONCLUSION:** While video technology appears to improve pharmacist efficiency, preliminary results suggest that comprehension may or may not be comparable.

**274. Health related quality of life in Hispanic versus non-Hispanic White congestive heart failure patients and their relationship to hospital admissions and emergency department visits.** Stanley Snowden, Pharm.D.<sup>1</sup>, Matthew Borrego, Ph.D.<sup>1</sup>, Teddy Warner, Ph.D.<sup>2</sup>, James Nawarskas, Pharm.D.<sup>1</sup>, Joe Anderson, PharmD<sup>1</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Department of Family & Community Medicine, University of New Mexico, Albuquerque, NM

**PURPOSE:** This study sought to identify potential health disparities in health related quality of life (HRQOL) between Hispanic and Non-Hispanic White heart failure (HF) patients and translate potential HRQOL differences into measurable healthcare utilization as defined by hospital admissions and emergency department visits.

**METHODS:** A medical records review of Hispanic and non-Hispanic White HF patients from the University of New Mexico Hospital HF clinic was conducted with data from February 1st, 2011 to June 30th, 2012. Healthcare utilization was assessed by a retrospective cohort design. Identified cases (self-identified Hispanic ethnicity) and controls (non-Hispanic White) were included if they had completed a Minnesota Living with Heart Failure Questionnaire (MLHFQ). Patients were followed for six months after completion of the MLHFQ for determination of healthcare utilization.

**RESULTS:** A total of 265 patients were identified for inclusion (147 cases and 118 controls). Complete data collection is available thus far for 42 patients, of which, 23 (54.8%) were of self-identified Hispanic ethnicity. There were no differences in demographic variables between the two groups. Total MLHFQ score were low but not significantly different (48.7 versus 45.4, p=.75), between Hispanic and non-Hispanic White HF patients respectively. Domain scores for physical (18.8 versus 21.2, p=.59) and emotional domains (11.0 versus 9.7, p=.64) did not differ between Hispanic and non-Hispanic White patients. HRQOL did not correlate significantly with either hospital admissions (r=.09 versus r=-.02, p=.66) or emergency department (r=.15 versus r=.32, p=.25) visits at six months in Hispanic and non-Hispanic White patients respectively.

**CONCLUSIONS:** Thus far our analysis has demonstrated Hispanic HF patients treated at University of New Mexico Hospital have a similar level of HRQOL and healthcare resource utilization as non-Hispanic White patients. Once all data has been collected the investigators will develop conceptual risk models to predict healthcare utilization in this patient population.



**275. Time to target temperature: a comparison of two therapeutic hypothermia protocols.** *Jessica Schaad, PharmD*, Michael Bentley, PharmD; Department of Pharmacy, Carilion Clinic, Roanoke, VA

**PURPOSE:** To evaluate if an adjustments made to the pharmacologic management of shivering during therapeutic hypothermia decreased time to target temperature (32–34°C).

**METHODS:** Patients treated with therapeutic hypothermia following cardiac arrest between July 2010 and October 2012 were retrospectively evaluated. Since the protocol change occurred in March 2012, patients were divided into one of two cohorts, prior to March 2012 (cohort 1 representing the retired protocol) or after March 2012 (cohort 2 representing the updated protocol). Data collection included demographics, time to target temperature, medications and dose administered hospital survival, and neurological outcome. The time required to reach target was the time difference between protocol initiation and the first temperature reading between 32–34°C. Neurological outcome was assessed using the Cerebral Performance Categories Scale.

**RESULTS:** Seventy-six patients were enrolled in the study, 38 in each cohort. The mean age was 61 years in each group. In the retired protocol group, 67% were male and 60% received early basic life support. For the updated protocol group, 60% were male and 54% received early basic life support. The average time to target temperature in the two groups were  $171 \pm 125$  minutes and  $145 \pm 112$  minutes, respectively. Patients treated with the retired protocol received an average of 6 medications to control shivering while those treated with the updated protocol received an average of 4. Fewer patients in the updated protocol survived to discharge (36.84% v 44.74%); however, all patients that did survive to hospital discharge had favorable neurological outcomes.

**CONCLUSION:** The patients treated with the updated therapeutic hypothermia protocol reached target temperature quicker than those treated with the retired protocol and received fewer medications.

**276. Short-term effects and safety of an accelerated intravenous iron regimen in patients with heart failure and iron deficiency.** Elizabeth A. Blair, PharmD<sup>1</sup>, Brent N. Reed, PharmD, BCPS<sup>2</sup>, Sarah B. Waters, ANP-BC<sup>3</sup>, Carla A. Sueta, MD, PhD<sup>4</sup>, Brian C. Jensen, MD<sup>4</sup>, Kirkwood F. Adams, Jr, MD<sup>4</sup>, Jo E. Rodgers, PharmD, FCCP, BCPS (AQ Cardiology)<sup>1</sup>; (1)Division of Pharmacotherapy and Experimental Therapeutics, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC (2)Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC (3)Center for Heart and Vascular Care, University of North Carolina Health Care, Chapel Hill, NC (4)Division of Cardiology, School of Medicine, University of North Carolina, Chapel Hill, NC

**PURPOSE:** Recent studies have demonstrated improved functional capacity and quality of life among patients with heart failure (HF) receiving intravenous (IV) iron therapy on a weekly outpatient basis. This study evaluated the short-term hematologic effects and safety of an accelerated IV iron regimen in hospitalized patients with HF and iron deficiency.

**METHODS:** In this non-randomized pilot study, hospitalized patients with HF and iron deficiency received IV sodium ferric gluconate 250 mg over two hours every 12 hours until calculated iron deficit was repleted. Patients were required to have anemia (serum hemoglobin  $\leq 12.0$  g/dL); iron deficiency was defined as ferritin  $< 100$  g/dL, or ferritin 100–300 g/dL with transferrin saturation  $< 20\%$ . Iron deficit was calculated using the Ganzoni equation. The primary endpoint was the change in hemoglobin from baseline to 1–4 weeks after final infusion. Safety assessments, including blood pressure and heart rate measurements, were performed every 15 minutes during infusions and every 30 minutes for 2 hours afterward. Patients were monitored for safety until follow-up was complete. A minimum of six patients will provide 90% power to detect a difference of 0.9 g/dL, assum-

ing a SD of 0.2 g/dL (two-sided alpha 0.025). We aim to recruit 12 patients.

**RESULTS:** Recruitment is ongoing with 11 patients enrolled. The average calculated iron deficit was  $1250 \pm 224$  mg. Hemoglobin concentrations increased from baseline to follow-up (mean  $\pm$  SD  $10.64 \pm 0.85$  g/dL to  $11.73 \pm 1.23$  g/dL, respectively). The average time to follow-up was  $12.5 \pm 6.3$  days. Common side effects during infusions included nausea and injection site pain. Common side effects during follow-up included thrombophlebitis, itching, nausea and diarrhea.

**CONCLUSION:** Preliminary results suggest an accelerated IV iron regimen in HF patients with iron deficiency may increase hemoglobin concentrations from baseline. Adverse effects were consistent with the reported safety profile of the drug.

**277. The influence of beta-blocker therapy on the hemodynamic response to intravenous inotrope in patients with acute decompensated heart failure.** Jonathan D. Cicci, PharmD, BCPS<sup>1</sup>, Ilya Danelich, PharmD, BCPS<sup>2</sup>, Brent N. Reed, PharmD, BCPS<sup>3</sup>, Elizabeth A. Blair, PharmD<sup>4</sup>, Patricia Chang, MD, MHS, FACC<sup>5</sup>, Jo E. Rodgers, PharmD, FCCP, BCPS (AQ Cardiology)<sup>6</sup>; (1)Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC (2)Department of Pharmacy, Mayo Clinic, Rochester, MN (3)Department of Pharmacy, University of North Carolina Health Care, Chapel Hill, NC (4)Division of Pharmacotherapy and Experimental Therapeutics, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC (5)Department of Medicine, Division of Cardiology, University of North Carolina Health Care, Chapel Hill, NC (6)Division of Pharmacotherapy and Experimental Therapeutics, Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC

**PURPOSE:** Studies assessing response to inotrope in the setting of beta blockade have been limited in size and design. This prospective, concurrent study compares the hemodynamic effects of dobutamine and milrinone in patients with acute decompensated heart failure at University of North Carolina Hospitals who are deemed by the healthcare team to require an inotrope trial, with or without concomitant beta-blocker therapy.

**METHODS:** Patients received dobutamine (1, 3, and 5 mcg/kg/min, titrated every 2 hours as tolerated) followed by milrinone (0.1, 0.2, 0.3, and 0.375 mcg/kg/min, titrated every 6–18 hours based on renal function as tolerated) in a stepwise manner. Thirty-five patients will provide 90% power to detect a change in Fick cardiac index (CI) of  $0.6 \pm 0.6$  L/min/m<sup>2</sup> compared to baseline (two-sided alpha 0.025). Hemodynamic parameters will be compared between patients receiving beta-blocker therapy versus patients not receiving beta-blocker therapy.

**RESULTS:** Of 19 patients enrolled, four were excluded (mean age  $56.3 \pm 17.8$  years, 78.6% male); not all patients completed each step of the inotrope trial. Twelve patients received beta-blocker and three did not receive beta-blocker. Dobutamine 5 mcg/kg/min yielded a mean ( $\pm$ standard deviation) increase in Fick CI of  $0.6 \pm 0.4$  L/min/m<sup>2</sup> in the presence of beta-blockers (n=8), compared to a mean increase of  $0.1 \pm 0.6$  L/min/m<sup>2</sup> in the absence of beta-blockers (n=2). Milrinone 0.3 mcg/kg/min yielded a mean increase in Fick CI of  $0.4 \pm 1.5$  L/min/m<sup>2</sup> in the presence of beta-blocker (n=9), compared to a mean increase of  $0.1 \pm 0.9$  L/min/m<sup>2</sup> in the absence of beta-blocker (n=2).

**CONCLUSION:** Preliminary results suggest that patients receiving beta-blocker therapy may have an improved response to inotropes compared to patients not receiving beta-blocker therapy. Patients receiving beta-blocker therapy may respond similarly to dobutamine and milrinone at comparable doses.

## Community Pharmacy Practice

**278. Assessing accuracy and impact on clinical decision-making of community-based blood pressure monitoring.** *Nicole Kitts, PharmD<sup>1</sup>, Samantha Karr, PharmD<sup>2</sup>, Mary Gurney, PhD, RPh<sup>2</sup>*; (1)Department of Pharmacy Practice, Midwestern University

College of Pharmacy – Glendale, Glendale, AZ (2) Midwestern University College of Pharmacy – Glendale

**PURPOSE:** This study examined the accuracy of community-based blood pressure monitors which are often used by patients in the community due to their accessibility. It also assessed the impact of these readings on the clinical decision-making of the primary care provider (PCP) and promoted the role of the pharmacist in managing blood pressure.

**METHODS:** Study subjects were recruited at Fry's Pharmacy in January and February 2013. A total of 51 patients were screened; 50 participants met criteria. After completion of a survey, subjects were educated about how their pharmacist could assist in achieving blood pressure control. They then had their blood pressure taken once utilizing a community-based blood pressure monitor and once utilizing a validated, automatic monitor. Each participant identified his or her PCP on the screening tool; the PCP was asked to complete a survey regarding the use of BP readings from community-based monitors.

**RESULTS:** There were significant differences between the two different monitors for both systolic blood pressure ( $p=0.006$ ) and diastolic blood pressure ( $p=0.012$ ) measurements. Recommendations for change in treatment (or initiation of blood pressure medication) would have been different for 36% of participants as only one of the two readings was above goal. In order to assess the clinical impact of these findings, surveys have been sent to identified PCPs. We anticipate results and study completion during summer 2013.

**CONCLUSION:** Based upon significant differences in blood pressure readings using a community-based blood pressure monitor, patients should be alerted to potential inaccuracies. Furthermore, pharmacists are in a key position to perform blood pressure monitoring while counseling patients on hypertension and proper blood pressure measurement.

## Critical Care

**279. Association between liver disease and QTc prolongation following antipsychotic treatment in critically ill patients.** J. Bradley Williams, Pharm.D., Cesar Alaniz, Pharm.D., Melissa Pleva, Pharm.D.; Department of Pharmacy, University of Michigan, Ann Arbor, MI

**PURPOSE:** To evaluate the potential association between liver disease and QTc prolongation in critically ill patients treated with quetiapine with or without concurrent haloperidol.

**METHODS:** The medical charts of patients admitted to the University of Michigan Hospital medical and surgical ICUs between July 2009 and June 2011 who received quetiapine (+/- haloperidol) were evaluated. Inclusion criteria were receipt of at least two doses of quetiapine and electrocardiograms (ECGs) before and after administration. Data collected included quetiapine doses, QTc interval measurements, serum electrolytes, and Child-Pugh score parameters. Changes in QTc intervals were compared between two patient cohorts, normal and impaired hepatic function.

**RESULTS:** Two patients in the control cohort ( $n=52$ ) experienced QTc interval increases of at least 60 ms from baseline versus no patients in the liver disease group ( $n=23$ ). Differences were not observed in other QTc parameters at baseline and follow up, including proportion of patients with QTc intervals greater than 500 ms and mean QTc interval lengths (liver disease group:  $465.4 \text{ ms} \pm 34.8$  versus control:  $451.1 \text{ ms} \pm 32.7$ ,  $p=0.09$  at baseline; liver disease group:  $462.6 \text{ ms} \pm 33.1$  versus control:  $447.8 \text{ ms} \pm 37.7$ ,  $p=0.11$  at follow up [mean  $\pm$  standard deviation]). Mean quetiapine doses prior to follow up ECGs were not different between the two groups (liver disease group:  $34.2 \text{ mg} \pm 13.2$  versus control:  $39.7 \text{ mg} \pm 22.4$ ,  $p=0.55$ ). The majority of patients in the liver disease cohort had either moderate ( $n=14$ ) or severe ( $n=7$ ) liver disease by Child-Pugh classification.

**CONCLUSION:** Our findings suggest that patients with impaired hepatic function are not at increased risk of QTc prolongation from use of quetiapine. Additional studies are needed to confirm these findings.

## Geriatrics

**280. Prevalence of anticholinergic medication use in the Program of All-Inclusive Care for the Elderly.** Les Covington, Pharm.D.<sup>1</sup>, Jamie McCarrell, Pharm.D.<sup>2</sup>; (1) Pharmacy Practice, Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, TX (2) Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, TX

**PURPOSE:** The Program of All-Inclusive Care for the Elderly (PACE) is a managed care program that employs an interdisciplinary team to provide all healthcare needs for participants. This study evaluated the prevalence of anticholinergic medication use in participants of the PACE program compared to that of subjects who resided within a traditional nursing home.

**METHODS:** A cross-sectional, retrospective chart review of 270 elderly (age  $\geq 65$ ) subjects in a PACE organization ( $n=146$ ) and nursing home facility ( $n=124$ ) in Amarillo, Texas was conducted on April 1, 2013. Subject demographics, medications, and institutional fall and hospitalization rates were collected. For documentation of anticholinergic medication use, the 2012 Beers Criteria and Anticholinergic Risk Scale (ARS) were utilized.

**RESULTS:** Total medication use was significantly lower in the PACE program (12.1 medications per subject vs. 20.8,  $p<0.05$ ) including anticholinergic medications (2.45% of total medications vs. 4.22%,  $p<0.05$ ) when compared to the nursing home facility. Further data analysis is pending and is expected to be completed by June 30, 2013.

**CONCLUSIONS:** PACE participants take fewer medications and are at lower risk of adverse effects from anticholinergic medications. Further data analysis is needed to assess the outcomes of falls and hospitalization rates. However, preliminary results suggest PACE participants benefit from less pill burden than individual receiving traditional nursing home care.

## Hematology/Anticoagulation

**281. The effects of recombinant activated factor VII dose on the incidence of thromboembolic events in patients with coagulopathic bleeding.** Mason Bucklin, Pharm.D., Nicole M. Acquisto, Pharm.D., Catherine Nelson, MD, Paul Bankey, MD; University of Rochester Medical Center, Rochester, NY

**PURPOSE:** The purpose of this single-center, retrospective cohort study was to determine if the dose of off-label recombinant activated factor VII (rFVIIa) affected the incidence of thromboembolic events.

**METHODS:** All adult patients that received off-label rFVIIa from 2005–2012 were included. The primary endpoint was the incidence of a thromboembolic event in the low dose ( $<50 \text{ mcg/kg}$ ) compared to the high dose ( $\geq 50 \text{ mcg/kg}$ ) cohort. Secondary endpoints compared time to thromboembolic event, incidence of arterial compared to venous events, and mortality. Relative risk was calculated for the primary endpoint with 95% confidence intervals. Other statistical tests used were two sided, and an alpha level of  $<0.05$  was considered significant.

**RESULTS:** There were 152 patients that received rFVIIa during the study period with 66 in the low dose cohort and 86 in the high dose cohort. Baseline characteristics were similar between groups, except lactate levels were higher in the high dose cohort. Mean total dose of rFVIIa was  $30.2 \text{ mcg/kg}$  ( $\text{SD} \pm 9.5 \text{ mcg/kg}$ ) in the low dose and  $99.8 \text{ mcg/kg}$  ( $\text{SD} \pm 64.7 \text{ mcg/kg}$ ) in the high dose cohort ( $p=0.0001$ ). The overall incidence of thromboembolic events was 12.5%. There were 12 (14%) events in the low dose cohort and seven (10.6%) in the high dose cohort,  $\text{RR}=0.76$  (95%  $\text{CI}$  0.31–1.82). There were no differences in any of the secondary outcomes. A higher incidence of thromboembolic events in cardiothoracic surgery (20.8%) and penetrating trauma patients (21.4%) was seen compared to the remaining cohort (6.7%).

**CONCLUSION:** No significant difference in the incidence of thromboembolic events was seen between low dose versus high dose rFVIIa over a seven year period at our institution. However, due to the relatively low overall incidence and a small sample size, type II error may be present.

## Infectious Diseases

### 282. CLINICAL impact of discordant prescribing of fluoroquinolones and alternative treatments in *E. coli* pyelonephritis.

*Minh Hong, Pharm.D.*; Texas Tech Health Sciences Center School of Pharmacy, Lubbock, TX

**PURPOSE:** To determine the impact of discordant prescribing of Fluoroquinolones (FQ) in *E. coli* pyelonephritis on hospital length of stay (LOS) and early clinical response (ECR). Previous trials have shown significant worsening in these outcomes when FQ were given to patients with resistant *E. coli* strains. A secondary objective is to compare the effectiveness of FQ, ceftriaxone, piperacillin/tazobactam (PIP/TAZO) and carbapenems in order to find an alternative for the treatment of *E. coli* pyelonephritis.

**METHODS:** Using data retrospectively collected through the institution's electronic records, we compared discordant and concordant FQ prescribing for LOS and ECR. We also compared FQ, ceftriaxone, PIP/TAZO, and carbapenems for these clinical outcomes.

**RESULTS:** There were 49 patients included in the comparison between discordant (n=9) and concordant (n=40) FQ prescribing. There was significantly lower ECR in patients with discordant FQ prescribing (95.0% versus 55.6%,  $p=0.0074$ ) and a trend toward longer LOS (3.0 + 2.0 versus 4.0 + 2.3,  $p=0.0571$ ). Illness severity, estimated using SAPS II score, was similar between groups ( $p=0.717$ ). ECR was significantly higher in the ceftriaxone group (50/53, 94.3%) than either the discordant FQ (5/9, 55.6%,  $p=0.006$ ), PIP/TAZO (15/20, 75%,  $p=0.031$ ) or the carbapenem groups (9/13, 69.2%,  $p=0.024$ ). LOS was significantly longer in the carbapenem group vs. all other groups ( $7.0 \pm 7.7$  days vs.  $3.5 \pm 3.0$  days,  $p<0.0001$ ).

**CONCLUSION:** At 18.4% discordant rate, there was a significantly decreased ECR and a trend toward increased length of stay when fluoroquinolones were used in FQ-resistant *E. coli*. Regarding alternative treatment for *E. coli* pyelonephritis, ceftriaxone was as effective as concordant FQ, and significantly better than discordant FQ. Carbapenems were shown to be inferior to both concordant FQ and ceftriaxone in the treatment of *E. coli* pyelonephritis.

### 283. Risk factors for unfavorable short-term treatment outcome in patients with invasive *Pseudomonas aeruginosa* infection.

*V. Paul DiMondi, PharmD*<sup>1</sup>, Mary Townsend, PharmD, AAHIVP<sup>2</sup>, Richard Drew, PharmD, MS, BCPS, FCCP<sup>1</sup>; (1) Duke University Hospital, Durham, NC (2) Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC

**PURPOSE:** Invasive infections with *Pseudomonas aeruginosa* (PA) are associated with significant morbidity and mortality. While risk factors for mortality have been identified, their influence on short-term outcomes impacting treatment selection has not been reported. We explored the relationship between select risk factors and short-term treatment outcomes.

**METHODS:** This IRB-approved single-center, retrospective case-cohort study included patients >18 years of age with culture-confirmed PA bacteremia and/or pneumonia receiving antimicrobial agent(s) active against PA. Outcome was categorized as either unfavorable or favorable at treatment day 5. Pre-defined risk factors were compared between groups utilizing univariate and multivariate analysis.

**RESULTS:** The population consisted of 117 patients (40 [34%] and 77 [66%] in the unfavorable and favorable groups, respectively). Baseline characteristics including age (mean of 63 years), gender (55% male), Charlson score, creatinine clearance, and body mass index were comparable between groups. Piperacillin/tazobactam was the most common monotherapy antibiotic (46% and 33% in unfavorable and favorable groups, respectively). Combination therapy primarily consisted of a beta-lactam plus ciprofloxacin in both unfavorable (10%) and favorable (20%) outcome groups. The univariate analysis indicated that SIRS, direct ICU admission, vasopressor therapy, and receipt of less than two microbiologically-active antibiotics were associated with an unfavorable outcome. Multivariate analysis revealed an inde-

pendent association of an unfavorable outcome and the following: vasopressor therapy (odds ratio [OR] 6.0; 95% confidence interval [95%CI] 2.3,17) and receipt of less than two active antibiotics (OR 3.8; [95% CI] 1.2, 14).

**CONCLUSION:** Treatment with less than two agents with activity against PA was associated with an unfavorable short-term treatment outcome in patients with bacteremia and/or pneumonia.

## Medication Safety

### 284. Pharmacist-physician collaboration in perioperative medication reconciliation: the IMPROVE clinic.

*Patrick Cogan, Pharm.D.*<sup>1</sup>, Danielle Pierini, Pharm.D.<sup>1</sup>, Katherine Vogel Anderson, Pharm.D., BCACP<sup>2</sup>, Eric Rosenberg, MD, MSPH, FACP<sup>3</sup>; (1) Department of Pharmacotherapy and Translational Research, University of Florida College of Pharmacy, Gainesville, FL (2) Department of Pharmacotherapy and Translational Research, Division of General Internal Medicine, University of Florida College of Pharmacy and Medicine, Gainesville, FL (3) Division of General Internal Medicine, UF Department of Medicine, University of Florida College of Medicine, Gainesville, FL

**PURPOSE:** This study's aims are to determine whether joint pharmacist-physician evaluation of patients in a preoperative assessment clinic improves: medication reconciliation, chronic disease medication utilization, medication adherence, and acceptance of perioperative recommendations.

**METHODS:** The pharmacist investigator contacts patients referred to the IMPROVE clinic before non-vascular, non-cardiac surgery by telephone, to collect a preoperative medication history. The physician investigator then examines the patient during a face-to-face appointment to assess chronic disease states and pre-operative risk; recommendations regarding the management of medications perioperatively are recorded in the electronic medical chart and forwarded to surgical service. Following surgery, the pharmacist sees the patient in clinic to perform postoperative medication reconciliation. When indicated, pharmacist recommendations are communicated to the physician investigator and to the patient's primary care provider.

**RESULTS:** Data collection is ongoing. Preoperative medication histories have been completed for 14 patients: 38 medications had to be added, 27 medications had to be discontinued, and 17 medications were edited to reflect the correct dose. Three patients have had surgery; documentation of directions regarding medications prior to surgery was found for 1 patient. Two patients have completed postoperative assessments: Three medications had to be added, and three medications had to be discontinued. Both patients received discharge medication lists. One patient was not given directions about which medications to resume (and therefore resumed none), while the other patient was prescribed a post-operative pain medication for which there was a documented allergy.

**CONCLUSION:** Preliminary results indicate that medication documentation errors are prevalent, both pre- and post-operatively. Documentation of perioperative medication management is incomplete and patients are not consistently told to restart medications that are held before surgery.

## Nutrition

### 285. The impact of whey protein supplementation on muscle strength and body composition: a systematic review and meta-analysis.

Darren Hein, Pharm.D., Philip Gregory, Pharm.D., FACN, Andrew Abe, Pharm.D., Amy Wilson, Pharm.D., Zara Risoldi Cochrane, Pharm.D.; School of Pharmacy and Health Professions, Creighton University, Omaha, NE

**PURPOSE:** Whey protein (WP) is commonly sold in pharmacies and used by patients interested in gaining lean body mass and improving strength. The primary objective of this study was to determine the effect of WP supplementation on muscle strength and body composition in healthy, resistance-trained, adult subjects.



**METHODS:** A systematic search was conducted using PubMed, Google Scholar, and the Natural Medicines Comprehensive Database. Randomized-controlled trials (RCTs) assessing WP supplementation in combination with prolonged resistance-type exercise were selected for inclusion. Outcome measures selected for analysis included one-repetition maximum (1-RM) bench press, 1-RM squat/leg press, body weight, percent body fat, and lean body mass. Study results were pooled into a single data set and re-analyzed using the software program Comprehensive Meta-Analysis, Version 2.

**RESULTS:** Data were included from eight RCTs including 165 subjects. Upon preliminary analysis supplementation with WP led to statistically significant increases in 1-RM bench press (difference in mean change from baseline: 5.3 kg; 95% CI 0.7–10.0;  $p=0.024$ ), 1-RM squat/leg press (difference in mean change from baseline: 15.2 kg; 95% CI 4.9–25.5;  $p=0.004$ ), body weight (difference in mean change from baseline: 2.3 kg; 95% CI 0.4–4.1;  $p<0.001$ ), and lean body mass (difference in mean change from baseline: 1.4 kg; 95% CI 0.9–1.9;  $p<0.001$ ) compared to the control group. No difference in body fat percentage was found. Results will be finalized upon receipt of additional raw data from relevant studies, expected shortly.

**CONCLUSION:** Supplementation with WP increases muscle strength (1-RM bench press and 1-RM squat/leg press), body weight, and lean body mass in healthy, resistance-trained, adult subjects. WP could be recommended in healthy individuals seeking increases in strength, weight, and/or lean body mass.

## Pain Management/Analgesia

**286. Effect of clinical pharmaceutical care in patients with cancer pain patients in China.** Zhengzheng Xie, M.S.<sup>1</sup>, Lulu Sun, B.S.<sup>1</sup>; (1)Pharmacy Department, Beijing Shijitan Hospital Capital Medical University, Beijing, China

**BACKGROUND:** In China, pain experienced by cancer patients is often overlooked, even when they are admitted into the hospital, since the doctor's efforts focused on treatment of the disease rather than pain. In 2011, "The Creation of a Demonstration Ward for Cancer Pain Standardized Therapy" was initiated in China, it was organized by the Chinese Ministry of Health (MOH), and required pharmacist participation to provide better care to cancer patients.

**PURPOSE:** To determine the effect of clinical pharmacy services on cancer pain management in China.

**METHODS:** In the first week, patients only received routine medical care but without pharmaceutical care. In the second week, pharmacist provided clinical pharmacy services which included: identification of problems associated with drug therapy, optimization of drug therapy regimens, and provision of patient education. After receiving one week of such clinical pharmaceutical care, the effect on cancer pain, quality of life (QOL), medication compliance and incidence of adverse drug reactions were assessed.

**RESULTS:** Clinical pharmaceutical care was provided to 43 patients with cancer pain. 76 drug-therapy interventions were provided. The patients' mean  $\pm$  SD numeric rating pain scores (NRS) decreased significantly from (6.93  $\pm$  1.52) to (1.83  $\pm$  1.43) after the intervention ( $p<0.01$ ). The pain of eight patients (18.6%) achieved complete remission, 18 (41.9%) achieved obvious remission, 7 (16.2%) achieved moderate remission, 8 (18.6%) achieved mild remission, and 2 (4.7%) no remission. The overall rate of pain relief was 76.7%. Karnofsky score score of three patients (7%) had been obviously improved (KPS increase  $\geq 20$  points) after the pharmaceutical care, 25 (58.1%) had mild improvement (KPS increase  $\geq 10$  points), and 15 (34.9%) were relatively stable (KPS score change  $<10$ ). Compared with the baseline before pharmaceutical care, the patients medication compliance was significantly changed ( $p<0.01$ ).

**CONCLUSION:** Provision of clinical pharmaceutical care in China has resulted in improved cancer pain management, as shown by increased pain relief and quality of life.

## Pharmacoeconomics/Outcomes

**287. Cost-effectiveness analysis of alogliptin in type 2 diabetes mellitus: a payer perspective.** Dhruv Patel, PharmD, Candidate, Bik-Wai Bilyick Tai, PharmD, Anandi Law, B.Pharm PhD; College of Pharmacy, Western University of Health Sciences, Pomona, CA

**PURPOSE:** Inadequate type 2 diabetes management has a substantial economic burden in the United States. Currently, metformin is commonly prescribed as the first-line drug in type 2 diabetes. However, monotherapy is often insufficient, and addition of a second oral agent is required to maintain glycemic control. Alogliptin, a highly selective, oral dipeptidyl peptidase-4 (DPP-4) inhibitor was recently approved as an adjunct to metformin for treating type 2 diabetes. Since there is a paucity of economic analysis conducted on this new drug, our study aims to determine the cost effectiveness of alogliptin versus other DPP-4 inhibitors as an adjunct to metformin in type 2 diabetes from a payer perspective.

**METHODS:** A decision tree analysis was performed to determine the cost effectiveness of alogliptin (25 mg) compared to sitagliptin (100 mg), saxagliptin (5 mg), and linagliptin (5 mg) when added to metformin as a second-line therapy, using a US payer perspective. Data including rates of clinical success and adverse effects were obtained from four randomized, controlled trials (NCT00286442, NCT0086515, NCT00121667, NCT00601250), in which adults with type 2 diabetes had matching demographic and baseline characteristics. Clinical success was defined as achieving an HbA1c goal of less than 7% at the end of week 24. Costs of medications, major adverse events, and laboratory tests were obtained from published sources in 2013 US dollars. Sensitivity analysis will be conducted to examine the robustness of the results.

**RESULTS:** The total cost per patient per month calculated for alogliptin, sitagliptin, saxagliptin, and linagliptin, were \$312, \$311, \$311 and \$305, respectively. Compared to alogliptin and saxagliptin, sitagliptin was the dominant drug. Incremental cost-effectiveness ratio for linagliptin versus sitagliptin was \$1.51 per percentage of clinical success gained.

**CONCLUSION:** Current analysis suggested the four DPP-4 inhibitors had similar cost-effectiveness. The final results following sensitivity analysis will be tabulated and presented.

**288. Management and impact of bleeding events with dabigatran, rivaroxaban, and warfarin.** Daniel M. Yarabinec, PharmD<sup>1</sup>, Deanne L. Hall, PharmD<sup>2</sup>, James C. Coons, PharmD<sup>2</sup>; (1) University of Pittsburgh Medical Center, Pittsburgh, PA (2) University of Pittsburgh School of Pharmacy/University of Pittsburgh Medical Center, Pittsburgh, PA

**PURPOSE:** Patients who bleed on dabigatran or rivaroxaban may be more difficult to manage compared to warfarin since no reversal agents have been identified. This study compared the strategies used to manage bleeding events in patients on these medications, and assessed the impact of bleeding events on healthcare utilization.

**METHODS:** This was a retrospective cohort review of patients who presented to UPMC Presbyterian Shadyside between 10/19/2010–9/30/2012. Patients that had an ICD9 code for bleeding and were receiving dabigatran, rivaroxaban, or warfarin prior to presentation were included. Warfarin patients were matched to dabigatran or rivaroxaban patients in a 2:1 ratio based on age. Additional inclusion criteria included: diagnosis of atrial fibrillation and charges for a targeted bleeding reversal strategy (fresh frozen plasma [FFP], recombinant factor VIIa [rFVIIa], prothrombin complex concentrate [PCC], activated PCC [aPCC], vitamin K, activated charcoal, and/or dialysis). Healthcare resources examined were hospital length of stay (LOS) and blood transfusions. Patients' aggregate costs of stay were also determined.

**RESULTS:** We identified 599 patients that met the all inclusion criteria ( $n=584$ , warfarin;  $n=13$ , dabigatran;  $n=2$ , rivaroxaban); 45 patients total were included in the matched analysis. Reversal

strategies among all groups included only vitamin K, dialysis, and rFVIIa. There was no use of other targeted reversal therapies. Dabigatran and warfarin patients required comparable amounts of blood transfusions, but had a shorter median LOS (5 vs. 9 days) and smaller median aggregate cost of stay (\$114,000 vs. \$165,000). Rivaroxaban patients had fewer blood transfusions compared to warfarin, but a longer median LOS and larger median aggregate cost of stay. Final analyses are pending.

**CONCLUSION:** Targeted reversal strategies were variable and included only vitamin K, dialysis, and rFVIIa. Healthcare utilization appears to be less with dabigatran than warfarin. The healthcare utilization analysis of rivaroxaban is limited due to sample size.

## Pharmacogenomics/Pharmacogenetics

**289. Description and feasibility of a comprehensive warfarin pharmacogenetics service.** *Katarzyna Drozda, Pharm.D.<sup>1</sup>, Edith A. Nutescu, PharmD<sup>1</sup>, Adam P. Bress, Pharm.D.<sup>1</sup>, William Galanter, MD<sup>2</sup>, James M. Stevenson, Pharm.D.<sup>1</sup>, Julio D. Duarte, Pharm.D., Ph.D.<sup>3</sup>, Larisa H. Cavallari, Pharm.D.<sup>1</sup>;* (1) University of Illinois at Chicago College of Pharmacy, Chicago, IL (2) Section of General Internal Medicine, Department of Medicine, University of Illinois at Chicago, Chicago, IL (3) Institute for Personalized Respiratory Medicine, University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** To determine the procedural feasibility of a pharmacist-led, interdisciplinary, warfarin pharmacogenetics service at the University of Illinois Hospital and Health Sciences System (UI-Health) in the initial 9 months of operation.

**METHODS:** Genotyping is automatically ordered for each new warfarin order at UI-Health. A clinical pharmacist screens each order for appropriateness. If deemed appropriate, genotyping for *VKORC1* and *CYP2C9* is performed, with results targeted to be available before the second warfarin dose is administered. A consultation is automatically provided by the pharmacogenetics service to assist with genotype interpretation and to give dose recommendations. Daily dose recommendations, adjusted based on genotype, clinical factors, and INR response, are provided until hospital discharge or dose stabilization. We sought to determine the percent of genotype-guided dose recommendations available prior to the second warfarin dose, as well as the medical staff's adherence to dose recommendations.

**RESULTS:** Of 590 genotype orders during the first 9 months of the service, 286 were deemed appropriate. For 116 patients on the service who consented to data collection, 75% of genotypes were available prior to the second warfarin dose. The median (range) time from the genotype order to the genotype result was 27 (2–80) hours, and the time to genotype-guided dosing recommendation was 30 (3–82) hours. Seventy-seven percent of warfarin doses ordered by the medical staff were within 0.5 mg of the dose recommended by the pharmacogenetics consult service. The median (range) length of hospital stay was 5 days (<24 hour to 97 days). Fifty-three percent of the enrolled patients were referred to the UI-Health Antithrombosis clinic for follow-up.

**CONCLUSION:** A comprehensive approach to genotype-guided warfarin therapy is feasible from a procedural standpoint. Future studies will examine the clinical and cost effectiveness of this approach to warfarin dosing.

## Transplant/Immunology

**290. Impact of Thymoglobulin dosing: is the current approach successfully treating acute cellular rejection in kidney allografts?.**

*Mary Moss, PharmD<sup>1</sup>, Robert Dupuis, PharmD, BCPS<sup>2</sup>, Jennifer Deyo, PharmD<sup>1</sup>, Tomasz Kozlowski, MD<sup>3</sup>, Anthony Chhay, PharmD<sup>2</sup>, RuthAnn M. Lee, PharmD, CPP<sup>2</sup>;* (1) Department of Pharmacy, University of North Carolina Memorial Hospital, Chapel Hill, NC (2) UNC Eshelman School of Pharmacy, Chapel Hill, NC (3) Department of Surgery, UNC School of Medicine, Chapel Hill, NC

**PURPOSE:** Rabbit antithymocyte globulin (rATG, Thymoglobulin<sup>®</sup>) is indicated for treatment of renal transplant rejection.

Despite extensive use for treatment of acute cellular rejection (ACR), the ideal dosing regimen has yet to be determined. The purpose of this study is to evaluate the impact of rATG dosing approaches for ACR therapy in kidney transplant recipients (KTR).

**METHODS:** Retrospective analysis evaluating 64 KTRs treated with rATG for ACR (2004 – 2010). Data was analyzed by comparing groups based on return to baseline serum creatinine (Scr) and recurrence of ACR (rACR). Dosing factors for rATG therapy, concomitant methylprednisolone (MP) dose, and graft function data were evaluated. Other outcomes included hematologic toxicities and incidence of infectious complications.

**RESULTS:** Baseline characteristics were comparable between groups. Of 64 patients, 28 (44%) KTR returned to baseline Scr post-treatment whereas 36 (56%) did not. CD3-based dosing strategy was used in 16 (57%) patients who did return to baseline Scr compared to 33 (92%) patients who did not (p=0.001). Additionally, rACR was seen in 35 (55%) patients. CD3-based dosing was used in 32 (91%) patients with rACR versus 18 (60%) without rACR (p=0.0035). All patients received steroids, but MP dose  $\geq 1$  g was seen in 16 (46%) patients with rACR and 21 (70%) patients without rACR (p=0.05). Although not significant, patients with rACR were more likely to receive cumulative rATG dose <9 mg/kg and to have dose reductions compared to those not experiencing rACR.

**CONCLUSION:** CD3-based dosing is a significant factor associated with not returning to baseline Scr and increased recurrence of ACR. Cumulative MP dose <1 g is significantly associated with higher incidence of ACR recurrence. Fixed dosing with a cumulative methylprednisolone dose >1 g may be necessary to achieve return to baseline Scr and prevent recurrent episodes of ACR.

**291. What's the IMPACT? Utilization review of six months of valganciclovir prophylaxis for cytomegalovirus in transplant patients.**

*Marissa Brokhof, PharmD, BCPS, Jillian Descourouez, PharmD, BCPS, Margaret Jorgenson, PharmD, BCPS, Kimberly Holdener, PharmD; University of Wisconsin Hospital and Clinics, Madison, WI*

**PURPOSE:** Recently, Humar and colleagues (IMPACT) demonstrated that continuing valganciclovir prophylaxis for 200 days significantly reduced the incidence of cytomegalovirus viremia for up to one year, when compared with 100 days of prophylaxis in high-risk patients. As a result of this trial, our institution implemented a new protocol, extending prophylaxis with valganciclovir from 90 to 180 days in recipients of abdominal organ transplants for which it was indicated. The purpose of this study is to determine if patients are able to complete the full six months of valganciclovir prophylaxis, including an evaluation of the rate of discontinuation and associated risk factors.

**METHODS:** This is a retrospective chart review evaluating the utilization of six months of valganciclovir prophylaxis for cytomegalovirus in abdominal transplant recipients. Data was analyzed using descriptive statistics. A total of 142 patients met study inclusion. The primary outcome measure assessed was discontinuation rate of valganciclovir.

**RESULTS:** Valganciclovir prophylaxis was continued for the full duration of six months in approximately 80% (n=113) of patients. Incidence of cytomegalovirus infection at one year was 6% (n=7) in those who completed six months of valganciclovir prophylaxis and 14% (4/29) in those whose prophylaxis was terminated early (p=0.24). A total of 46 out of 142 patients (32%) were leukopenic during the prophylactic period and dose reduction of mycophenolate occurred in 76% of these patients. A granulocyte colony-stimulating factor was required in 12% (n=17) patients.

**CONCLUSION:** The majority of transplant recipients are able to continue six months of prophylaxis. Incidence of cytomegalovirus infection is over twice as high in patients whose valganciclovir is dose-reduced or stopped. In the event of leukopenia, dose of mycophenolate is reduced a majority of the time. Future analyses to determine if rejection is increased in patients who mycophenolate was reduced or stopped is warranted.

**292. Analysis of dosing strategies for secondary prophylaxis for prevention of Cytomegalovirus (CMV) recurrence in solid organ transplantation.** *Danya Roshdy, PharmD<sup>1</sup>, Cassandra Baker, PharmD<sup>2</sup>, Robert Dupuis, PharmD, BCPS<sup>3</sup>, Jennifer Deyo, PharmD<sup>4</sup>, RuthAnn M. Lee, PharmD, CPP<sup>3</sup>;* (1)Department of Pharmacy/School of Pharmacy, University of North Carolina Hospital, Chapel Hill, NC (2)Department of Pharmacy/School of Pharmacy, University of North Carolina Hospital, Chapel Hill, NC (3)UNC Eshelman School of Pharmacy, Chapel Hill, NC (4)Department of Pharmacy, University of North Carolina Memorial Hospital, Chapel Hill, NC

**PURPOSE:** Several strategies exist to prevent primary Cytomegalovirus (CMV) disease, however data is limited with regards to optimal dosing and duration of secondary prophylaxis (spx) for CMV. Despite consensus guidelines recommending one to three months of spx, recent survey reports 40% do not implement any spx. Given the financial burden and side effects associated with valganciclovir, optimal dosing and duration for spx based on risk is yet to be established. The objective of the study is to identify factors that may influence optimal dosing and duration for spx and identify risk factors for recurrence of CMV in solid organ transplant recipients.

**METHODS:** This was a retrospective analysis of 59 kidney, liver, lung, heart, and pancreas transplant recipients within the University of North Carolina (UNC) Hospitals that had CMV viremia or disease and received spx post-treatment from 2002 to 2012. Data was analyzed by comparing groups based on recurring CMV (CMVr) disease versus non recurring CMV disease. Characteristics of CMV disease, dosing characteristics for valganciclovir therapy, demographic and graft function data were collected.

**RESULTS:** Out of 59 patients, 11 (19%) had CMVr. Of the patients that had CMVr, the majority (55%) were D+/R- CMV serostatus. Duration of spx was significantly longer in the CMVr group ( $126 \pm 94$  days vs  $82 \pm 53$  days). There was no difference in valganciclovir dosing characteristics, demographics or baseline immunosuppression regimens between the two groups. The majority of patients were receiving tacrolimus and mycophenolate (86% and 81%,  $p=ns$ ).

**CONCLUSION:** D+/R- CMV serostatus, and longer duration of spx had higher incidence of CMVr. Overall incidence of CMVr was low in our institution despite varying duration of spx. Therefore, one month prophylaxis may be safe and effective to prevent further recurrence of disease. Further analysis is warranted to identify significant risk factors associated with CMVr.

## Student Submissions

### ADR/Drug Interactions

**293. The impact of acid-suppression therapy on iron supplementation in the pediatric intensive care unit.** *K. Ashley Jones, Pharm. D. Candidate 2014<sup>1</sup>, Allison Chung, Pharm. D., BCPS<sup>1</sup>, Rosa Vidal, M.D.<sup>2</sup>, Sheryl Falkos, M.D.<sup>2</sup>;* (1)Department of Pharmacy Practice, Auburn University, Harrison School of Pharmacy, Mobile, AL (2)Department of Pediatrics, University of South Alabama, College of Medicine, Mobile, AL

**PURPOSE:** Several in vivo studies have shown that chronic histamine (H<sub>2</sub>) antagonist or proton pump inhibitor (PPI) use increases gastric pH. Other studies reported that iron absorption can be impaired when the gastric pH is elevated. The purpose of this study is to observe the clinical impact of acid suppression therapy, either oral/IV ranitidine or esomeprazole, on oral iron supplementation.

**METHODS:** In this prospective, observational, single blind, controlled trial, patients admitted to the pediatric intensive care unit (PICU) who were identified as requiring iron supplementation were assigned to one of three treatment arms: iron supplementation plus H<sub>2</sub> antagonist or iron supplementation plus PPI or iron supplementation plus both H<sub>2</sub> antagonist and PPI. Patients prescribed a ferrous sulfate regimen without acid suppression therapy were used as a comparator. The primary outcome analyzed was the incidence and persistence of anemia, while secondary outcomes included gastric pH, serum iron levels, any increase in

hemoglobin (Hgb) and hematocrit (Hct), and total iron binding capacity (TIBC).

**RESULTS:** Results are in progress. Thirty-four patients have been enrolled in the study, including 56% females and 44% males. Ethnicities include 53% Caucasian, 35% African American, 3% Asian, 3% Hispanic, and 6% unknown patients. Patients' ages ranged from 0 months to 10 years, and weight ranged from 2.8 kg to 38 kg.

**CONCLUSIONS:** At preliminary analysis, it appears that a majority of patients absorbed the iron therapy despite being on acid-suppression therapy. Project will be completed August 2013.

## Adult Medicine

**294. Corticosteroid dosing and antibiotic selection in the treatment of acute exacerbations of COPD.** *Ryan Owens, PharmD Candidate, Takova Wallace, PharmD Candidate, Kurt Wargo, PharmD;* Auburn University Harrison School of Pharmacy, AL

**PURPOSE:** Acute exacerbations of chronic obstructive pulmonary disease (COPD) are often treated with corticosteroids and antibiotics, a practice that is supported by the Global Initiative on Obstructive Lung Disease (GOLD) guidelines. The GOLD guidelines offer specific recommendations for corticosteroid dosing, but provide vague recommendations for antibiotic selection. Therefore, the goal of this study is to compare current practice trends at an 881-bed community hospital in North Alabama to established GOLD guideline recommendations. Three main outcomes will be assessed in this study: 1) comparison of corticosteroid prescribing practices to GOLD guideline recommendations; 2) evaluate the variable glucose effects of steroid dosing during COPD exacerbation; 3) comparison of antibiotic selection to GOLD guideline recommendations.

**METHODS:** Medical records of 200 patients with COPD exacerbation admitted between November 2011 and November 2012 to an 881-bed tertiary care hospital in North Alabama were reviewed. Patients' medical history, glucose readings, and specific drug management prior to admission, in-hospital course, and at hospital discharge were documented.

**RESULTS:** Results are pending

**CONCLUSION:** Pending results

**295. Assessment of a weight-based vancomycin dosing protocol in adult medicine patients.** *Jessica Patanella, PharmD Candidate<sup>1</sup>, John Allen, PharmD, BCPS<sup>2</sup>, Sarah A. Treadway, PharmD, BCPS<sup>2</sup>, Robert Helmer, PharmD, BCPS<sup>3</sup>, Seng Huot, PharmD Candidate<sup>4</sup>, Meredith Jernigan, PharmD<sup>5</sup>;* (1)School of Pharmacy, Auburn University Harrison School of Pharmacy, Mobile, AL (2)Auburn University Harrison School of Pharmacy, Mobile, AL (3)Department of Pharmacy Practice, Auburn University Harrison School of Pharmacy, Mobile, AL (4)Auburn University Harrison School of Pharmacy (5)University of Florida College of Pharmacy

**PURPOSE:** Vancomycin is a frequently utilized antibiotic in the treatment of serious gram-positive infections. In order to optimize therapy, current guidelines recommend weight-based dosing (Loading dose: 25–30 mg/kg; Maintenance dose: 15–20 mg/L) with a goal of achieving target trough concentrations of 15–20 mg/L. The purpose of this study was to assess the impact of a weight-based vancomycin dosing protocol following guideline recommendations in adult medicine patients on initial dosing regimens and trough concentrations.

**METHODS:** This was a retrospective chart review comparing vancomycin therapy in adult medicine patients who received at least one dose of vancomycin during the pre- or post-protocol implementation periods (Pre:12/1/2012–2/28/2013; Post:4/1/2013–6/30/2013). The primary outcome was the percentage of patients who achieved an initial trough concentration of 15–20 mg/L. Secondary outcomes included median initial serum trough concentration; percentage of patients receiving appropriate loading and maintenance dosages based on the protocol; time to first dose of vancomycin; timing of trough levels; time to achievement of goal trough concentrations; and percentage of patients with an increase in serum creatinine concentrations of 0.5 mg/L or 50%



on two consecutive occasions. All parameters were compared in pre- and post-protocol implementation groups.

**RESULTS:** Data points including vancomycin trough concentrations, dosing, trough timing, and vancomycin induced nephrotoxicity from before and after protocol implementation will be compared and presented.

**CONCLUSION:** A weight-based vancomycin dosing protocol was developed and implemented among adult medicine patients receiving vancomycin at an academic medical center. We predict that utilization of this protocol will significantly impact the initial trough concentration and initial dosing regimens, thus increasing compliance with guideline recommendations.

## Ambulatory Care

**296. Interim results from a cardiologist-pharmacist collaboration to improve blood pressure in an ambulatory cardiology clinic.** *Michael Kelly, B.S., Dave Dixon, PharmD; Virginia Commonwealth University School of Pharmacy, Richmond, VA*

**PURPOSE:** Indigent patients requiring cardiovascular care are seen one half-day per week in an ambulatory, cardiology fellow's clinic at VCU Health System. A pharmacist collaborated with the attending cardiologist to assist with medication titration and management. The aim of this study was to describe the pharmacist impact on blood pressure (BP) and characterize the interventions made by the pharmacist.

**METHODS:** Electronic medical records of patients seen at least once by the pharmacist between June 1, 2012 and January 7, 2013 were reviewed to obtain the patient's medical history, initial and most recent BP, and pharmacist interventions. The primary endpoint was mean change in systolic and diastolic BP from baseline to most recent visit. Patients were excluded from the primary endpoint if they presented to clinic in hypertensive crisis or if a follow-up BP was unavailable.

**RESULTS:** Out of 38 patients seen by the pharmacist during the study period, 29 met inclusion criteria for the primary endpoint. Mean systolic BP decreased from  $135.5 \pm 19.3$  mmHg at baseline to  $126.0 \pm 18.1$  mmHg at follow-up ( $p=0.014$ ). Diastolic BP and goal achievement improved but was not found to be statistically significant. All 38 patients were included in the characterization of pharmacist interventions, which found a total of 51 interventions (31 related to antihypertensives; 20 related to dyslipidemia, diabetes, COPD, and smoking cessation) and identification of 17 drug-related problems.

**CONCLUSIONS:** Patients seen by the pharmacist had significant improvements in systolic BP. A cardiologist-pharmacist collaboration may be an effective method to improve blood pressure in an ambulatory cardiology clinic.

**297. Satisfaction and efficacy of an internal proactive smoking cessation telephone counseling service.** *Jie Lin Soong, BS, Pharm<sup>1</sup>, Zhen Ou, BA<sup>1</sup>, Lori Wilken, PharmD<sup>2</sup>; (1) College of Pharmacy, University of Illinois at Chicago, Chicago, IL (2) Department of Pharmacy Practice, College of Pharmacy, University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** This is a prospective, research survey assessing patient satisfaction with and effectiveness of the smoking cessation telephone counseling service at the University of Illinois Hospital.

**METHODS:** From September 2012 through May 2013, 271 consults were generated. Eighty-two patients received telephone counseling post-discharge from the hospital and were followed up at 30 days for a telephone survey. Primary outcomes included improvement in stages of change, motivation and confidence levels in quitting tobacco. Secondary outcomes included self-reported continuous and point prevalence abstinence rates at 30 days, as well as patient satisfaction of the duration and frequency of calls, and the contents of the telephone counseling session. Primary outcomes were analyzed using the Wilcoxon signed rank test, while secondary outcomes were evaluated using simple descriptive statistics.

**RESULTS:** Eighteen patients completed the survey, while the remaining patients were either lost to follow-up or had refused to

do the survey. There was no significant difference before and after the telephone counseling session in regards to the stage of change ( $p=0.10$ ), motivation levels ( $p=0.80$ ) or confidence levels ( $p=0.89$ ) to quit tobacco. Self-reported continuous and point prevalence abstinence rates at 30 days were 16.7% and 22.2%, respectively. Majority of patients felt the duration of call was just nice (83.3%), but having only one call was too little (77.8%). Overall satisfaction of the consult service was noted at 83.1%.

**CONCLUSION:** Patients are highly satisfied with tobacco treatment phone consults post-discharge. Although efficacy with the current service was not statistically significant, there was a trend towards improvement in the stages of change, motivation, and confidence levels to quit smoking. A limitation of the study is the small sample size, which decreases the sensitivity of the study to detect significant effects of the telephone counseling service.

**298. Student pharmacist medication reconciliation in an outpatient family medicine center.** *Anthony Anderson, PharmD Candidate, Miranda R. Andrus, Pharm.D., BCPS; Auburn University Harrison School of Pharmacy, Auburn, AL*

**PURPOSE:** This study describes and quantifies medication reconciliation efforts by student pharmacists in an outpatient family medicine center.

**METHODS:** A retrospective review was completed of standard medication reconciliation forms that were completed by 4th year student pharmacists during patient interviews from May 2012 to April 2013 in an outpatient setting. The total number of interviews was recorded as well as the incidence of each discrepancy. Discrepancies were defined as medications taken differently than listed in the electronic health record (EHR) per patient reporting, non-adherence with chronic medications, medications no longer taken, medications missing from EHR, and any over-the-counter (OTC) and herbal medications not listed.

**RESULTS:** A total of 557 reconciliation forms were reviewed from 12 student pharmacists. A total of 1783 discrepancies were found with an average of 3.2 discrepancies per patient. Discrepancies included medications no longer taken (43.0%), OTC and herbal medications that need to be added (18.8%), prescription medications that need to be added (14.9%), medications taken differently than listed in EHR (14.6%), and non-adherence with chronic medications (8.8%). Patient counseling was performed 159 times during the interviews, and 198 allergies were clarified with 74 new allergies added to the EHR.

**CONCLUSION:** Student pharmacist based medication reconciliation in an outpatient family medicine center resulted in correction of many discrepancies in EHR medication lists. Student pharmacists can play a vital role in medication reconciliation and have a significant impact on patient care. Incorporating them in the process is a cost effective way to expand clinical pharmacy services, assist with patient education, and improve patient safety.

**299. Beyond gout: review of current and future uses for colchicine.** *Mollie Reidland, Pharm.D Candidate<sup>1</sup>, Kristen Taylor, Pharm.D. Candidate<sup>1</sup>; (1) Southwestern Oklahoma State University College of Pharmacy, Weatherford, OK*

**PURPOSE:** Recent published literature as well as ongoing trials present colchicine as an attractive candidate for treatment and prevention of inflammatory-mediated conditions. This review seeks to summarize and present what is known and what is currently under investigation regarding indications for the use of colchicine.

**METHODS:** Database searches of Medline, Google Scholar, Web of Knowledge, and clinical trial registries were conducted using the keywords colchicine, Colcrlys, colchicine, colchin, and trimethylcolchic acid. Articles were initially screened for potential inclusion by abstract. Candidates for inclusion were independently read and evaluated by two independent reviewers. The main findings of each study as well as inclusion or exclusion status were recorded in a table.

**RESULTS:** Pending project completion.

**CONCLUSION:** Pending project completion. Estimated completion date 8/2013.

## Cardiovascular

**300. Evaluation of dabigatran in a community hospital with respect to appropriateness of dosing, indication and safety.** *Sun Min, Pharm.D. Candidate<sup>1</sup>, Margaret Riley, PharmD Candidate 2014<sup>2</sup>, Anastasia Roberts, Pharm. D.<sup>3</sup>, Katie Buehler, PharmD<sup>3</sup>, Michael Daly, PharmD, MSCI<sup>3</sup>; (1) St. Louis College of Pharmacy, St. Louis, MO (2) Pharmacy Practice Division, Saint Louis College of Pharmacy, Saint Louis, MO (3) Pharmacy Practice, St. Louis College of Pharmacy, St. Louis, MO*

**PURPOSE:** Warfarin has historically been used as the predominant anticoagulation strategy for prophylaxis and treatment of thromboembolic disorders arising from atrial fibrillation. However, its disadvantages are well known and include a narrow therapeutic index, multiple drug interactions, delayed time to onset, and frequent monitoring. Dabigatran etexilate, a direct thrombin inhibitor, presents less complexity in prescribing and has emerged as an alternative therapy to warfarin. Even though it does not require routine monitoring, there are concerns associated with its use, such as lack of an antidote, dose adjustments in special populations, and limited guidance to manage drug interactions with p-glycoprotein inducers and inhibitors. The purpose of this study is to describe and evaluate the use of dabigatran at a community hospital in order to identify potential areas for improvement in prescribing and monitoring.

**METHODS:** This study has been approved by the Institutional Review Board. A retrospective chart review is being conducted for approximately 500 patients who received at least one dose of dabigatran from December 2, 2010 to June 2, 2012 at Missouri Baptist Medical Center. Patients whose creatinine clearance cannot be calculated are being excluded. The appropriateness of use of dabigatran is being evaluated based upon the United States Food and Drug Administration approved recommendations for stroke prophylaxis in the setting of nonvalvular atrial fibrillation as well as Health Canada-approved recommendations for prevention of venous thromboembolism after hip or knee replacement surgery. Data being collected and evaluated includes patients demographics, clinical indications for anticoagulation, concomitant medications to screen for drug interactions, and incidents of bleeding (either minor or major) as defined in the Randomized Evaluation of Long-term Anticoagulation Therapy (RE-LY) trial.

**RESULTS:** It is anticipated that all data collection and analysis will be completed in time to be discussed at the Scientific Poster Presentation.

**301. Safety outcomes in high risk patients receiving triple therapy after percutaneous coronary intervention.** *Molly Kinsella, Pharm.D. Candidate, Shannon W. Finks, Pharm.D., Kelly C. Rogers, Pharm.D.; Department of Clinical Pharmacy, University of Tennessee College of Pharmacy, Memphis, TN*

**PURPOSE:** Individuals with coronary heart disease undergoing percutaneous coronary intervention (PCI) require dual antiplatelet therapy with a P<sub>2</sub>Y<sub>12</sub> antagonist (i.e. clopidogrel) and aspirin. Oftentimes, these patients have compelling indications for anticoagulation with warfarin thus requiring triple therapy (TT). The benefits of preventing thrombus formation must be carefully weighed against the risk of bleeding in patients receiving TT. There is no consensus on how to best manage these patients, other than a careful individualized approach. This ongoing study evaluates safety outcomes in patients receiving TT with warfarin, clopidogrel, and aspirin concomitantly.

**METHODS:** A retrospective analysis of computerized medical records of veterans undergoing heart catheterization with or without PCI on concomitant anticoagulation and antiplatelet therapies was performed. Indication for TT, CHADS<sub>2</sub> scores, HAS-BLED scores, warfarin and aspirin dose, concomitant medications, hospital admissions, and thromboembolic events were recorded. Bleeding was defined using TIMI classification.

**RESULTS:** Sixty-six patients met inclusion criteria. Fifty-three (80%) received PCI, with 41 (77%) of those receiving a drug-eluting stent. Forty-two (64%) had atrial fibrillation. The average length of TT was 16.5 months ± 15.9. Thirty-two patients (48%)

bled according to TIMI criteria. A total of 65 bleeds occurred in these 32 patients; 16 (25%) met TIMI major or minor criteria. Twenty-six (40%) bleeds occurred within 90 days of initiating TT; average INR during bleeding episodes was 2.59. Fifty-six (85%) received GI prophylaxis, however, only 3 (5%) patients suffered a GI bleed. Twenty-one (32%) bleeds resulted in hospital visits. Three (5%) bleeds required a transfusion. No thromboembolic events or deaths occurred.

**CONCLUSION:** In this small population undergoing heart catheterization, bleeding while on TT was high and required additional hospital visits. Many bleeds occurred early in therapy. Strategies to reduce bleeding in patients requiring TT are of paramount importance.

**302. Circulating inflammatory potential in patients with coronary artery disease.** *Heidi Cunniff, Pharm.D. Candidate 2015<sup>1</sup>, Matthew Campen, Ph.D., M.S.P.H.<sup>1</sup>, Mario Aragon, Ph.D. Candidate<sup>1</sup>, Joe Anderson, PharmD<sup>2</sup>, James Nawarskas, Pharm.D.<sup>2</sup>; (1) Pharmaceutical Sciences, University of New Mexico, College of Pharmacy, Albuquerque, NM (2) College of Pharmacy, University of New Mexico, Albuquerque, NM*

**PURPOSE:** Recent studies have found that patient serum can induce a range of inflammatory responses in cultured endothelial cells that appears consistent with overall health and environmental factors. The objective of this study is to determine if circulating factors in the serum of patients with coronary artery disease (CAD) can trigger endothelial cell inflammatory responses likely to promote cardiovascular disease via atherosclerosis.

**METHODS:** Determination of upregulation of adhesion molecules is assessed in two ways. 1) quantitative Polymerase Chain Reaction (qPCR) and 2) flow cytometry. With qPCR, confluent human coronary artery endothelial cells (hCAECs) are *physically* exposed to the serum of CAD patients and healthy individuals (as controls) and incubated for four hours. RNA is then isolated from the hCAECs, and levels of intercellular adhesion molecule-1 (ICAM) and vascular cell adhesion molecule-1 (VCAM) are measured via qPCR. With flow cytometry, confluent hCAECs are exposed to CAD serum and healthy serum as exposed and controls, respectively. The endothelial cells are then incubated with ICAM and VCAM antibodies that are pre-conjugated with fluorochromes of distinct wavelengths. The adhesion molecule-antibody-fluorochrome conjugate are then detected via flow cytometry.

**RESULTS:** This study is still in progress and will likely be completed by the end of July 2013. Preliminary work highlighted a role for advanced age (>60 years) in driving substantial inflammatory responses in endothelial cells. For the CAD subjects' serum, the mean values of ICAM and VCAM expression will be compared between the control group and group exposed to CAD serum as a Student's T-test.

**CONCLUSION:** We hypothesize that *if* there are circulating factors in the serum of CAD patients that damage and activate endothelial cells, then the endothelial cells will trigger vascular inflammatory responses upon damage and result in expression and upregulation of adhesion molecules and chemokines.

## Clinical Administration

**303. Development of a tool to facilitate achievement of specialty pharmacy accreditation standards.** *Joe Moore, Bachelor of Arts<sup>1</sup>, Lindsey Poppe, PharmD, MS, BCPS<sup>2</sup>, Scott Savage, PharmD, MS<sup>3</sup>; (1) University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC (2) Department of Pharmacy, University of North Carolina Hospitals, Chapel Hill, NC (3) University of North Carolina Hospitals, Chapel Hill, NC*

**PURPOSE:** URAC's Specialty Pharmacy Accreditation is a rigorous and comprehensive evaluation process that is required for inclusion within the Blue Cross Blue Shield of North Carolina specialty pharmacy provider network. This poster describes the creation and utilization of a gap analysis tool to identify the required steps to meet URAC specialty pharmacy accreditation

standards and assist in remediating deficiencies in current pharmacy policies.

**METHODS:** A gap analysis tool was created in Microsoft Excel using the URAC Specialty Pharmacy Accreditation Guide, Version 2.0. The tool was populated with all 41 of the core pharmacy standards as well as the 55 specialty pharmacy standards and their respective weights as assigned by URAC. Each quality standard was comprised of up to 12 individually-weighted criteria. The existing hospital pharmacy policies were considered for compliance with the criteria for each standard set out by URAC and graded as either "Full" (A hospital policy existed and completely satisfied the evidence required to meet the criteria during the initial desktop review), "Partial" (A hospital policy pertaining to the standard existed but did not completely satisfy the evidence required to meet the criteria) or "None" (No hospital policy existed that addressed the standard), and color-coded for easy identification.

**RESULTS:** In total, there were more than 400 weighted criteria included in the tool, only 42 of which were graded as having "Full" compliance at the time the tool was created. Recommendations of what actions needed to be taken to meet full compliance were included and the progress of recommended action plans for criteria graded as "Partial" or "None" was tracked in the tool.

**CONCLUSION:** A "specialty pharmacist" position was created and made responsible for implementing the recommendations contained within the tool. Materials were submitted to URAC for a successful on-site visit to be completed by June 30, 2013.

## Critical Care

### 304. Assessment of adverse events and predictors of neurologic recovery of an institution-specific therapeutic hypothermia protocol.

Jolie Gallagher, PharmD Candidate<sup>1</sup>, Robert MacLaren, PharmD<sup>1</sup>, Sara Varnado, PharmD<sup>1</sup>, Lam Nguyen, PharmD<sup>1</sup>, John Shin, PharmD<sup>1</sup>; (1)University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO

**PURPOSE:** To assess the occurrence of adverse events and predictors of good vs. poor neurologic recovery of an institution-specific hypothermia protocol.

**METHODS:** A single center, retrospective chart audit of 91 patients who received therapeutic hypothermia for  $\geq 6$  hours. Adverse events included electrolyte, glucose, and coagulation abnormalities and the occurrence of shivering during cooling or seizure, acute kidney injury (AKI) or infection within five days of cooling. Cerebral performance categories (CPC) scores delineated neurologic recovery (CPC of 1-3) and poor neurologic outcomes (CPC of 4 or 5). These groups were compared using univariate analyses. Parameters with p-values  $< 0.2$  were evaluated for effect on neurologic recovery using backward multivariate logistic regression analysis.

**RESULTS:** Forty-two patients (46.2%) had neurologic recovery. Demographic parameters were similar between groups. Hospital mortality rates for good vs. poor recovery were 2.4% vs. 93.9% ( $p < 0.00001$ ), respectively. Common adverse events were glucose  $< 60$  mg/dL (98.9%), shivering (84.6%), heart rate  $< 60$  bpm (58.2%), electrolyte abnormalities (26.4-91.3%), AKI (52.8%), infection (48.4%), and INR  $> 1.5$  (40.7%). Characteristics independently associated with neurologic recovery included shorter times to hypothermia (OR=1.53 per hour less, CI 1.11-2.5), goal temperature (OR=1.48 per hour less, CI 1.01-2.45), and spontaneous circulation (OR=1.11 per minute less, CI 1.02-1.28) as well as development of infections. Seizure occurrence (OR $< 0.0001$ , CI=0-0.1) and the need for insulin (OR=0.061, CI 0.003-0.565) or epinephrine (OR=0.05, CI 0.0025-0.475) were inversely related to neurologic recovery.

**CONCLUSION:** Adverse events of therapeutic hypothermia are numerous and frequent. While neurologic recovery is primarily driven by the rapidity of returning spontaneous circulation and providing therapeutic hypothermia, some adverse events such as seizure and the administration of insulin or epinephrine are associated with poor outcome. These interventions were independent

of developing hyperglycemia or hemodynamic instability and warrant investigation. Infections as a predictor of neurologic recovery likely relates to patient survival and development of infections during hospital stay.

### 305. Predicting response to methylene blue for refractory vasoplegia following cardiac surgery.

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**PURPOSE:** Vasoplegic syndrome (VPS) affects up to 25% of patients following cardiac surgery and is characterized by severely decreased mean arterial pressure (MAP) refractory to traditional vasopressors. The use of methylene blue (MB) in the treatment of VPS following cardiac surgery is common, but the patient population most likely to receive benefit has yet to be identified. The objective of this retrospective study is to determine ideal candidates for the use of MB in the case of VPS following cardiac surgery.

**METHODS:** Patients receiving MB for VPS from January 2004 to May 2012 were included. Patients with a contraindication to MB, and those with multiple MB charges were excluded. Data collected included patient age, gender, ethnicity, weight, SCr, the time of the day the medication was administered, prior or current angiotensin-converting-enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) use, and prior or current serotonergic-agent use. Response was defined as an increase in MAP of greater than or equal to 4 mmHg, a decrease in lactate of greater than or equal to 0.4 mmol/L or greater than or equal to a 10% decrease in any vasopressor dose within the first 2 hours post MB dose. Differences between groups were analyzed using t-tests, chi-squared and step-wise methods for inclusion in a predictive logistic model.

**RESULTS:** There were 106 patients included, 88 were responders and 16 were non-responders. Patients were less likely to be a responder if they were on an ACEI or ARB (62.5% vs 35.6%,  $p = 0.04$ ). Pre-operative serotonergic-agent use showed no difference between responders and non-responders. Choice of vasopressor medication, time of administration and initial vasopressor dose showed no statistical difference between groups.

**CONCLUSION:** Methylene blue exerts a positive response in most cardiac surgery patients with VPS. The use of an ACE inhibitor or ARB pre-operatively may decrease the efficacy of MB.

### 306. Prolonged hypoglycemia secondary to insulin glargine in a septic, critically ill patient receiving hemodialysis.

J. Cole Larsen, PharmD Candidate<sup>1</sup>, Leslie A. Hamilton, PharmD, BCPS<sup>2</sup>, Katie J. Suda, PharmD, MS<sup>1</sup>; (1)University of Tennessee Health Science Center, College of Pharmacy, Memphis, TN (2)University of Tennessee Health Science Center, College of Pharmacy, Knoxville, TN

**PURPOSE:** Long-acting insulins, such as insulin glargine, have been found to be a safe and effective chronic treatment for patients with diabetes. However, there has been much debate in the literature over glycemic control in the critically ill. Furthermore, few data are available to guide clinicians in adjusting insulin in patients who experience hepatic or renal dysfunction. This case describes the first example, to our knowledge, of extended hypoglycemia from a regularly prescribed dose of insulin glargine in a patient with acute kidney injury.

**METHODS:** The patient is a 45 year-old white male who was admitted to our institution with septic osteomyelitis three weeks post motor vehicle accident. At the time of the event, the patient was intubated, experienced acute kidney injury, and received continuous enteral nutrition. After two days of requiring high doses of sliding scale regular insulin, insulin glargine was increased. This adjustment provided one day of euglycemia before causing



33 hours of life-threatening hypoglycemia. The patient required frequent dextrose injections throughout the event and eventually recovered to baseline.

**RESULTS:** There are several potential etiologies of this case. No single factor is likely responsible for the event but rather a combination of factors. Critically ill patients are at an increased risk of hypoglycemia and this patient's worsening renal function could have exacerbated his hypoglycemia. Lastly, the patient was given over 100 units of regular insulin in the two previous days, which could have accumulated and exacerbated the effect of the insulin glargine.

**CONCLUSION:** Non-intensive glycemic control should be used in critically ill patients. This case further demonstrates how volatile this population can be. It also warrants caution with the use of long-acting insulins, except in patients with very stable requirements.

**307. Assessment of a weight-based vancomycin dosing protocol in critically ill patients.** *Seng Huot, PharmD Candidate<sup>1</sup>, Meredith Jernigan, PharmD<sup>2</sup>, Sarah A. Treadway, PharmD, BCPS<sup>3</sup>, Robert Helmer, PharmD, BCPS<sup>4</sup>, Jessica Patanella, PharmD Candidate<sup>5</sup>, John Allen, PharmD, BCPS<sup>3</sup>;* (1) Auburn University Harrison School of Pharmacy (2) University of Florida College of Pharmacy (3) Auburn University Harrison School of Pharmacy, Mobile, AL (4) Department of Pharmacy Practice, Auburn University Harrison School of Pharmacy, Mobile, AL (5) School of Pharmacy, Auburn University Harrison School of Pharmacy, Mobile, AL

**PURPOSE:** Vancomycin is a frequently utilized antibiotic in critically ill patients with serious gram-positive infections. In order to optimize therapy, current guidelines recommend weight-based dosing (Loading dose: 25–30 mg/kg; Maintenance dose: 15–20 mg/L) with a goal of achieving target trough concentrations of 15–20 mg/L. The purpose of this study was to assess the impact of a weight-based vancomycin dosing protocol in critically ill patients on initial dosing regimens and trough concentrations

**METHODS:** This was a retrospective chart review comparing vancomycin therapy in patients located in the Surgical Trauma Intensive Care Unit, Medical Intensive Care Unit, and Burn Intensive Care Unit who received at least one dose of vancomycin during the pre- or post-protocol implementation periods (Pre: 12/1/2012–2/28/2013; Post: 4/1/2013–6/30/2013). The primary outcome was the percentage of patients who achieved an initial trough concentration of 15–20 mg/L. Secondary outcomes included median initial serum trough concentration; percentage of patients receiving appropriate loading and maintenance dosages based on the protocol; time to first dose of vancomycin; timing of trough levels; time to achievement of goal trough concentrations; and percentage of patients with an increase in serum creatinine concentrations of 0.5 mg/L or 50% on two consecutive occasions. All parameters were compared in pre- and post-protocol implementation groups.

**RESULTS:** Data points including vancomycin trough concentrations, dosing, trough timing, and vancomycin induced nephrotoxicity from before and after protocol implementation will be compared and presented.

**CONCLUSION:** A weight-based vancomycin dosing protocol was developed and implemented among critically ill patients receiving vancomycin at an academic medical center. We predict that utilization of this protocol will significantly impact the initial trough concentration and initial dosing regimens, thus increasing compliance with guideline recommendations.

## Drug Information

**308. Assessment of drug information resource preferences and curriculum preparedness by pharmacy students.** *Nader Nassar, BS<sup>1</sup>, Janon Khedir Al-tiae, BS<sup>2</sup>, Renee Papageorgiou, BA<sup>3</sup>, Mallory McCullough, BS<sup>4</sup>, Micheline Goldwire, PharmD, MSc, BS<sup>5</sup>;* (1) School of Pharmacy, Regis University, Westminster, CO (2) School of Pharmacy, Regis University, Golden, CO (3) School

of Pharmacy, Regis University, Lakewood, CO (4) School of Pharmacy, Regis University, Arvada, CO (5) School of Pharmacy, Regis University, Denver, CO

**PURPOSE:** The intent of this study is two-fold. First to determine pharmacy student preferences for drug information (DI) resources and if these differ according to year in school and second to determine if DI skills are taught early enough in the curriculum and if students feel prepared to answer DI questions on their experiential rotations.

**METHODS:** Pharmacy students at Regis University School of Pharmacy have access to four drug compendia: Clinical Pharmacology, Facts & Comparisons, Lexicomp and Micromedex. Students are introduced to DI resources their first semester through one 2-hour laboratory session and class lecture. IPPE rotations begin second semester of the P1 year. DI skills are taught fall semester P2 year. To determine preferences for DI resources and perception of preparedness to answer DI questions, a 22-item survey was distributed to students (n=275). One rank-based question and 13 multiple-choice questions assessed student preferences; 5 curriculum questions and 3 demographic questions were included. Descriptive statistics will be used to analyze demographic data and logistic regression to determine inter-class variations.

**RESULTS:** Data collection and analysis are currently in progress. A total of 181 (66%) students completed surveys. Preliminary results show 50% chose Micromedex as their preferred database when answering DI questions. As students progressed through the program, they felt more adequately prepared to answer DI questions (P1, 34%; P2 90%, P3, 90%, P4 100%). Many students (61%) had previous pharmacy experience, whether this data correlates to a preferred choice of database will be determined. Results of the logistic regression between pharmacy classes are forthcoming.

**CONCLUSION:** Preliminary results indicate Micromedex as a preferred DI database and students further along in their education are comfortable answering DI questions. This research will aid in guiding curricula develop by ensuring students learn how to use all drug databases and are prepared to answer DI question during experiential rotations.

**309. The use of a mobile application to enhance communication and accessibility for students and faculty.** *Kerian Miyashiro, PharmD, Candidate BS, Daniel Ng, PharmD, Candidate BS, Rahel Dawit, PharmD Candidate, Micheline Goldwire, PharmD, MSc, BS;* School of Pharmacy, Regis University, Denver, CO

**PURPOSE:** Consolidating routinely accessed resources for delivery via a mobile device will provide the user with one simple method for information retrieval. Improved communications between Regis University School of Pharmacy (SOP) students and faculty as well as improved accessibility to online resources are also benefits. The purpose of this study is to evaluate student and faculty perceptions about improved communications and accessibility/usability of information and resources available through a designated mobile application.

**METHODS:** A mobile application programmed via LiveCode Community Edition was developed; however, after meeting with Information Technology Services, use of a mobile content management system appears to be more feasible. Resources to be consolidated include SOP news, links to drug information databases, SOP specific information (e.g., student handbook, course schedules), and frequently visited sites (e.g., email and E\*Value). A preliminary survey was distributed to fourth-year students (n=73) and faculty (n=28) to identify: 1) if they would use a mobile application and 2) potential components they would find useful. Implementation of the mobile application is planned for August 2013. Use of individual components will be tracked. A post-implementation survey to assess faculty and student accessibility/usability perceptions will be distributed one month after release of the mobile application.

**RESULTS:** Based on responses from the preliminary survey, 89% (n=65) would use a mobile application. Potential users would like access to drug information databases (98%), E\*Value (78%), email (77%), calendar of events (72%), exam schedules (63%),

RUSOP news (63%), class schedules (57%), OEE updates (52%), and other (9%). Results from the post-implementation survey will be available in late September.

**CONCLUSION:** Based on preliminary data, a mobile application developed specifically for SOP faculty and students would be used. Final conclusions will be available after implementation to support development of a mobile application to improve communications and accessibility/usability of routinely used resources.

## Education/Training

**310. Assessment of student pharmacist experience at an interprofessional student-run free clinic.** Kyle Turner, PharmD Candidate 2014<sup>1</sup>, Holly Gurgle, PharmD, BCACP, CDE<sup>2</sup>, Angela Hardcastle, PharmD Candidate 2014<sup>1</sup>, Eman Biltaji, BPharm MS<sup>3</sup>, Carrie McAdam-Marx, RPh MS, PhD<sup>3</sup>; (1) College of Pharmacy, University of Utah, Salt Lake City, UT (2) Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City, UT (3) Department of Pharmacotherapy & Pharmacotherapy Outcomes Research Center, University of Utah College of Pharmacy, Salt Lake City, UT

**PURPOSE:** Healthcare delivery models are increasingly focused on the use of interprofessional teams. This study assessed student pharmacist experience working in an interprofessional, student-run free clinic.

**METHODS:** Primary care patient visits at a student-run free clinic were conducted by volunteer teams of two physician assistant students and a student pharmacist. Physician, physician assistant, and clinical pharmacist preceptors serve as attendings. An eleven item Likert scale survey was developed. Questions focused on student attitudes toward primary care clinical pharmacy, caring for underserved patients, and working in interprofessional teams. Student pharmacists were offered the survey before and after their volunteer commitment. Survey responses were anonymous and students were only offered the survey during their first volunteer experience. Survey responses were summarized using descriptive statistics and Wilcoxon signed-rank test.

**RESULTS:** From January to May 2013, 28 third (N=25) and fourth (N=3) professional year student pharmacists volunteered at the clinic and completed the survey. After volunteering, students were more familiar with the pharmacist's role on the primary care team ( $p < 0.001$ ). Student interest in practicing in primary care after graduation increased ( $p = 0.007$ ). Volunteering also improved students' ability to develop patient-centered, therapeutic plans as part of a multidisciplinary team ( $p = 0.03$ ), communicate therapeutic plans to other healthcare students or professionals ( $p = 0.006$ ) and patients ( $p = 0.003$ ) and provide culturally competent care ( $p = 0.01$ ). After volunteering, all students "strongly agreed" or "agreed" that learning with other healthcare students and professionals increases their ability to take a patient history, complete a physical exam, and felt that patients would benefit by receiving care from interprofessional teams.

**CONCLUSION:** A volunteer experience at an interprofessional, student-run free clinic increased students' ability to develop and communicate care plans. The experience also increased familiarity and interest in primary care and underserved healthcare amongst student pharmacists, and it improved student attitudes toward interprofessional practice.

**311. Team Based Learning to prepare students for an emergency contraception counseling exercise.** Gina M. Prescott, Pharm.D., BCPS<sup>1</sup>, Lauren Stuczynski, Pharm.D. candidate<sup>2</sup>; (1) State University of New York at Buffalo, Buffalo, NY (2) State University of New York at Buffalo

**PURPOSE:** To evaluate students' perceptions on whether team-based learning (TBL) is an effective way to provide them with the knowledge necessary to effectively and confidently counsel patients on the use of emergency contraception (EC).

**METHODS:** Approximately 125 first-year pharmacy students in the University at Buffalo's School of Pharmacy and Pharmaceuti-

cal Sciences enrolled in PHM 516 (Self-Care Therapeutics) participated in a TBL session during a women's health practicum. At the end of the TBL session, each individual student had approximately 10 minutes to counsel a teaching assistant (TA) on the proper use of emergency contraception using the QUEST/SCHOLAR methods. The students were provided with an optional survey to provide baseline information with their ability or understanding of emergency contraception and/or counseling. The surveys were conducted before and after the TBL session and counseling.

**RESULTS:** The data collected has not yet been analyzed pending IRB approval, but is expected to be completed by August. The students' confidence/knowledge survey questions on EC, mean grades for student readiness quizzes, and gender will be analyzed with descriptive statistics. A nonparametric student t-test will be utilized to assess if a difference exists between male and female students.

**CONCLUSION:** Although the data has not yet been analyzed, it is expected that the results will show that TBL is an effective way to prepare pharmacy students for counseling on emergency contraception.

**312. Assessment of mentor involvement with pharmacy students pursuing post-graduate residency training.** Marley Linder, Pharm.D. Candidate<sup>1</sup>, Drayton Hammond, Pharm.D., MBA<sup>2</sup>, Sandra Garner, Pharm.D., BCPS, FCCP<sup>1</sup>, P. Brandon Bookstaver, Pharm.D., BCPS (AQ-ID) AAHIVP<sup>3</sup>; (1) South Carolina College of Pharmacy – MUSC Campus (2) University of Florida Health Jacksonville (3) South Carolina College of Pharmacy, Columbia, SC

**PURPOSE:** The objective of this study is to elucidate the professional relationships between pharmacy students pursuing post-graduate residency training (PGRT) and their mentors during pharmacy school.

**METHODS:** An IRB-approved survey was emailed in April and May 2013 to deans and faculty members representing all colleges and schools of pharmacy in the United States. All survey responses were recorded anonymously using SurveyMonkey@.Pharmacy students in the Class of 2013 seeking PGRT were eligible for inclusion. Comparator groups were matched and unmatched students. Students were asked to assess the level of satisfaction with mentor activities using a Likert scale (1 meaning strongly agree to 5 meaning strongly disagree), rank the importance of six pre-identified mentor activities, and indicate the desired relative amount of mentorship with PGRT preparation activities. Types of preparation methods, number of mentors, and manner of mentor determination were assessed in addition to demographic data. Nominal variables were evaluated with descriptive statistics and chi-square test or Fisher exact test when appropriate.

**RESULTS:** Two-hundred sixty-eight students from 39 colleges and schools of pharmacy responded (matched  $n = 226$ , unmatched  $n = 42$ ). Compared with students who did not match in 2013, students who matched were more satisfied with mentorship on preparation on a curriculum vitae ( $p = 0.026$ ), interviews ( $p < 0.0001$ ), regional and national meetings ( $p = 0.047$ ), programs to apply to ( $p = 0.0002$ ), and rank list determination ( $p = 0.03$ ). The matched group also found mentorship with curriculum vitae preparation ( $p = 0.008$ ) and programs to apply to ( $p = 0.0075$ ) more important than unmatched students. There were no statistically significant differences in the preparation methods, number of mentors, or manner of mentor determination between groups.

**CONCLUSION:** Pharmacy students pursuing PGRT who matched perceived more value from a mentor-protégé relationship than unmatched students.

**313. Interprofessional education campaign on improving medication adherence.** Megan Elavasky, Pharm D Candidate<sup>1</sup>, Allen Dai, Pharm D Candidate<sup>1</sup>, Mary E. Fredrickson, Pharm.D. Candidate<sup>1</sup>, Michelle Poole, Pharm D Candidate<sup>1</sup>, Morgan Sherritt, Pharm D Candidate<sup>1</sup>, Susan Fosnight, RPh CGP, BCPS<sup>1</sup>; (1) Northeast Ohio Medical University, Rootstown, OH

**PURPOSE:** The purpose of our research was to evaluate the effects of a medication adherence education campaign to health care providers.

**METHODS:** Northeast Ohio Medical University (NEOMED) developed an interprofessional team to organize and run a "Script Your Future" program. The program was an outreach to health care providers and the community to educate about methods to improve adherence. The NEOMED campaign specifically targeted improving awareness of the importance of providing medication adherence counseling and skills in providing this counseling. The team was led by two faculty members and two pharmacy students. The team grew to six faculty members, one PGY1 pharmacy resident, and twenty-six pharmacy and medicine students that participated in planning, development of resources, or staffing of community events. The group developed disease specific resources, general adherence tips, and organized two community events including an "adherence fair" which targeted both patients and providers education on methods to improve adherence. A post campaign survey was developed to provide feedback concerning the campaign.

**RESULTS:** Through meetings with faculty physicians, emails to pharmacy students, medicine students, and preceptors, 801 providers or soon-to-be providers were provided succinct information to improve medication adherence. As part of the campaign, 1,112 patient counseling sessions on adherence were documented and reported in the target month of February. This included 256 counseling sessions on diabetes management, 140 on respiratory management, and 530 on cardiovascular disease management. Additional outcomes are pending and will report on the post-campaign survey. Responses to this survey will be used to improve our campaign next year.

**CONCLUSIONS:** During the 2013 NEOMED Script Your Future campaign, 801 health care providers and students were provided information to improve medication adherence. There were 1112 documented patient medication adherence counseling sessions reported during the target month as part of this campaign. Further results are pending.

## Emergency Medicine

**314. Antibiotic stewardship in the emergency department: reducing the inappropriate use of piperacillin/tazobactam.** . Elaine Fosmire, PharmD Candidate<sup>1</sup>, Sarah Norskog, PharmD Candidate<sup>1</sup>, Kevin Kaucher, PharmD<sup>2</sup>, Jeffrey Sankoff, MD, FACEP<sup>3</sup>, Michelle Haas, MD<sup>4</sup>; (1) Acute Care Pharmacy, Denver Health Medical Center (2) Acute Care Pharmacy/Emergency Department, Denver Health Medical Center (3) Emergency Department, Denver Health Medical Center (4) Division of Infectious Diseases/Department of Medicine, Denver Health Medical Center

**PURPOSE:** Antibiotic stewardship programs promote the rational use of antibiotics, which assists in limiting the emergence of antibiotic resistant pathogens, adverse events and increased costs associated with inappropriate broad-spectrum agent use. Few emergency departments have incorporated antibiotic stewardship programs despite antimicrobial agents being the second most common agent prescribed. This project was established to implement a multidisciplinary antibiotic stewardship program in the Emergency Department (ED) at Denver Health Medical Center (DHMC) to reduce the inappropriate utilization of piperacillin/tazobactam and increase adherence to established DHMC infectious disease (ID) antibiotic stewardship guidelines.

**METHODS:** At the end of 2012, antibiotic stewardship guidelines were simplified and distributed to ED staff, targeting medical residents for specific education on guideline and antibiotic regimen changes. To measure the impact of this intervention, the pharmacy system will be queried to identify all administration of piperacillin/tazobactam in the DHMC ED from January 2013 through September 2013. Intern pharmacists will perform retrospective chart reviews to determine the intended indication for antibiotic therapy and, using the DHMC ID antibiotic stewardship guideline, determine on a case-by-case basis if use was appropriate or inappropriate. These data will be compared to

pre-intervention data and to data queried from the pharmacy system database on cefepime and levofloxacin administration in the DHMC ED allowing analysis on a month-by-month basis to elucidate any trends. It is hoped a decrease in inappropriate piperacillin/tazobactam administration with a proportional increase in cefepime and levofloxacin administration will be seen, while an increase in appropriate piperacillin/tazobactam administration will also be demonstrated. We are in the process of gaining Colorado Multiple Institutional Review Board (COMIRB) approval to complete this quality assurance project.

**315. Pharmacy intern program for documenting vaccinations in the emergency department.** Keyvan Nekouei, PharmD Candidate<sup>1</sup>, Kevin Kaucher, PharmD<sup>2</sup>, Kristi Yamasaki, PharmD<sup>3</sup>; (1) Inpatient Pharmacy, Denver Health Medical Center, Denver, CO (2) Acute Care Pharmacy/Emergency Department, Denver Health Medical Center (3) Denver Health Medical Center

**PURPOSE:** Since May, 2012 Colorado has experienced over 100 cases of pertussis monthly. Throughout this epidemic, emergency departments continue to provide high rates of tetanus vaccinations. Unfortunately, inability to access vaccine histories has resulted in administration of inappropriately timed and duplicate vaccinations. The primary objectives of this study are to increase vaccine documentation, prevent inappropriate vaccinations, and assign cost avoided through increased documentation percentages compared to historical controls. This intern led program looks to establish a role for pharmacy in improving emergency department immunization practices.

**METHODS:** This study is exempt from Institutional Review Board approval as no patient identifiers will be used, collected or analyzed for research. All data that will be used is currently being collected for hospital administrative purposes. Physical vaccination logs kept by emergency department nursing staff will be collected and stored in the ED pharmacy satellite. Pharmacy interns will then record all patient vaccinations into VaxTrax – a web-based vaccine administration and inventory system. Using historical vaccination records found in VaxTrax, interns will identify all cases in which Tdap vaccinations were given to those who've already received a Tdap booster vaccine per ACIP guidelines, which is considered an inappropriate vaccination. We will analyze data from October 2012 to September 2013; a continuation from our initial pilot program in October 2012. The data from this program will be used to identify if over-immunization is a problem in the emergency department, what the monetary benefit to improving documentation could be and ways to improve the vaccination practices of emergency department care providers.

## Endocrinology

**316. Pharmacodynamic effects of low-dose pioglitazone in nondiabetic patients with the metabolic syndrome.** Anh Vu, Pharm.D. Candidate<sup>1</sup>, Amber Beitelshees, Pharm.D., MPH<sup>2</sup>, Ronald Prigeon, MD<sup>2</sup>, Maha Sidhom, B.A.<sup>1</sup>, Brooke Bredbeck, B.S.<sup>1</sup>, Julie Predhomme, ANP<sup>1</sup>, Lisa Kosmiski, M.D.<sup>3</sup>, Christina Aquilante, Pharm.D.<sup>1</sup>; (1) University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO (2) University of Maryland, Baltimore (3) University of Colorado School of Medicine, Aurora, CO

**PURPOSE:** Pioglitazone beneficially modulates components of the metabolic syndrome, but is associated with dose-dependent adverse effects (e.g., weight gain). The objective of this study was to compare the effects of low-dose pioglitazone (7.5 mg daily) versus placebo on plasma adipocyte-derived cytokines, C-reactive protein (CRP), and components of the metabolic syndrome in non-diabetic adults.

**METHODS:** Nondiabetic men and women between 30 and 60 years of age with a clinical diagnosis of the metabolic syndrome were enrolled in this prospective, double-blind study. Participants were randomly assigned to 8 weeks of treatment with pioglitazone 7.5 mg daily (n=15) or placebo (n=17). The primary endpoint was the change in plasma high molecular weight



(HMW) adiponectin from baseline to week 8. Secondary end-points included changes in plasma total adiponectin, omentin, CRP, body weight, insulin sensitivity (by IVGTT), glucose, lipids, and blood pressure. Week 8 variables were compared between groups by ANCOVA with treatment group as the fixed effect and the respective baseline variable as the covariate.

**RESULTS:** The study included 32 participants with the metabolic syndrome (56% women, 72% Caucasian, 72% obese, and 63% impaired fasting glucose). Pioglitazone was associated with a significant increase in HMW adiponectin levels from baseline to week 8 as compared with placebo (+47% vs -10%,  $p < 0.001$ ). The change in HMW adiponectin was significantly correlated with the change in insulin sensitivity in the pioglitazone group ( $r = 0.784$ ,  $p = 0.003$ ). There were no significant differences in changes in total adiponectin, omentin, and CRP levels between the groups. Likewise, changes in body weight, insulin sensitivity, glucose, lipids, and blood pressure did not differ between pioglitazone and placebo.

**CONCLUSION:** These findings demonstrate that low-dose pioglitazone favorably modulates HMW adiponectin, which was correlated with an improvement in insulin sensitivity, in nondiabetic adults with the metabolic syndrome. Additional, larger studies of low-dose pioglitazone in this patient population are warranted.

## Geriatrics

**317. Student College of Clinical Pharmacy (SCCP) provides education regarding counseling of patients with COPD for Akron Area Agency on Aging care managers.** . Mary E. Fredrickson, Pharm.D. Candidate, Patrick J. Gallegos, Pharm.D., R.Ph. BCPS, Mate Soric, Pharm.D., BCPS, Susan Fosnight, RPh CGP, BCPS, Elizabeth Legros, Pharm.D. Candidate, Aleta Smithbauer, Pharm.D. Candidate; Northeast Ohio Medical University, Rootstown, OH

**PURPOSE:** The purpose of the study is to evaluate the efficacy of a Student College of Clinical Pharmacy presentation seeking to improve case managers' understanding of proper inhaler use and patient counseling techniques in patients with COPD. The study will also assess 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 regarding methods to improve their understanding of proper inhaler use in patients with COPD and how to properly counsel these patients. This presentation will be delivered on multiple occasions in the summer of 2013. We will be administering voluntary and confidential pre- and post-surveys to the care managers. The surveys will be 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.

## Health Services Research

**318. Development of strategy and support plan of hospital pharmaceutical care service R&D in Korea.** Chae-Reen Jeong, B.S.<sup>1</sup>, Nayoung Han, MS<sup>1</sup>, YunKyoung Song, M.S.<sup>1</sup>, Jeong-Hyun Yoon, PharmD<sup>2</sup>, Dong Chul Suh, Ph.D<sup>3</sup>, Jung Mi Oh, PharmD<sup>1</sup>; (1) College of Pharmacy, Seoul National University, Seoul, South Korea (2) College of Pharmacy, Pusan National University, Pusan, South Korea (3) College of Pharmacy, Chung-Ang University, South Korea

**PURPOSE:** The importance of pharmaceutical care service R&D has been growing recently to meet the needs of medication therapy and to deliver demonstrable value related to optimization of drug treatments. The final goal of this project was to identify the

core areas for the R&D of pharmaceutical care services and develop the strategic plans for hospital pharmacies.

**METHODS:** This project was undertaken by a team of highly qualified researchers and experts in the area of pharmaceutical care services and a body of External Expert Panel (EEP) was also created from the key groups leading the area in Korea. First, after investigating the current status of hospital pharmaceutical care service R&D in Korea compared with foreign status, we analyzed the clinical, economic and humanistic outcomes of the services. Strategic plans were initially derived through PEST and SWOT analysis. Decision tree tables were proposed based on the analysis results, and the priority of the suggested agenda was determined by Analytic Hierarchy Process (AHP).

**RESULTS:** We derived 13 hospital pharmaceutical care agendas taking into account public health, service improvement, economics, and particularities of the pharmaceutical care system. The 'Development of pharmaceutical care service center for metabolic/chronic disease' project accounted for the highest priority.

**CONCLUSION:** The results should be utilized by the government to nationally support the development of the standards and relevant regulations related pharmaceutical care services in Korea. This study will strengthen global competition of pharmaceutical care service and ultimately improve the quality of life of the patients we care. [Acknowledgement: This study was supported by a grant of the Korea Healthcare technology R&D Project, Ministry of Health & Welfare, Republic of Korea. (A120190)].

## Herbal/Complementary Medicine

**319. A comparative study of the effects of the ethanolic extract of the seeds of *Leucaena leucocephala* (Leguminosae) and *Mimosa pudica* (Fabaceae) on the hair follicle damage and hair growth retardation of a BALB/c mouse.** Giannina Richelle Chan, Bachelor of Science in Pharmacy Major in Clinical Pharmacy; Precious Bagazin, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Maureen Bautista, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Christine Beatrice Gison, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Joanne Fritzie Talvo, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Christlan Tolentino, Bachelor of Science in Pharmacy Major in Clinical Pharmacy; Department of Pharmacy, University of Santo Tomas, Manila, Philippines

**PURPOSE:** This study addressed hirsutism as a primary disease, or as adverse effect of drug use, where too much hair is a problem to patients. This study compared hair growth inhibition properties of *Leucaena leucocephala* and *Mimosa pudica*, efficacy on controlling hair growth and inducing hair follicular damage on BALB/c mice. Percolation extracted mimosine, which is the alkaloid responsible for hair growth inhibition of the two plants.

**METHODS:** Qualitative and quantitative methods were done to determine if mimosine was present in the two plant extracts. A twenty-one day animal testing was conducted on four groups of partially shaved BALB/c mice. Comparative studies were done between the results from the two plant sources, and statistical data was used to compare and contrast the effects on the animal models.

**RESULTS:** Groups treated with *L. leucocephala* and *M. pudica* have significantly shorter hair lengths. There was no sufficient evidence that mean hair diameters of the different groups differ significantly. Hair regrowth assay showed significant difference between the groups only in days 7 and 11, and that both *M. pudica* and *L. leucocephala*. Are significantly different with Eflornithine but evidence that *M. pudica* and *L. leucocephala* are significantly different wasn't statistically established. With the percentage hair regrowth, *L. leucocephala* gave the slowest average growth rate of 9.51% among groups. Hair follicular damage was seen in groups treated with the two extracts. Assessment of erythema, edema and petechiae daily showed absence of the skin reactions.

**CONCLUSION:** *M. pudica* and *L. leucocephala* extracts were comparable to the positive control. *L. leucocephala* is more effective

tive as a hair growth inhibitor than *M. pudica*. Both are statistically equally effective in hair growth inhibition. Both extracts did not cause adverse skin reactions. Mouse hair analysis showed sufficient evidence that *L. leucocephala* and *M. pudica* promotes hair growth retardation by damaging hair follicles.

## HIV/AIDS

**320. Control of HIV viremia in indigent/low-income HIV-infected subjects.** *Travis Ast, Pharm.D. Candidate 2014, R. Chris Rathbun, Pharm.D., BCPS, Michelle Liedtke, Pharm.D., BCPS, Misty Miller, Pharm.D., BCPS; Department of Clinical and Administrative Sciences, College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City, OK*

**PURPOSE:** Chronic suppression of HIV viremia is essential to decrease HIV and non-HIV morbidity and mortality. Control of HIV viremia in indigent/low income populations has historically been lower than rates achieved in clinical trials. We describe the prevalence of viral suppression in a cohort of patients treated at a multidisciplinary, Ryan-White funded clinic that includes HIV specialty pharmacists.

**METHODS:** A retrospective, observational study was conducted to examine the prevalence of viral suppression. Electronic medical records for indigent/low income HIV-infected patients at the University of Oklahoma Health Sciences Center (OUHSC) Infectious Diseases Institute were reviewed. Eligible patients were receiving antiretroviral therapy through the HIV drug assistance program between January 1, 2010 and May 15, 2013, had at least six months of viral load data, and received care from an HIV specialty pharmacist. Antiretroviral treatment-naïve and treatment-experienced patients were included. Demographic data that were collected included, gender, age, and ethnicity. Descriptive and inferential statistics were conducted, with an a priori level of significance set at <0.05.

**RESULTS:** A total of 719 patients (81% male, 57% Caucasian) met eligibility criteria. The median number of viral load measurements and duration of follow-up for the patient cohort were 9 (IQR: 6–10) and 1001 days (IQR: 720–1115), respectively. Six hundred sixty-one (92%) patients achieved a viral load <50 copies/mL during the 3.5 year evaluation period. Three hundred fifty-two patients (49%) maintained continuous viral suppression <50 copies/mL for greater than 12 months, and 69% maintained continuous suppression <200 copies/mL. The median duration of viral suppression <200 copies/mL for the cohort was 667 days (IQR:369–1004).

**CONCLUSION:** Viral suppression rates were high in this mixed population of treatment-naïve and treatment-experienced patients compared with historical reports. Sustained viral suppression is achievable in indigent/low income patients managed in a multidisciplinary clinic.

## Infectious Diseases

**321. Novel double and triple antibiotic combinations at clinically relevant concentrations against polymyxin B resistant *Pseudomonas aeruginosa*.** *Michael D. Bear, PharmD Candidate, Amy Suen, PharmD Candidate, Justin Lenhard, PharmD Candidate, Zackery Bulman, PharmD Candidate, Neang S. Ly, PhD Candidate, Gauri Rao, PharmD, Patricia N. Holden, BS, Brian T. Tsuji, PharmD; University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY*

**PURPOSE:** Therapeutic options for newly-emerging strains of multi-drug resistant *P. aeruginosa* (PA) are diminishing rapidly. We evaluated the bactericidal activity and pharmacodynamics of novel two and three drug combinations of polymyxin B (PB), doripenem (DORI), and piperacillin-tazobactam (PT) against PB-resistant *P. aeruginosa*.

**METHODS:** Double and triple combinations were evaluated in time killing experiments using a PB-resistant PA clinical isolate ( $10^8$  CFU/mL) against clinically relevant concentrations in multiple arrays of PB (2, 4, 6 mg/L), DORI (2.5, 25, 50 mg/L) and PT (94/10, 169/17, 209/24 mg/L). Bacterial killing was evaluated at 0,

1, 2, 4, 8, 24, 25, 26, 28, 32, and 48 hours. Validation experiments were performed by creating and using a PA strain resistant to all three drugs. An area based pharmacodynamic approach characterized cumulative effect (AUCCFU<sub>0-48</sub>).

**RESULTS:** For monotherapy, the reduction in AUCCFU<sub>0-48</sub> for PB2, PB4, PB6 was similar to growth control; DORI2.5, DORI25 and DORI50: -1.5, -1.7 and -1.9; PT94, PT169, PT209: -0.7, -1.2 and -1.3. There was no increase in killing for two drug combination regimens involving PB, with reductions in AUCCFU<sub>0-48</sub> for PB2 + DORI2.5: -1.2; PB2 + DORI25: -1.7, PB2 + DORI50: -1.7; PB2 + PT209: -1.4. For double beta-lactam combinations, no additional killing over DORI alone was observed, with a reduction in AUCCFU<sub>0-48</sub> for DORI2.5 + PT169: -1.7; DORI25 + PT169: -1.8; DORI50 + PT209: -1.8. For triple combinations, an increase in maximum effect was minor with reduction in AUCCFU<sub>0-48</sub> for PB2 + DORI25 + PT169: -2.4; PB4 + DORI25 + PT169: -2.4; PB6 + DORI25 + PT169: -2.5. Overall, high concentration DORI based regimens were the most promising.

**CONCLUSION:** The pharmacodynamics of double and triple drug combinations of PB, DORI and PT were characterized. In the face of PB resistance, DORI based regimens were the most effective by overcoming a high bacterial density of PA resulting in bactericidal killing. These results are promising as treatment options for persistent infections due to PA such as bi-lobar pneumonia.

**322. A retrospective evaluation of the effectiveness of vancomycin continuous infusion versus intermittent dosing.** *Kimberly J. Won, Pharm.D. Candidate, Tyree H. Kiser, PharmD, FCCP, BCPS; University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO*

**PURPOSE:** The aim this study was to compare the safety, efficacy, dosing, and monitoring of continuous infusion (CI) versus intermittent dosing (INT) vancomycin therapy in hospitalized patients.

**METHODS:** This IRB-approved, retrospective, case-control study enrolled patients who received vancomycin while admitted to the University of Colorado Hospital between January 1, 2005 and March 31, 2013. Patients were evaluated for time within therapeutic range (trough concentrations 10–20 mcg/mL for INT and random concentrations 20–30 mcg/mL for CI), number of dose adjustments, length of hospital stay, and initial total daily dose (TDD) and vancomycin level.

**RESULTS:** A total of 120 patients (n=60 per group) were evaluated. Patients receiving CI spent more time within therapeutic range than those receiving INT (62% ± 38% vs. 45% ± 28%, respectively; p=0.006) and required less dose adjustments (1.02 ± 1.17 vs. 2.31 ± 2.19; p=0.0001). The mean TDD was similar for both groups [2531 ± 1003 mg (32 ± 16 mg/kg/d) vs. 2567 ± 876 mg (32 ± 12 mg/kg/d)] for CI and INT, respectively; p=0.77. Mean ± SD first steady state concentrations were within their respective goal ranges of 20–30 mcg/mL and 10–20 mcg/mL (24.2 ± 7 mcg/mL, 14.4 ± 7 mcg/mL). There were no significant differences in mortality (4 deaths vs. 10 deaths; p=0.15), median length of hospital stay (12.0 days vs. 11.0 days; p=0.44), average duration of vancomycin treatment (11.7 days vs. 11.8 days; p=0.99), and the median serum creatinine change from baseline (-0.23 ± 0.8 mg/dL vs. -0.04 ± 0.6 mg/dL; p=0.21) between the two groups.

**CONCLUSION:** In this study, CI vancomycin therapy maintained a greater percentage of time within therapeutic range, required less dose adjustments, and provided similar efficacy and safety compared to INT vancomycin. Further research is needed to investigate the safety, efficacy and dosing strategies of CI vancomycin in hospitalized patients.

**323. Impact of documented antimicrobial allergies on prescribing practices.** *Krutika Mediwala, PharmD Candidate<sup>1</sup>, Raychel Holte, PharmD Candidate<sup>1</sup>, Margaret Korn, PharmD Candidate<sup>1</sup>, P. Brandon Bookstaver, PharmD, BCPS (AQ-ID) AAHIVP<sup>2</sup>; (1)South*

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**PURPOSE:** The presence of antimicrobial allergies, specifically those without a documented reaction, may drive prescribing of alternative antibiotics, resulting in a negative clinical impact. The objective of this study is to determine the impact caused by documentation of antimicrobial allergies on antimicrobial prescribing at a tertiary care medical center.

**METHODS:** Patients admitted between November 2010 and February 2011 at Palmetto Health Richland were screened for study inclusion and categorized in "Antibiotic Allergy" and "No Documented Antibiotic Allergy" groups. A random sample of patients were included if they were prescribed antibiotic(s) while hospitalized, allergies were documented (not necessarily reconciled), and 18 years or older. The primary endpoint is the difference in antibiotic utilization between the two groups. Secondary endpoints include length of antibiotic therapy, length of hospitalization and treatment-related adverse events. Data collection was performed via the electronic medical record. Descriptive statistics will be applied to the dataset. Continuous variables will be compared with T-test and nominal data compared with Chi-square test.

**RESULTS:** To date, 150 patients have been analyzed, each group including 75 patients. The majority of patients were African-American (55%) and female (66%). Significantly more females were in the antibiotic allergy group compared to those with no antibiotic allergy, 84% vs. 48%. The most common allergies reported were to penicillins, followed by sulfonamides. Twenty-eight percent of allergies were completely reconciled. Antibiotics were primarily prescribed for skin and soft tissue infections, pneumonia, and urinary tract infections and were similar between groups. Patients with a documented allergy were more likely to receive vancomycin (53% vs. 37%), fluoroquinolones (65% vs. 37%), and carbapenems (46% vs. 12%) compared to those without a documented allergy. Penicillins and cephalosporins were more commonly prescribed in patients without documented allergies.

**CONCLUSION:** Unreconciled allergy documentation is common and significantly influences the selection of antimicrobial therapy.

**324. Vancomycin pharmacodynamics against heterogeneous vancomycin-intermediate *Staphylococcus aureus* bloodstream isolates with accessory gene regulator dysfunction: Challenging the AUC/MIC paradigm.** Amy Suen, PharmD Candidate<sup>1</sup>, Iris Wang, PharmD<sup>1</sup>, Tina Khadem, PharmD<sup>1</sup>, Michael D. Bear, PharmD Candidate<sup>1</sup>, Justin Lenhard, PharmD Candidate<sup>1</sup>, Jack Brown, PharmD, MS<sup>2</sup>, Brian T. Tsuji, PharmD<sup>1</sup>; (1) University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (2) Strong Hospital, University of Rochester Medical Center, NY

**PURPOSE:** *S. aureus* possesses exceptional virulence and a remarkable ability to adapt under the pressure of antibiotic therapy. The accessory gene regulator (*agr*) is the master regulator of virulence and resistance. We examined the response of a heterogeneous vancomycin-intermediate *S. aureus* (hVISA) clinical isolate from a bloodstream infection that displayed *agr* dysfunction to vancomycin in a hollow fiber infection model.

**METHODS:** A clinical hVISA isolate displaying *agr* dysfunction was studied in a hollow fiber infection model that simulated human doses with a free AUC/MIC of 450 given every 12 hours over 240 hours at an initial inoculum at 10<sup>8</sup> colony forming units (CFU)/mL with serial sampling. Bacterial subpopulations were analyzed by plating on vancomycin-containing agar of 2, 4, and 8 mg/L. Pharmacokinetics (PK) and pharmacodynamics (PD) were analyzed by integrating area under the CFU/mL curve over 240 hours.

**RESULTS:** Against the clinical hVISA bloodstream isolate, vancomycin displayed log<sub>10</sub> CFU/mL bacterial reductions on day 1, 2, 3, 4, 5, 6, 8, and 10 of -2.3, -2.9, -3.6, -3.9, -4.0, -0.7, +1.2, and +2.0 respectively with a significant regrowth phenomena occurring at day 5-6. Although there was no detection of resistant subpopulations up to day 4, on day 5 hVISA resistance was sequentially amplified from 2.30, 6.51, 8.81 and 9.90 log<sub>10</sub> CFU/mL on plates containing 2 mg/L of vancomycin. The total reduction of bacterial area at a free AUC/MIC of 450 was -1.39. For

resistant subpopulation analyses, exposure to vancomycin at 2 mg/L, 4 mg/L, and 8 mg/L resulted in an increase in bacterial area of 10.84, 10.97 and 10.94 log<sub>10</sub> CFU/ml over 240 h respectively.

**CONCLUSION:** *Agr* dysfunction may be an adaptation mechanism of *S. aureus* persistence in the face of continued vancomycin exposure. These data have implications of optimal vancomycin dosing in persistent MRSA bacteremia.

**325. Coccidioidal osteomyelitis: A case report.** Negin S. Moon, Pharm.D. Candidate<sup>1</sup>, ViVi T. Nguyen, Pharm.D. Candidate<sup>1</sup>, Kara A. Williams, Pharm.D. Candidate<sup>1</sup>, Chad M. VanDenBerg, Pharm.D., BCCP<sup>1</sup>, John P. Ouderkerk, M.D.<sup>2</sup>, Vanhida Huang, Pharm.D., BSPHM<sup>1</sup>; (1) Department of Pharmacy Practice, Mercer University College of Pharmacy, Atlanta, GA (2) Infectious Diseases Group of Atlanta, Atlanta, GA

**PURPOSE:** Osteomyelitis due to disseminated *Coccidioides immitis* infections is rare and seldom documented in literature. *Coccidioides* is a fungus found in dry soil and endemic to areas of low rainfall in the southwestern United States, parts of Mexico, and Central and South America. Coccidioidomycosis, also known as Valley Fever, is a common cause of respiratory infections which are typically self-limiting and rarely manifest into extrapulmonary complications such as osteomyelitis. The current treatment of choice for coccidioidal osteomyelitis is an azole antifungal along with surgical debridement. Amphotericin B may also be used as either second line therapy or for severe cases. The combination treatment of an azole plus amphotericin B continues to be evaluated. Hence, we sought to describe an unusual patient case of coccidioidal osteomyelitis treated with combination therapy in Atlanta, Georgia, a non-endemic region of the United States.

**METHODS:** A retrospective medical chart review was conducted. **RESULTS:** A 36 year-old African-American male, who was incarcerated in a penitentiary, presented with osteomyelitis of the ankle secondary to coccidioidomycosis. Two months prior to hospitalization, the patient was transferred to Georgia from another federal penitentiary in southern California. Intravenous fluconazole 800 mg was administered daily as initial therapy for two weeks without resolution. Based on treatment recommendations, the patient's therapy was subsequently switched to a combination of intravenous liposomal amphotericin B 350 mg and oral itraconazole 200 mg administered daily for the duration of hospitalization. Response was noted symptomatically and microbiologically after induction of combination therapy and the infection eventually resolved. The patient was discharged with a recommendation for suppressive therapy at the site.

**CONCLUSION:** While documented, coccidioidal osteomyelitis is still rare, particularly in non-endemic regions; therefore further investigation is warranted, and clinicians in all geographical areas should be aware of the importance of travel history as well as prompt diagnosis and treatment.

**326. Factors influencing initial vancomycin trough concentrations in an adult inpatient population: a retrospective analysis.** Emily Higdon, BSPS, Mark Kirkikis, BSPS, Zachary Brent, BSPS, Kayla R. Stover, Pharm.D., BCPS, S. Travis King, Pharm.D., BCPS; School of Pharmacy, University of Mississippi School of Pharmacy, Jackson, MS

**PURPOSE:** Therapeutic drug monitoring of vancomycin is utilized daily to tailor therapy, improve outcomes, and minimize resistance. Identifying factors associated with therapeutic or non-therapeutic concentrations may help guide empiric therapy. Our aim was to determine the correlation of patient and disease characteristics with vancomycin serum concentrations.

**METHODS:** This retrospective chart review included patients treated with vancomycin that had an initial trough drawn between 10/1/12 and 5/31/13. Patients who were pregnant, less than 18 years old, or with unstable renal function or end-stage renal disease were excluded. Patients were also excluded if they received vancomycin at inconsistent dosing intervals or had an



inappropriately drawn trough. Patient characteristics, concomitant therapies, comorbidities, and vancomycin regimen specifics were collected to determine their association with vancomycin troughs. A multivariate linear regression analysis was performed to delineate correlation. An  $\alpha$  of 0.05 was defined as the significance level.

**RESULTS:** One hundred forty-nine patients were screened; 69 patients met inclusion criteria. The primary reason for exclusion was an inappropriately drawn trough ( $n=56$ ). Of the 69 included patients, 29 had therapeutic troughs (42.1%) and 40 did not (57.9%). Age ( $p<0.0001$ ), total daily dose (TDD) of vancomycin ( $p<0.0001$ ), and increased serum creatinine concentration ( $p<0.0001$ ) were directly associated with elevated vancomycin trough concentrations. Presence of diabetes mellitus ( $p=0.003$ ) and male gender produced an inverse association with vancomycin trough concentrations. When adjusted for total body weight, presence of diabetes maintained an inverse association ( $p=0.002$ ); male gender did not ( $p=0.055$ ).

**CONCLUSION:** Several factors may influence serum vancomycin trough concentrations, including age, gender, dose, and comorbidities. The inverse association of diabetes and trough concentrations is a novel finding. These associations should be considered in the empiric dosing of vancomycin in adult inpatients. Further study is needed to assess potential modifications to dosing nomograms, as well as explore the diabetes-trough association.

**327. Review of aerosolized antimicrobials for the treatment of hospital-acquired and ventilator-associated pneumonia.** Patricia Avalos, B.S., Fatima M. Ali, Pharm.D., BCPS, College of Pharmacy, Roosevelt University College of Pharmacy, Schaumburg, IL

**PURPOSE:** Aerosolized antimicrobials such as amikacin, aztreonam, colistin, gentamicin, and tobramycin may have a beneficial role in the treatment of multi-drug resistant (MDR) hospital-acquired pneumonia (HAP) and ventilator associated pneumonia (VAP). This review compiled the current literature to assess the safety and efficacy of aerosolized antimicrobials for the treatment of HAP and VAP.

**METHODS:** Literature that evaluated the safety and efficacy of aerosolized antimicrobial therapy in the treatment of HAP and VAP were included. PubMed searches with the following MeSH terms and key words were utilized: aerosolized, antimicrobials, anti-bacterial agents, anti-infective agents, antibiotics, pneumonia, ventilator-associated pneumonia, hospital-acquired pneumonia, inhalation, administration, aminoglycosides, amikacin, aztreonam, colistin, gentamicin, and tobramycin.

**RESULTS:** The search generated 709 results, 70 are included in this literature review. The remaining 639 articles were excluded for the following reasons: indications other than cystic fibrosis (320), cystic fibrosis (310), commentary (9). Other indications consisted of aspiration pneumonia, atelectasis, bronchiectasis, respiratory infections, or respiratory failure. The benefits of aerosolized antimicrobials vary throughout the literature. Aerosolized antimicrobials have a perceived benefit of a lower incidence of systemic toxicity because the inhaled antimicrobial is administered directly to the site of infection compared to systemic antimicrobials. The results regarding improvement of clinical symptoms, eradication of the pathogen, effect on ventilator days, and mortality are inconclusive as majority of the literature in these patient populations are retrospective studies or case reports.

**CONCLUSION:** According to the IDSA Practice Guidelines, treatment for HAP and VAP should utilize appropriate systemic antimicrobials targeting the offending pathogen. Aerosolized antimicrobials may be added as adjunctive therapy in patients with MDR gram-negative pneumonia that have failed systemic therapy. Randomized clinical trials are needed to establish whether aerosolized antimicrobials are beneficial in the treatment of multi-drug resistant HAP and VAP.

**328. Defining the relationship between antibiotic exposure and virulence in hypermutator strains of *Pseudomonas aeruginosa*.** Zackery Bulman, PharmD Candidate<sup>1</sup>, Michael D. Bear, PharmD

Candidate<sup>1</sup>, Justin Lenhard, PharmD Candidate<sup>1</sup>, Amy Suen, PharmD Candidate<sup>1</sup>, Neang S. Ly, PhD Candidate<sup>1</sup>, Patricia N. Holden, BS<sup>1</sup>, Mark Sutton, PhD<sup>2</sup>, Brian T. Tsuji, PharmD<sup>1</sup>; (1)University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY (2)University at Buffalo Department of Biochemistry, Buffalo, NY

**PURPOSE:** The impact of antibiotics on virulence of *P. aeruginosa* (PA), the primary pathogen in nosocomial pneumonia and the leading cause of infection in cystic fibrosis, has not yet been fully elucidated. Analysis of PA populations in patients with chronic infections reveals a high proportion of DNA repair deficient hypermutator strains. Our objective was to compare the virulence of PA hypermutator strains to that of the wild-type bacteria (PAO1) before and after treatment with polymyxin B.

**METHODS:** The virulence of PAO1 was compared to that of two isogenic hypermutator strains (mutM and mutS) using a waxworm (*Galleria mellonella*) killing assay. Bacteria were injected at  $10^2$  CFU/waxworm and incubated at 37°C. Mortality was assessed at the following time points: 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24 hours. To analyze the antibiotic exposure-virulence relationship, time kill assays were performed with a clinically relevant concentration of polymyxin B (8 mg/L) for 24, 48, or 72 hours. These bacteria were then injected into the waxworms.

**RESULTS:** Prior to antibiotic treatment, PAO1/mutM/mutS caused death in 95% of the waxworms within 24 hours with 73% dying between 18–22 hours. Survival (%) of PAO1/mutM/mutS were as follows: 0–16 h: 100,85,100; 17 h: 95,80,100; 18 h: 85,75,80; 19 h: 60,70,45; 20 h: 30,40,15; 21 h: 20,10,10; 22 h: 10,5,5; 23 h: 10,0,5; 24 h: 5,0,0. Time kill experiments with an inoculum of  $10^8$  CFU/mL for PAO1, mutM and mutS strains of PA after 24 hours with polymyxin B revealed log reductions of 2.0, 0.5 and 0.6 in CFU/mL respectively. Antibiotic exposure determinations on virulence are ongoing.

**CONCLUSION:** The data supports that the relative virulence of PA wild-type and hypermutator strains was not significantly different ( $p>0.05$ ) prior to antibiotic treatment. Our preliminary data suggests that exposure to polymyxin B may attenuate the virulence of the bacterial strains, especially with therapy extended past 24 hours.

**329. Evolution of vancomycin resistance in *Staphylococcus aureus*: rational dosing strategies to prevent persistence of small colony variants.** Justin Lenhard, PharmD Candidate, Amy Suen, PharmD Candidate, Michael D. Bear, PharmD Candidate, Zackery Bulman, PharmD Candidate, Patricia N. Holden, BS, Brian T. Tsuji, PharmD; University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY

**PURPOSE:** *S. aureus* has a remarkable ability to persist in the face of antimicrobial therapy. Our objectives were to characterize the impact of the small colony variant (SCV) on vancomycin pharmacodynamics, and to utilize reconstructive biology to define the evolutionary phenotypes of *S. aureus* subpopulations of the SCV.

**METHODS:** The MRSA strain COL displaying the normal phenotype (NP) and its isogenic SCV strain Ia48 were evaluated with time killing experiments at a starting inoculum of  $10^8$  CFU/mL. A heterogeneous inoculum was created using multiple ratios of NP/SCV of 100/0, 99/1, 80/20, 40/60, and 0/100. Samples were evaluated at 0, 1, 2, 4, 8, 24, 26, 28, 32, and 48 hours using vancomycin concentrations of 0, 0.5, 1, 2, 4, 8, 16, 32, 64, and 128 mg/L. Vancomycin pharmacodynamics were determined using area under the CFU curve and a Hill type maximal effect mathematical model.

**RESULTS:** Vancomycin concentrations  $>16$  mg/L against exclusively NP populations (ratio 100/0) achieved bactericidal activity ( $>4.3$  log<sub>10</sub> CFU/mL reduction at 48 hours), while against exclusively SCV populations (0/100) did not achieve bactericidal killing (1.0 log<sub>10</sub> CFU/mL maximum reduction at 48 hours). In mix culture experiments (80/20 and 40/60), maximum log bacterial reductions were  $>4.3$  and  $>3.2$  at 48 hours respectively. The SCV decreased vancomycin killing activity ( $E_{max}SCV=1.06$ ,

$E_{max}NP=2.17$ ,  $R^2>0.99$ ). As the proportion of the SCV in heterogeneous populations increased, vancomycin's maximal effect decreased ( $E_{max80/20}$  population=1.93,  $E_{max40/60}$  population=1.66,  $R^2>0.99$ ). In the evolutionary analysis, selective vancomycin pressure of  $\geq 16$  mg/L shifted a SCV minority (80/20) into a majority (40/60) by 28 hours, amplifying the SCV subpopulation by  $>250\%$ .

**CONCLUSION:** In the presence of a high inoculum, the reduction in vancomycin activity against the SCV phenotype of *S. aureus* results in selection for SCV strains at high drug concentrations. These results have implications for treatment of persistent high bacterial density infections such as device-related endocarditis.

### 330. Septic abortion due to Salmonella bacteremia: a case report.

Vivi T. Nguyen, Pharm.D. Candidate<sup>1</sup>, Negin S. Moon, Pharm.D. Candidate<sup>1</sup>, Yutaka Onuki, PharmD<sup>1</sup>, Kara A. Williams, Pharm.D. Candidate<sup>1</sup>, John P. Ouder Kirk, M.D.<sup>2</sup>, Rebecca S. Lee, PharmD<sup>1</sup>, Chad M. VanDenBerg, Pharm.D., BCCP<sup>1</sup>, Vanthida Huang, Pharm.D., BSPHM<sup>2</sup>; (1) Department of Pharmacy Practice, Mercer University College of Pharmacy, Atlanta, GA (2) Infectious Diseases Group of Atlanta, Atlanta, GA

**PURPOSE:** *Salmonella*, gram-negative bacteria, is associated with 42,000 cases of food-borne illness in the United States annually, although milder cases often go unreported. Symptoms of Salmonellosis are usually self-limiting in nature and include diarrhea, fever, and abdominal cramps. In more severe cases, *Salmonella* can infect the blood and other parts of the body requiring immediate and aggressive antibiotic therapy. *Salmonella* bacteremia in pregnancy is rare and if untreated can cause intrauterine infection and ultimately fetal demise. Thus, we describe a case of *Salmonella* bacteremia with no known origin in a pregnant patient leading to spontaneous abortion.

**METHODS:** A retrospective medical chart review was conducted. **RESULTS:** A 39-year-old African-American female presented to the emergency department at 11 weeks gestation with a spiking fever, vaginal bleeding, and a 2-day history of rigor and chills. Approximately 10 days prior to admission, the patient reported experiencing diarrhea that was self-limiting. The patient further reported no recent history of travel, consumption of contaminated food, or contact with any animal or reptile. A fetal ultrasound was performed and revealed an embryo with no cardiac activity. Subsequently, the patient spontaneously aborted the fetus. Two separately obtained blood cultures were positive for *Salmonella*, leading to the clinical diagnosis of septic abortion. Treatment was initiated for *Salmonella* bacteremia with ciprofloxacin 400 mg intravenously every 12 hours and ceftriaxone 2 g intravenously every 24 hours. The patient responded to therapy and was in stable condition when discharged home to complete the 14-day course of intravenous antibiotics. At the 2-week follow-up visit, the infection was completely resolved.

**CONCLUSION:** Salmonellosis in pregnancy is rare; however, a differential diagnosis should include *Salmonella* if the patient presents with acute diarrheal illness. Further investigation is warranted; however, prompt treatment of Salmonellosis is crucial in preventing maternal and fetal sequelae.

### 331. Modeled efficacy of three times weekly cefazolin dosing in hemodialysis patients to treat infective endocarditis.

Jacob Kesner, Pharm.D. Candidate, Renee Mercier, Pharm.D., J. Michael Yardman-Frank, B.S. Candidate, A. Mary Vilay, Pharm.D.; University of New Mexico, Albuquerque, NM

**PURPOSE:** Clinicians preferentially prescribe cefazolin 2 g IV three times weekly post-hemodialysis to treat infective endocarditis (IE) caused by methicillin-susceptible *Staphylococcus aureus* (MSSA), largely based on the convenient dosing schedule. Our goal was to determine the efficacy of this cefazolin regimen in treating MSSA IE in hemodialysis patients using an *in vitro* endocarditis model.

**METHODS:** The model consisted of a vessel filled with broth and fitted to a series of pumps. Simulated endocardial vegetations

(SEVs) were inoculated with MSSA 1199 and submerged in the vessel. Cefazolin was added to the model and its pharmacokinetics was simulated for renal failure and normal renal function. At predetermined time points, SEVs were removed, homogenized, and plated to determine bacterial density as measured by colony forming units (CFUs). The effects of cefazolin 2 g post-hemodialysis on SEV bacterial density over 48 and 72 h dosing intervals were tested. Cefazolin 2 g q8 h was the comparator. Growth controls, without cefazolin, for renal failure and normal renal function were also conducted. Analysis of variance (ANOVA), with Sidak post-hoc, compared CFUs observed at time 0, 48, and 72 h.

**RESULTS:** There was a difference in SEV bacterial density between experimental arms at baseline ( $p<0.001$ ). Therefore change in CFUs at 48 and 72 h compared to baseline was assessed. At 48 and 72 h there was significant decrease in SEV bacterial density in models containing cefazolin compared to their respective growth controls ( $p<0.001$ ). However there was no difference in overall SEV bacterial density change between renal failure arms (both the 48 and 72 h interval) and normal renal function models with cefazolin ( $p>0.05$ ).

**CONCLUSIONS:** No difference in SEV bacterial density change between renal failure and normal renal function models with cefazolin suggests that the common cefazolin 2 g post-hemodialysis regimen may be as effective as q8 h for normal renal function in treating MSSA IE.

### 332. Exploring the association between diabetes and tuberculosis: impact on culture conversion and requirements of drug therapeutic monitoring.

Nisha Patel, Pharm.D./MBA<sup>1</sup>, Chandni Patel, Pharm.D.<sup>1</sup>, Christina M. Madison, Pharm.D., BCACP<sup>2</sup>; (1) School of Pharmacy, Roseman University of Health Sciences, Henderson, NV (2) Roseman University of Health Sciences, Henderson, NV

**PURPOSE:** Diabetics are at a 30% higher risk for developing tuberculosis than non-diabetics since they are immunocompromised. This study aims to evaluate diabetics with tuberculosis on time to culture negativity or culture conversion in addition to assessing the need to conduct therapeutic drug monitoring.

**METHODS:** In this retrospective study, medical records of patients will be reviewed and those with the diagnosis of both tuberculosis and diabetes will be identified.

**RESULTS:** Data collection is ongoing.

**CONCLUSION:** Diabetics can take longer to culture convert, due to delayed/impaired medication absorption from inadequate glucose control. Thus, they can require a longer duration of treatment to decrease the risk of reactivation of disease as compared to non-diabetics. Non-diabetics tuberculosis patients without resistant organism will need a total of 6 months treatment for pulmonary disease whereas diabetics may need up to 9 months. Furthermore, diabetics diagnosed with tuberculosis could benefit from therapeutic drug monitoring for optimized care early in the course of treatment due to delayed response to therapy. Patients whom are indicated to receive therapeutic drug monitoring include those who have not shown clinical improvement for at least 2 months on treatment appropriately weight based dosing. Therefore, identifying diabetic patients with tuberculosis at time of diagnosis may warrant early monitoring of therapeutic drug levels and adjusting treatment may decrease time to culture negativity and increase overall patient outcomes.

### 333. Evaluation of vancomycin-resistant Enterococcal urine isolates at a tertiary medical center.

Marla D. Koch, PharmD Candidate, Celeste R. Caulder, PharmD, Nicole Smith, PharmD Candidate, P. Brandon Bookstaver, PharmD, BCPS (AQ-ID) AAHIVP; South Carolina College of Pharmacy-USC Campus, Columbia, SC

**PURPOSE:** The increase in incidence of vancomycin-resistant enterococcus (VRE) has led to prescribing newer, costly therapies including daptomycin and linezolid. The purpose of this study is to report antimicrobial regimens utilized in microbiologic

confirmed VRE UTIs, evaluate antimicrobial susceptibilities and examine patient-related outcomes.

**METHODS:** All non-pregnant, adult subjects with a confirmed VRE UTI were screened for study inclusion from January 2006 through December 2011. Beginning in late 2010, susceptibility testing of all VRE isolates was performed via E-test for fosfomycin, daptomycin, and doxycycline. Additional susceptibility data were obtained through automated reporting with Vitek II system. Subject data were collected retrospectively using the electronic medical record. The primary objective was to describe antimicrobial therapy for VRE UTIs and determine susceptibility profiles of routinely screened agents. Secondary endpoints include the percent of treatment failures and antibiotic-related costs.

**RESULTS:** A total of 215 encounters were included during the 6 year study period. The average subject age was 58 years and 30.2% were male. Approximately 37% of patients presented with community acquired infection. More than half of patients (50.7%) received active antimicrobial therapy as follows: daptomycin (n=54), linezolid (n=44), doxycycline (n=7). The mean length of treatment was 8.72 days and the median was 7 days. There was no difference in treatment duration among agents. Microbiology susceptibilities for fosfomycin (n=74), daptomycin (n=74) and doxycycline (n=74) resulted in MIC<sub>90</sub> of 128, 4, and 24 respectively. Only 3% of isolates were susceptible to nitrofurantoin.

**CONCLUSIONS:** Use of daptomycin and linezolid for VRE urine cultures was high at our institution prompting a targeted stewardship initiative. Fosfomycin may represent a reasonable alternative for treatment.

**334. A practical pharmacokinetic comparison of three piperacillin-tazobactam administration methods.** Justin M. Miranda, B.S., Pharm. D. Candidate, Andy J. Orsa, Pharm. D. Candidate, Roy T. Hendley, M.S., Pharm. D. BCNPS; Texas Tech University Health Sciences Center School of Pharmacy, Lubbock, TX

**PURPOSE:** The emergence of antibiotic resistance is a major public health concern, with fears expressed that effective antibiotic treatment options will soon be exhausted. Approximately 70% of intensive care unit (ICU) patients are administered antibiotics. A number of studies have suggested that 50% of all antimicrobial use may be considered inappropriate; leading to adverse outcomes. In particular, inadequate antibiotic administration in the ICU has shown to significantly increase the length of hospital stay, duration of mechanical ventilation and prolong clinical resolution in hospital-acquired pneumonia (HAP). Studies with piperacillin-tazobactam (TZP) have evaluated new methods of administration to exceed rising minimum inhibitory concentrations (MIC), extend its utility, and achieve optimal outcomes. This study evaluates three different administration methods of TZP using practical, bedside pharmacokinetic estimations to provide some clarity and evidence to support their utilization.

**METHODS:** A practical, bedside pharmacokinetic analysis was constructed using Microsoft® Excel®. Percent Time > MIC of TZP using three different administration methods (traditional, 3-hour extended infusion, and continuous infusion) for a *Pseudomonas aeruginosa*-induced HAP was evaluated. The % Time > MIC threshold of ≥80% was used to compare the utility of the three administration methods for a MIC values range of 1–128 mcg/mL for *P. aeruginosa*.

**RESULTS:** Preliminary results reveal the standard infusion method was sufficient in obtaining % Time > MIC of ≥80% for MICs 1–4 mcg/mL. The benefits of continuous and extended infusions become apparent as the MIC increase in susceptibility. A more thorough analysis will be reported.

**CONCLUSION:** This study demonstrated that patient, medication, and organism characteristics play a role in determining which dosing method is optimal. Extended and continuous infusion may be beneficial in *P. aeruginosa*-induced HAP as the MICs increase. However, the practicality of such method may be difficult to incorporate. A more thorough comparison of these methods will be completed.

## Medication Safety

**335. Comparison of the top-10 most problematic pediatric medications ranked by pediatric pharmacists and pediatric prescribers.** HyeJin Son, Pharm.D. Candidate, Alyssa A. Laurich, Pharm.D. Candidate, Katie D. Patterson, Pharm.D. Candidate, Ashley E. Earley, Pharm.D., Melissa M. Shipp, Pharm.D., Kelly B. Walls, Pharm.D., Forrest L. Smith, Ph.D., Kenneth M. Yates, M.S., D.V.M., Julie C. Kissack, Pharm.D., BCPP; Harding University College of Pharmacy, Searcy, AR

**PURPOSE:** This survey measured the consensus opinion of pediatric pharmacists compared to pediatric prescribers (pediatricians, physician assistants, and nurse practitioners) on ranking medication categories from least to most problematic regarding patient safety, and the top-10 most problematic pediatric medications.

**METHODS:** Participants ranked the top-10 from a list of 50 medications for three areas: problems in dosing, adverse effects and medication errors. Medications from each area were summed and ranked from 1 to 50 to identify the top-10 list. The 11 medication categories and 50 medications were drawn from expert consensus, the Institute for Safe Medication Practice high-alert medication list, and medication alerts/reviews of pediatric literature.

**RESULTS:** The survey was completed by 232 pharmacists and 56 prescribers. Primary practice sites of participants were mainly children's hospitals (64%) and pediatric units (20%) in 38 states plus the District of Columbia and 3 Canadian provinces. Regarding overall pediatric patient safety, pharmacists ranked anticoagulants as most problematic, and opioids and electrolytes ranked equally as moderately problematic. The most problematic medications, according to pharmacists, from first to tenth were: 1-insulin, 2-vancomycin, 3-warfarin, 4-heparin, 5-methadone, 6-digoxin, 7-morphine, 8-gentamicin, 9-potassium phosphate and 10-(tied) amphotericin B & fentanyl. In comparison, prescribers ranked opioids as most problematic and sedatives as moderately problematic. The most problematic medications, according to prescribers, from first to tenth were: 1-insulin, 2-heparin, 3-morphine, 4-digoxin, 5-warfarin, 6-fentanyl, 7-vancomycin, 8-amphotericin B, 9-potassium chloride, and 10-amiodarone. Both pharmacists and prescribers ranked gastrointestinal medications as least problematic.

**CONCLUSION:** When overall results were compared, pharmacists and prescribers ranked problematic medications very similarly. Although there was slight disparity in the ranking order, both top-10 lists contained 80% of the same medications. Survey participants identified six medications identical to the top-10 high-alert medications surveyed in a pediatric ICU by Franke et al. in 2009.

**336. An evaluation of the impact of a dose calculator on the accuracy of gentamicin and vancomycin initial doses.** Anas Hamad, BSc MSc<sup>1</sup>, Gillian Cavell, BSc MSc<sup>2</sup>, James Hinton, BSc PhD<sup>2</sup>, Paul Wade, BSc MSc<sup>3</sup>, Cate Whittlesea, BSc MSc PhD<sup>1</sup>; (1) Institute of Pharmaceutical Science, King's College London, London, United Kingdom (2) Pharmacy Department, King's College Hospital Foundation Trust, London, United Kingdom (3) Pharmacy Department, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom

**PURPOSE:** Gentamicin and vancomycin are narrow-therapeutic-index drugs known for their high toxicity and need for extra care and continuous therapeutic drug monitoring. Clinical decision support (CDS) tools have been effective in reducing dose errors. A calculator for gentamicin and vancomycin doses in adults was recently implemented in the hospital to improve prescribing and reduce dosing errors. The aim of this study is to evaluate the impact of this dose-calculator on the accuracy of gentamicin and vancomycin initial doses.

**METHODS:** The study used a pre-post intervention design. Data were collected using electronic patient records. Random samples of gentamicin and vancomycin initial doses administered between 01/01/2011 – 31/08/2011 (before calculator implementation) were assessed retrospectively. Following the calculator promotion, doses were reassessed prospectively. Any gentamicin dose not within 10% and any vancomycin dose not within 20% of the



guideline-recommended dose were considered wrong. This study was categorised as a service evaluation and no ethical approval was required. However, it was registered with the Trust's Clinical Effectiveness and Audit Department. Statistical data analysis was performed using SPSS®.

**RESULTS:** The calculators' page on the intranet has been hit 346 times in the first month following the calculator implementation\*. Results from this month show that gentamicin dose errors were reduced from 61.5% (120/195) to 41.3% (38/92). Incorrect vancomycin loading doses were reduced from 58.1% (90/155) to 36.4% (24/66). Incorrect vancomycin maintenance doses were reduced from 55.5% (86/155) to 34.8% (23/66). Both loading dose and maintenance dose were incorrect in 37.4% (58/155) of patients before and in 12.1% (8/66) after the calculator implementation.

**CONCLUSIONS:** The interim results give an indication that the number of gentamicin and vancomycin dose errors has been reduced after the calculator implementation. Therefore, the calculator seems to be an effective tool in improving the accuracy of gentamicin and vancomycin initial doses.

\*Interim-post-implementation-data-(only-for-June-2013)-are-presented-here; results-are-due-for-completion-by-early-August.

**337. Assess the knowledge and perceptions of middle school and high school-aged students about alcohol and prescription drug abuse.** Jennifer A. Kelleher, BA, Sing N. Chhay, BS, Kowk Hung Ip, BS, Christopher M. Devine, BA, Helen C. Pervanas, Pharm.D.; MCPHS University, Manchester, NH

**PURPOSE:** Alcohol and prescription drug abuse in teens continues to be a nationwide concern. The purpose of the study was to educate adolescents and teens about the dangers associated with alcohol and prescription drugs and to determine their perceptions regarding these substances.

**METHODS:** Student pharmacists representing the campus organization Student Pharmacists Against Prescription Drug Abuse (SPARxDA), conducted an educational program at the Boys and Girls Club of Souhegan Valley located in Milford, New Hampshire. Prior to the educational program a 9 question survey focusing on peer pressure, use of drugs and alcohol and safety of over-the-counter and prescription medications was administered to the participants.

**RESULTS:** Forty-four teens completed the survey. The majority of the participants were Caucasian (72%) and were female (52%) with a median age of 13 years. Most of the participants believe alcohol (39%) and illegal drugs (34%) are most abused by teens versus prescription drugs (4%). Fifty-two percent of the participants reported that prescription drugs are safer than illegal drugs. Of the middle school-aged participants (11–12 years of age) 81% believe that prescription drugs are safer than illegal drugs versus 21% of thirteen to eighteen year-olds.

**CONCLUSION:** Despite their potential to cause harm if misused, a high percentage of middle school-aged children perceived prescription medications to be safer than illegal drugs. More education about medication safety is needed at a younger age to develop a common knowledge that prescription medications can be equally as dangerous as illegal drugs if not taken as prescribed by a provider.

**338. A chemical analysis of currently available melatonin products in the United States.** Hanna Savaryn, PharmD Candidate, Erica Caffarini, PharmD Candidate, Matthew Fete, PhD, Leticia Shea, PharmD, Robert Haight, PhD Candidate; Regis University School of Pharmacy

**PURPOSE:** 1) To determine an effective analytical extraction method. 2) To quantify the concentration of melatonin in over-the-counter (OTC) products analyzing individual tablet strength and average concentrations.

**METHODS:** Ultraviolet/Visible (UV/Vis) Spectroscopy and High Pressure Liquid Chromatography Mass Spectrometry (HPLC MS) was used to quantify tablet concentration. Sixteen different formulations/lot numbers of currently available melatonin supplements were analyzed. Melatonin solubility in ethanol allows

extraction from commercial formulations (Melatonin  $\lambda_{max}=277$ ). To ensure accuracy of extraction, the remaining powder from each sample was analyzed to ensure full extraction of melatonin had been achieved.

**RESULTS:** A total of 16 formulations of melatonin were analyzed using a one sample t-test. Six formulations were found to have a statistically significant difference ( $p \leq 0.05$ ) in melatonin than that stated on the product label. The following table displays the results.

Brand Name	Stated Strength	Avg. Conc.	Std. Dev
Face Values	3	3.004811	0.225
Mason SL	2.5	1.835103***	0.301
Alteril	2	0.718966***	0.114
Nature Made	3	3.160888	0.228
Safeway	3	3.103918	0.342
Walgreens	1	0.26441***	0.021
Sleep Soundly	10	9.109087	1.154
Slumber Aid	2.5	0.615022***	0.237
Holista	10	10.65741	0.911
Nature's Bounty	5	4.623326	0.908
Natrol	10	8.857737	2.521
21st Century	5	5.111358	0.678
Natrol	5	5.000073	0.749
Sundown	3	2.741327	0.285
TrueFit	3	2.668522**	0.305
Nature's Bounty	3	2.580716**	0.327

\* $\alpha \leq 0.05$

\*\* $\alpha \leq 0.03$

\*\*\* $\alpha \leq 0.01$

**CONCLUSION:** Consumers have a right to know that there is inconsistency in tablet strength in dietary supplement products. As determined by this analysis, inconsistent tablet strength has been found in approximately 38% of the products.

**339. Use of a student in evaluating Joint Commission medication management standards.** Taryn Mancarella, B.S. Chemistry, B.S. Biology<sup>1</sup>, Rachel Mikhail, PharmD<sup>2</sup>; (1)Massachusetts College of Pharmacy and Health Sciences University, MA (2)UMass Memorial Medical Center, MA

**PURPOSE:** The Joint Commission grants accreditation to institutions based on compliance with a set of safety standards. Standard MM.04.01.01: Medication orders are clear and accurate and standard MM.03.01.01: The hospital safely stores medications were identified sources of common errors within our institution. An audit of current policy and procedure was completed in order to create awareness in recognizing and preventing medication errors and improve patient safety. The purpose of this project was to identify and correct common prescribing errors and also, to develop a standardized process of identifying expired medications to ensure no expired medication reaches the patient.

**METHODS:** Medication orders were selected randomly from the University and Memorial campuses on a monthly basis to determine compliance with current hospital policy. Handwritten, electronic orders and medication reconciliation forms were included in this study. The primary outcome was to determine a 6-month compliance rate. Secondary outcome was to provide risk reduction strategies for improvement of patient safety. One pyxis machine was evaluated at the University campus each month to identify expired medication. The primary outcome was to identify and remove expired medications from pyxis. Secondary outcome was to create a standardized process of identifying expired medications. Data collection and evaluations are currently being conducted and will be completed in August 2013.

## Nephrology

**340. Medication management services for dialysis patients in Brazil.** Daniele Alcantara, Pharmacy student<sup>1</sup>, Katie Cardone, Pharm.D., BCACP, FNKF<sup>2</sup>, Alexander Prokopenko, Pharmacy student<sup>3</sup>, Amy Barton Pai, BS, Pharm.D., BCPS, FASN, FCCP<sup>2</sup>; (1)Pharmacy, Universidade de São Paulo, Ribeirão Preto, Brazil

(2) Albany College of Pharmacy and Health Sciences, Albany, NY (3) Pharmacy, Albany College of Pharmacy and Health Sciences

**PURPOSE:** Chronic kidney disease can progressively lead to end-stage renal disease requiring dialysis or transplant. The number of dialysis patients is increasing worldwide principally as consequence of hypertension and diabetes. In Brazil, according to the Sociedade Brasileira de Nefrologia (SBN), the estimated number of dialysis patients at 2011 was 91,314. These patients have many comorbidities requiring a complex medication regimens and thus have a high likelihood on Medication Related Problems (MRPs). In the US, pharmacists providing direct patient care and identifying and resolving MRPs has been shown to reduce medication costs and length of hospitalizations. (Pai et al. *Pharmacotherapy* 2009) However in Brazil, clinical pharmacy services are not widespread but are expanding. The purpose of this research is to evaluate Brazilian nephrologists knowledge, skills and attitudes towards medication management services (MMS) in dialysis patients, perceived benefits of these services and desired components of MMS.

**METHODS:** We constructed a survey based on focus group input that will be validated in Portuguese. We propose to disseminate the survey electronically by using the SBN list serve. The SBN membership is comprised of nephrologists practicing in dialysis clinics and other clinical venues in Brazil. Questions cover demographic data, desired service components, previous knowledge of MMS and medication use of the patients based on the personal experience of the physician. IRB approval is pending.

**RESULTS:** The results of the survey will be presented at the Annual Meeting.

**CONCLUSION:** It is anticipated that medication related problems are common in dialysis patients in Brazil and that nephrologists need more education on potential MMS in this population.

**341. Changes in serum fibroblast growth factor 23 during the use of calcium carbonate concurrent with calcitriol in stage 3 CKD patients.** *Ga Hyeon Lee, BS<sup>1</sup>, Nayoung Han, MS<sup>2</sup>, Su Hyun Hong, MS<sup>2</sup>, Yon Su Kim, M.D., Ph.D<sup>3</sup>, Whan Gyun Shin, Pharm.D.<sup>4</sup>, Jung Mi Oh, PharmD<sup>2</sup>;* (1) College of pharmacy, Seoul National University, Seoul, South Korea (2) College of Pharmacy, Seoul National University, Seoul, South Korea (3) Seoul National University Hospital, Seoul, South Korea (4) Department of Pharmacy, Seoul National University, South Korea

**PURPOSE:** Chronic kidney disease (CKD) patients often demonstrate disturbances in mineral bone metabolism, which, when uncontrolled, exert detrimental effects on the bone, parathyroid, and vasculature, consequently leading to increased cardiovascular disease (CVD) risks. Recently, fibroblast growth factor-23 (FGF-23) was identified as a key regulator maintaining serum phosphorus level in CKD. However, mechanisms of FGF-23 not yet fully defined, and there have been inconsistent outcomes regarding effects of medications modifying FGF-23. The purpose of this study was to investigate the effect of calcium carbonate in conjunction with calcitriol on FGF-23 in CKD.

**METHODS:** In this parallel, open-label trial, thirty adult CKD stage three patients were randomly assigned to calcitriol or calcitriol with calcium carbonate for 8 weeks. Primary end-point was the difference in percent change of serum FGF-23 from baseline between two groups. Additional outcomes were percent change-differences between serum calcium, phosphate, intact parathyroid hormone, and 25(OH)D from baseline.

**RESULTS:** A total of 25 patients completed this study. There was no difference between two groups for FGF-23 percent change from baseline ( $p=.202$ ). Serum FGF-23 level decreased significantly after treatment with calcitriol alone ( $p=.022$ ), though there was no difference in percent changes between treatment groups with regards to calcium, phosphate, iPTH, and 25(OH)D. In the group administered with the calcium carbonate, the level of FGF-23 decreased compared to baseline although the decrease was not statistically significantly. Regarding safety issues, only one case of mild gastrointestinal discomfort was reported in the calcitriol group.

**CONCLUSION:** From this study, unlike calcitriol alone, administration with calcium carbonate did not affect the decrease in FGF-23. Overall cancellation effect of calcium contained probably contributed to the outcome. Further trials are warranted to demonstrate interaction between FGF-23 and PTH, and impact of vitamin D on CVD in CKD patients.

## Neurology

**342. Fixed drug eruption in an epileptic patient previously receiving phenytoin.** *Keaton Smetana, PharmD Candidate<sup>1</sup>, Katie J. Suda, PharmD, MS<sup>1</sup>, Leslie A. Hamilton, PharmD, BCPS<sup>2</sup>;* (1) University of Tennessee Health Science Center, College of Pharmacy, Memphis, TN (2) University of Tennessee Health Science Center, College of Pharmacy, Knoxville, TN

**PURPOSE:** Rash is a common adverse effect experienced with phenytoin and other aromatic antiepileptic medications. We report an incident of fixed drug eruption (FDE), differing from previous reports, following the rapid administration of phenytoin in a patient who had received treatment with phenytoin since 2005.

**METHODS:** A 52 year-old African American female presented with severe left thigh pain of unknown etiology. She had a past medical history of generalized seizure disorder treated with phenytoin for seven years without incident. During admission a nurse witnessed a seizure and consequently loading and maintenance doses of phenytoin were administered to obtain a therapeutic serum concentration and prevent further seizures. The patient had a history of noncompliance with multiple subtherapeutic phenytoin levels. Subsequently, unifocal blue discolored spots appeared, progressing to a bullous component that was positive for skin sloughing. Drug-induced fixed drug eruption was diagnosed and attributed to treatment with phenytoin.

**RESULTS:** Serum concentrations of phenytoin are possibly associated with the risk of developing drug-induced skin eruptions. In the patient case presented here, the outcome of the possible adverse drug reaction may have been due to the rate at which phenytoin was administered to obtain a therapeutic concentration. Use of the Naranjo adverse drug reaction probability scale indicated a probable relationship with a score of 5 between the phenytoin and the development of a FDE.

**CONCLUSION:** Clinicians should be cognizant of drug-induced FDE in patients just initiated and those receiving long-term treatment with phenytoin. The administration rate of phenytoin may be associated with the development of FDE.

## Nutrition

**343. Bile acid-induced apoptosis and inflammation are attenuated by omega-3 long-chain polyunsaturated fatty acids in a macrophage model.** *Timothy Howze, BS, Peihong Guan, BS, Richard A. Helms, Pharm.D., Emma M. Tillman, Pharm.D.;* University of Tennessee Health Science Center, Memphis, TN

**PURPOSE:** Parenteral nutrition (PN)-associated liver disease (PNALD) is one of the most alarming complications of long-term PN. Studies have shown improvements in PNALD with omega-3 long-chain polyunsaturated fatty acids ( $\omega$ 3PUFA) containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Anti-inflammatory and anti-apoptotic effects have been attributed to  $\omega$ 3PUFA. The liver is a complex organ that consists of both parenchymal and non-parenchymal cells. The non-parenchymal Kupffer cells act as macrophages and secrete pro-inflammatory cytokines. The purpose of this study was to examine the anti-inflammatory and anti-apoptotic effects of  $\omega$ 3PUFA on macrophage response to bile acid-induced cellular injury.

**METHODS:** Human acute monocytic leukemia cells (THP-1) were used as a surrogate for the Kupffer cells and cultured and treated with 200  $\mu$ mol/L of chenodeoxycholic acid (CDCA)  $\pm$   $\omega$ 3PUFA (5  $\mu$ mol/L EPA and 5  $\mu$  DHA). Ethanol (EtOH),  $\omega$ 3PUFA alone, and staurosporine served as controls. After treatment, cellular supernatant and cells were collected for nuclear protein extraction. Apoptosis was measured using Caspase 3/7 assays. Cytokines (IL-1 $\beta$ , IL-6, TNF- $\alpha$ ) were measured

using enzyme-linked immunosorbent assay (ELISA) in both supernatant and nuclear protein.

**RESULTS:** Treatment of THP-1 cells with CDCA and  $\omega$ 3PUFA resulted in a 26% decrease of apoptosis in comparison to CDCA alone ( $p < 0.01$ ). Both TNF- $\alpha$  and IL-1 $\beta$  production decreased by 16% ( $p = 0.038$ ) and 19% ( $p = 0.03$ ), respectively. There was no change in IL-6 concentration with either treatment group. There was also no significant difference in data collected via supernatant and protein.

**CONCLUSION:** Inflammation and apoptosis in THP-1 cells was induced by CDCA alone and attenuated by co-incubation of CDCA and  $\omega$ 3PUFA. The attenuation of cellular injury in this model of Kupffer cells provides a basis for future studies to determine the interaction of Kupffer cells and hepatocytes in order to understand the role of  $\omega$ 3PUFA in the treatment of PNALD.

## Oncology

**344. Pancolitis associated with docetaxel-based chemotherapy in a patient with metastatic esophageal cancer involving liver dysfunction and neutropenia.** Nathan Cope, PharmD Candidate, Leslie A. Hamilton, PharmD, BCPS, J. Aubrey Waddell, PharmD, BCOP, FAPhA, Debbie C. Byrd, PharmD, BCPS; University of Tennessee Health Science Center, College of Pharmacy, Knoxville, TN

**PURPOSE:** Chemotherapy can induce many types of clinical emergencies including colitis. There is little literature evaluating whether patients who suffer from this adverse event can be re-challenged after recovery. Current treatments and clinical decisions involving chemotherapy-associated colitis are based on reviews, observations, and case reports. We present a novel case where the patient was successfully managed and re-challenged with chemotherapy.

**METHODS:** Patient is a 43-year-old white male diagnosed with metastatic esophageal carcinoma. Liver involvement prevented the inclusion of docetaxel in the first cycle of chemotherapy. After addition of the taxane in the second cycle, he developed pancolitis. The patient was managed with fluids, antibiotics, and a liquid-only diet. Due to the timing of neutropenia and onset of abdominal symptoms, it is likely this was a chemotherapy-induced colitis and the transient drop in neutrophils complicated the situation. Despite this clinical emergency, he recovered and was re-challenged, receiving a reduced dose of docetaxel in the third cycle of chemotherapy without incident.

**RESULTS:** Docetaxel in combination with fluorouracil and cisplatin may result in chemotherapy-induced pancolitis. Neutropenia can complicate recovery, or even progress a colitis-free patient to neutropenic colitis. Patients with abdominal pain and bloody diarrhea with or without neutropenia should be evaluated aggressively for colitis, whether neutropenic in origin or chemotherapy-induced. A granulocyte-colony-stimulating factor may be administered to help neutrophils recover. The timing of his scheduled pegfilgrastim administration may have influenced his recovery and later ability to be re-challenged.

**CONCLUSION:** Treating patients with docetaxel-based chemotherapy should be cautious when patients present with abdominal distress. Diagnosis and treatment must be swift to ensure early intervention and favorable outcomes. Patients who recover from docetaxel-associated pancolitis may potentially be re-challenged, but must be evaluated on a patient-by-patient basis. If a patient is re-challenged, a reduction in the dose of docetaxel may be warranted.

**345. Interstitial pneumonitis from treatment with gemcitabine in pancreatic cancer.** Brolin B. Poole, PharmD Student<sup>1</sup>, Leslie A. Hamilton, PharmD, BCPS<sup>1</sup>, Megan Brockman, PharmD, BCPS<sup>2</sup>, Debbie C. Byrd, PharmD, BCPS<sup>1</sup>; (1) University of Tennessee Health Science Center, College of Pharmacy, Knoxville, TN (2) University of Tennessee Medical Center, Knoxville, TN

**PURPOSE:** Gemcitabine is an agent utilized in the treatment of various forms of cancer. The use of gemcitabine may lead to

numerous adverse effects ranging from mild to very severe, such as interstitial pneumonitis. The diagnosis of this complication is based on multiple laboratory findings and high clinical suspicion. Presented is a patient with laboratory findings, clinical suspicion, and onset consistent with gemcitabine-induced pneumonitis.

**METHODS:** A 76 year-old white female who was treated with gemcitabine for pancreatic cancer. A few months after the initiation of the therapy she was admitted to the hospital for worsening dyspnea and cough. High clinical suspicion, laboratory findings, and onset after initiation of therapy led to the diagnosis of gemcitabine-induced interstitial pneumonitis. Steroid therapy with methylprednisone was initiated and the patient's clinical symptoms and radiographic findings improved.

**RESULTS:** Gemcitabine-induced interstitial pneumonitis is well-described in the literature. It is a rare but serious complication associated with gemcitabine therapy. Patients present with worsening dyspnea; however, most patients only require supportive care and discontinuation of the drug for treatment. In severe cases supplemental oxygen and steroid therapy must be used before resolution of symptoms. Radiographic findings such as bilateral infiltrates should be completely resolved after therapy.

**CONCLUSION:** Early recognition of interstitial pneumonitis from gemcitabine is a key factor in patient outcomes. Diagnosis should be based on radiographic findings, clinical symptoms, and clinical suspicion. Physicians should be aware of this adverse effect, to provide prompt treatment for resolution of symptoms and to decrease associated mortality

**346. Evaluation of liver dysfunction as prognostic factor with survival after yttrium-90 radioembolization used to treat liver malignancies.** Adam Henrie, B.S., Paulina Deming, PharmD, Kristina Wittstrom, PhD; College of Pharmacy, University of New Mexico, Albuquerque, NM

**PURPOSE:** While several studies have examined the prognostic factors associated with survival after resection and systemic chemotherapy for hepatocellular carcinoma (HCC) and metastatic colorectal cancer (mCRC), little data are available regarding variables associated with survival in patients receiving radioembolization. The aim of this study is to determine if liver function tests (LFTs) and prognostic factors, specifically variables used to assess liver function through scoring systems such as the Model for End-Stage Liver Disease (MELD) and AST to Platelet Ratio Index (APRI) prior to radioembolization correlate to survival after the procedure.

**METHODS:** This descriptive, observational study is designed as a retrospective chart review of patients older than 18 years of age undergoing radioembolization for HCC and mCRC from 2004 through 2012 at the University of New Mexico Hospital. Data collected include baseline demographic data such as age, sex, and date of death as well as variables needed for radioembolization dosing such as body surface area, liver tumor volume, % lung shunting and type of liver malignancy. Laboratory data collected to assess degree of liver dysfunction include LFTs and variables required to determine MELD and APRI scores. Average time of survival after radioembolization will be compared and factors associated with assessment of liver function analyzed for correlation to average survival.

**RESULTS:** Data acquisition and analysis are currently underway. Complete results will be presented at the ACCP annual meeting.

**CONCLUSION:** Conclusion is pending completion of results and will be presented at the ACCP annual meeting.

**347. Characterization of chemotherapy induced nausea and vomiting outcomes in patients receiving melphalan-containing conditioning chemotherapy for autologous hematopoietic stem cell transplant.** Lindsay Schaack, Pharm.D., Candidate<sup>1</sup>, Stephen M. Clark, Pharm.D.<sup>2</sup>, Amber B. Clemmons, Pharm.D., BCOP<sup>1</sup>, David DeRemer, Pharm.D., BCOP<sup>1</sup>, Vamsi Kota, MD<sup>2</sup>; (1) University of Georgia College of Pharmacy (2) Georgia Regents Medical Center

**PURPOSE:** Herein we report the retrospective portion of a larger study which will serve as a comparator of antiemetic control



prior to the initiation of fosaprepitant for melphalan-containing conditioning regimens as the standard of practice in the prevention of chemotherapy induced nausea and vomiting (CINV) at Georgia Regents Medical Center. All patients in the retrospective cohort received standard CINV prophylaxis with dexamethasone, ondansetron, and lorazepam. Endpoints include percent of patients with no emesis, total number of emetic episodes per patient, total number of breakthrough antiemetic doses per patient, and complete response rate (no emesis or breakthrough antiemetic use).

**METHODS:** Medical records of 70 consecutive patients admitted for high-dose melphalan or BEAM (carmustine, etoposide, cytarabine, and melphalan) followed by an autologous hematopoietic stem cell transplant (auto-HSCT) were reviewed. Patients' demographic data, cancer diagnosis, chemotherapy regimen (drug, dose and frequency), number of emetic episodes each day, and use of antiemetics each day were recorded. Data were collected for a defined assessment period which included days of melphalan and for five days thereafter.

**RESULTS:** Over the assessment period, no emesis was reported in 65.7% of patients. During the overall assessment period the mean number of emetic episodes per patient was 0.76, the mean number of breakthrough antiemetic doses per patient was 9.6, and the complete response rate was 1.4%.

**CONCLUSION:** This retrospective data characterizes CINV outcomes for auto-HSCT patients at our institution who received a standard three-drug prophylaxis regimen and will be utilized as the historical comparison in an ongoing, prospective study adding fosaprepitant to the prophylactic antiemetic regimen. The suboptimal prevention of CINV achieved in this population with standard prophylaxis supports the need for additional antiemetic strategies.

## Pain Management/Analgesia

**348. A retrospective analysis of intravenous acetaminophen use in spinal surgery patients.** *Vie Hoefling, PharmD Candidate<sup>1</sup>*, April N. Smith, PharmD, BCPS<sup>2</sup>; (1)School of Pharmacy and Health Professions, Creighton University, Omaha, NE (2)Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** Our study aims to compare postoperative opioid use by spinal surgery patients who received intravenous acetaminophen (IV APAP) to those who did not. The main objective will be to determine if IV APAP reduced postoperative opioid consumption, opioid related adverse effects, and visual analog scale (VAS) pain scores up to two days after surgery. Our goal is to determine if there is clinical benefit of IV APAP to justify its increased cost and administration time in spinal surgery patients.

**METHODS:** Intravenous acetaminophen was added to the Aleant Creighton formulary in January 2013. The electronic medical record will be accessed on all spinal surgery patients who received at least one dose of IV APAP pre or post operatively from January to July 2013. A comparator group will be comprised of all patients who had spinal surgery in the six month preceding the addition of IV APAP to the formulary. Baseline patient demographics will include age, sex, height, weight, and opioid use prior to admission. Surgery type and total operative time will also be reported. Data collection will include postoperative opioid consumption (in morphine equivalents), antiemetic and laxative usage, incidence of respiratory depression, and/or use of opioid reversal agent, and VAS pain scores.

**RESULTS:** Results for IV APAP doses received, opioid consumption, VAS pain scores, and laxative and antiemetic usage will be reported for day of surgery, postoperative day one and postoperative day two. Roughly one hundred patient records will be reviewed between the IV APAP group and the comparator group.

**CONCLUSION:** Results are anticipated to be used to assist therapeutic decision making in regard to continued use of IV APAP in this specific surgical population. Our results may also encourage further study of IV APAP in other types of surgery.

**349. Impact of postoperative intravenous acetaminophen on opioid requirements and pain scores following obstetric and gynecologic procedures.** *Laura Stoudenmire, PharmD<sup>1</sup>, Lauren Willis, PhD<sup>2</sup>, Christy Norman, PharmD, M.S.<sup>3</sup>*; (1)University of Georgia College of Pharmacy, Georgia Regents Health System, Augusta, GA (2)University of Georgia College of Pharmacy, Augusta, GA (3)Georgia Regents Health System, Augusta, GA

**PURPOSE:** The purpose of this study is to assess the impact of postoperative IV acetaminophen on opioid requirements and pain scores in patients following obstetric and gynecologic procedures.

**METHODS:** We conducted a retrospective cohort study of patients undergoing obstetric and gynecologic procedures. Opioid requirements 0–24 hours postoperatively served as the primary endpoint. Secondary endpoints included opioid requirements 24–48 hours postoperatively, daily pain scores, daily acetaminophen dose, and rate of adverse events. It was determined that 106 patients would be needed to detect a 30% difference in opioid requirements between study groups.

**RESULTS:** One hundred forty patients who underwent an obstetric or gynecologic procedure from January 2009 to April 2013 were included in this study. Baseline characteristics were similar between groups. In the first 24 hours postoperatively, there was no difference in opioid requirements between the IV acetaminophen and control groups (28.52 mg v. 35.45 mg,  $p=0.104$ ). A subgroup analysis performed on patients undergoing total abdominal hysterectomy also showed no difference in opioid requirements (32.03 mg v. 41.64 mg,  $p=0.756$ ). In the time period of 24–48 hours postoperatively, patients in the IV acetaminophen group required significantly more opioids than the control group (29.19 mg v. 18.17 mg,  $p=0.001$ ). There was no difference in pain scores between the groups 0–24 hours or 24–48 hours postoperatively. The incidence of adverse events did not differ between the two groups.

**CONCLUSION:** Postoperative administration of IV acetaminophen did not provide a significant opioid-sparing effect in patients undergoing obstetric and gynecologic procedures

**350. A comparative assessment of fentanyl patch prescribing practice in a community hospital.** *Bin Deng, Pharm D. Candidate*; School of Pharmacy, California Northstate University, College of Pharmacy, Rancho Cordova, CA

**PURPOSE:** Fentanyl transdermal patch is only indicated for chronic pain control and should only initiate when a patient demonstrates opioid tolerance, which is equivalent to 60 mg of oral morphine for a minimum of 7 days. The objective of this study is to assess physicians compliance with fentanyl prescribing guideline in a community hospital setting.

**METHODS:** A retrospective chart review of 266 patients was conducted between March 2011 and May 2012 at Santa Barbara Cottage Hospital. All patients who were on fentanyl patch prior to or after admission were included. The criteria used to evaluate fentanyl patch prescribing compliance were: (1) patient on fentanyl patch when ordered/admitted (2) patient on opiates prior to admission or during hospitalization for 7 days with a minimum daily dose of 60 mg oral morphine equivalents, (3) fentanyl patch use to manage chronic pain. Primary end point was compliance in individual patch strength. Secondary end point was adverse outcome, measured by naloxone usage. McNemar's test was used for statistical analysis.

**RESULTS:** Implementation of pharmacist driven fentanyl patch order set in 2012 resulted in 27% increase in compliance with fentanyl patch prescribing criteria (83% in 2012 vs. 54% in 2011,  $p<0.0001$ , OR 5.048, 95% CI: 3.139–8.491). All patches were correctly prescribed for chronic pain management. 12 mcg have lowest compliance rate (59%) compared to higher patch strength (74–100%). All individual patch strength increased compliance from 2011, range from 19% to 31%. Naloxone was administered to 1 patient in 2012 and 2 patients in 2011. No death resulted in all patients.

**CONCLUSION:** Implementation of pharmacists driven fentanyl patch order set significantly increased physician compliance with fentanyl patch prescribing guideline. Pharmacist should continue

to educate physicians and provide alternative treatment options for patients who do not meet the criteria of fentanyl patch prescribing guideline.

## Pediatrics

**351. LC-MS/MS quantification of buprenorphine, norbuprenorphine, methadone, and glucuronide conjugates in human umbilical cord plasma.** Amy Redmond, PharmD Candidate<sup>1</sup>, Jason Pryor, MD<sup>2</sup>, Darshan Shah, MD<sup>2</sup>, Stacy Brown, PhD<sup>3</sup>; (1)Department of Pharmaceutical Sciences, Bill Gatton College of Pharmacy at East Tennessee State University (2)Department of Pediatrics, Quillen College of Medicine at East Tennessee State University (3)Department of Pharmaceutical Sciences, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, TN

**PURPOSE:** To develop an LC-MS/MS method for the quantification of buprenorphine, norbuprenorphine, methadone, and glucuronide conjugates in human plasma for use in determination of drug and metabolite concentrations in human cord blood plasma of patients with opioid exposure during pregnancy.

**METHODS:** The method involved a protein precipitation with acidified acetonitrile followed by a solid phase extraction using Phenomenex Strata Drug B cartridges. Deuterium labeled internal standards were added to each sample to facilitate quantification. After extraction, the samples were then evaporated under nitrogen and reconstituted in methanol. Separation was performed using an Agilent Technologies Zorbax C8 column (50 × 2.1 mm with 5 micron particle size). For the HPLC method, a gradient elution was carried out over six minutes with an aqueous mobile phase A of 0.01% formic acid/0.1% ammonium hydroxide and 0.1% formic acid in acetonitrile for mobile phase B. Detection was achieved with a direct MS/MS method in positive electrospray mode.

**RESULTS:** The method was validated over three days. Norbuprenorphine, methadone, and buprenorphine had a linear range of 5–80 ng/mL. Norbuprenorphine-glucuronide had a linear range of 30–80 ng/mL, while buprenorphine-glucuronide had a linear range of 20–80 ng/mL. Percent error and percent relative standard deviation were <20% for all calibration points. Recovery of the glucuronide metabolites was >75% and recovery of buprenorphine, norbuprenorphine, and methadone was >89% at two concentrations. The validated method was applied to determine buprenorphine, norbuprenorphine, and glucuronide conjugate concentrations in cord blood plasma of ten patients with a history of prenatal opioid exposure.

**CONCLUSION:** The developed LC-MS/MS method for buprenorphine, norbuprenorphine, methadone, and glucuronide conjugates quantification is fast, accurate, and reproducible over a clinically relevant calibration range and can thus be used to determine umbilical cord blood plasma concentrations of these drugs in patients with prenatal opioid exposure.

**352. Effectiveness of a new age-based vancomycin dosing nomogram in the University of Colorado Hospital neonatal intensive care unit.** Michelle Ding, PharmD Candidate<sup>1</sup>, Ashley Reilly, PharmD<sup>2</sup>, Tyree H. Kiser, PharmD, FCCP, BCPS<sup>3</sup>; (1)School of Pharmacy, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO (2)Neonatal Intensive Care Unit, University of Colorado Hospital, Aurora, CO (3)University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO

**PURPOSE:** The purpose of this study was to evaluate the effectiveness of a new, more aggressive, vancomycin dosing guideline across different postmenstrual age (PMA)/days of life (DOL) groups for achieving goal trough concentrations compared to a previous dosing guideline.

**METHODS:** This retrospective cohort study evaluated vancomycin dosing and trough concentrations obtained from neonatal patients dosed according to the new dosing guideline (between September 2010 and December 2011) and according to the old guideline (between January 2009 and August 2010). The outcome

measures evaluated were the change in the percent of neonatal patients who achieved goal therapeutic trough (10–20 mcg/mL), subtherapeutic trough (<10 mcg/mL), and supratherapeutic trough (>20 mcg/mL). Each measure was stratified into one of eight groups by patient's PMA and DOL: (PMA<28;DOL≤14), (PMA<28;DOL>14), (PMA28–33;DOL≤14), (PMA28–33;DOL>14), (PMA34–37;DOL≤7), (PMA34–37;DOL>7), (PMA>37;DOL≤7), (PMA>37;DOL>7).

**RESULTS:** A total of 138 trough concentrations in 104 patients were evaluated. Despite overall improvement in the percentage of therapeutic trough concentrations (55% new guideline vs. 27% old guideline, p=0.003), no significant difference was observed in any individual age group. The new guideline reduced the percentage of subtherapeutic troughs in 3 of the 8 dosing groups (2/15 vs. 10/11, PMA<28, DOL≤14; p<0.0001), (0/13 vs. 7/9, PMA<28, DOL>14; p=0.0002), (0/4 vs. 13/15, PMA=28–33, DOL≤14; p=0.007). An increase in supratherapeutic troughs was observed in the PMA28–33, DOL≤14 group (3/4 vs. 0/15; p=0.004).

**CONCLUSION:** When stratified by age groups, utilization of a more aggressive vancomycin dosing guideline in NICU patients didn't result in significantly improved achievement of therapeutic trough concentrations, but did result in reduced subtherapeutic trough concentrations in three different age groups. Only one age group had an increased incidence of supratherapeutic trough concentrations. Further study is needed to establish the clinical significance of these findings and to determine the optimal dosing strategy for different age groups.

## Pharmacoeconomics/Outcomes

**353. Cost avoidance of using an automatic therapeutic interchange of racemic albuterol in place of levalbuterol.** Chad Weinhold, PharmD Candidate 2014; School of Pharmacy, Philadelphia College of Osteopathic Medicine, Suwanee, GA

**PURPOSE:** To determine if any cost avoidance would occur by utilizing an automatic therapeutic interchange of racemic albuterol for levalbuterol in a health system.

**METHODS:** An annual drug usage evaluation for levalbuterol 0.625 mg and 1.25 mg was completed for the time period of January 1, 2012 through January 31, 2013 across all patient populations. The annual cost avoidance of automatically substituting racemic albuterol in place of levalbuterol was determined by comparing the purchase costs and usage of levalbuterol 0.625 mg and levalbuterol 1.25 mg against the purchase costs of racemic albuterol 1.25 mg and racemic albuterol 2.5 mg. Racemic albuterol is a 50:50 mix of R- and S-enantiomers, whereas levalbuterol includes only the R-enantiomer. The consensus standard of substitution of racemic albuterol for levalbuterol occurs with a 2:1 ratio (e.g. albuterol 2.5 mg for levalbuterol 1.25 mg and albuterol 1.25 mg for levalbuterol 0.625 mg). Cost avoidance in this study was calculated using this ratio for substitution. Additionally, the cost avoidance at conversion rates between 70% through 100% was calculated, as obtaining full conversion of levalbuterol to racemic albuterol may be unrealistic.

**RESULTS:** There was a total of 15096 units of levalbuterol 0.625 mg and 17214 units of levalbuterol 1.25 mg used in the specified time period at an annual spending of \$49816 and \$68823, respectively. At a conversion rate of 70% up to the full conversion rate of 100%, total cost avoidance was in the range of \$71186 to \$101695.

**CONCLUSIONS:** The automatic therapeutic interchange of racemic albuterol in place of levalbuterol in a health system yields an annual cost avoidance from \$71186 to \$101695, depending on the annual rate of conversion. A protocol for automatic therapeutic interchange of racemic albuterol for levalbuterol can offer substantial savings, even at conversion rates of less than 100%.

**354. Reduction of re-dispensed medications from a pediatric satellite.** Tyler Vest, Pharm.D. Candidate 2016, Andrea Zuckerman, Pharm.D.; Department of Pharmacy, Cleveland Clinic, Cleveland, OH

**PURPOSE:** A significant number of doses are found to be missing from the nursing units at medication due times. Delays caused by the need to re-dispense doses could lead to adverse outcomes. We aim to analyze re-dispensed medications from a pediatric satellite pharmacy due to missing doses, attempt to identify causes of re-dispensed doses, and propose solutions to decrease re-dispenses.

**METHODS:** A real-time evaluation of re-dispenses was conducted over a four week period with a goal of 100 instances. After notification of a missing dose from nursing, an attempt to locate the dose was made. Available resources used to attempt to locate the dose included electronic medical record data, medication tracking software, and if necessary, physically locating doses on nursing units. Data collected included order number, medication, nursing unit, and reason for missing dose if this was able to be determined.

**RESULTS:** Data collection is ongoing. Although not every instance of missing doses during the study period was able to be captured, analysis of missing doses thus far has yielded several different causes of missing doses. Going forward, we will analyze all instances of missing doses to see if there are common issues that can be addressed with process changes. Larger numbers of missing doses are needed to draw general conclusions. Data collection and analysis will be completed by the time of presentation.

**CONCLUSIONS:** Although time-intensive, the analysis of missing doses to determine cause is an important undertaking and can lead to process changes to reduce instances of re-dispensed doses. Further analysis is contingent on ongoing research. Data collection is ongoing as of time of submission deadline.

## Pharmacoepidemiology

**355. Patient satisfaction with specialty pharmacy services for hepatitis C infection.** Meredith Manville, PharmD Candidate<sup>1</sup>, Linda Spooner, PharmD, BCPS<sup>1</sup>, George Abraham, MD, MPH<sup>2</sup>; (1)School of Pharmacy-Worcester/Manchester, Massachusetts College of Pharmacy and Health Sciences University, Worcester, MA (2)Saint Vincent Hospital, Worcester, MA

**PURPOSE:** A patient satisfaction survey was developed to quantify patients' perceptions of the services provided by specialty pharmacies for hepatitis C virus (HCV) infection treatment.

**METHODS:** Telephone patient surveys were utilized to evaluate satisfaction with specialty pharmacies used by patients with HCV infection during their treatment. Patients included in the study were prescribed medications for HCV infection by the physician provider at our HCV clinic between April 1, 2012 and June 1, 2013.

**RESULTS:** Data collection and analysis is currently ongoing with an expected end date of July 31st 2013. Thirty five patients were included in the study. Patient demographics were 86.11% male, with an average age of 47.5 years, 80.6% with genotype 1 infection, 69.4% were naive to treatment, and completed an average of 24.6 weeks of treatment at time of survey. Specialty pharmacies used were PharmaHealth Specialty Pharmacy (52.8%), CVS Caremark Specialty Pharmacy (36.1%) and other specialty pharmacies (11.1%). At this time, 17 of the 35 patients (48.6%) have been surveyed. Most patients (82.4%) rated their overall experience as excellent, and 94.1% would recommend the specialty pharmacies to others. Only 17.6% reported that they utilized auxiliary services, with 53% of patients stating the pharmacist services at the HCV clinic were comprehensive enough for them to not need the specialty pharmacy's services. Overall, 70.6% rated their experience with the specialty pharmacy higher than that of the retail pharmacies they have used for other medications.

**CONCLUSION:** With the involvement of the clinical pharmacist at the HCV clinic, patients were less inclined to utilize the auxiliary services offered by the specialty pharmacies. However, patients still rated their overall experience higher with the specialty pharmacies than retail pharmacies and were more likely to recommend the specialty pharmacies to others.

**356. Evaluation of outcomes of a pharmacist-performed tuberculosis testing initiative in New Mexico.** Brittni Gross, None<sup>1</sup>, Bernadette Johnson, Pharm.D.<sup>1</sup>, Amy Bachyrycz, Pharm.D.<sup>1</sup>, Diana Fortune, B.S.N.<sup>2</sup>, Dale Tinker, BA<sup>3</sup>, Sarah Babb, BS<sup>1</sup>; (1)College of Pharmacy, University of New Mexico, Albuquerque, NM (2)Tuberculosis Prevention Program, New Mexico Department of Health, Santa Fe, NM (3)New Mexico Pharmacists Association, Albuquerque, NM

**PURPOSE:** In March 2011 pharmacists were granted the authority to prescribe and administer tuberculosis (TB) tests in New Mexico (NM). The purpose of the study is to measure the impact of the NM Pharmacist TB testing program.

**METHODS:** This retrospective study included community pharmacies in NM that participated in TB testing from 2011 to 2013. Data collected included the number of pharmacists receiving the Department of Health TB testing training, the number of pharmacists prescribing and performing the test, the number of TB tests performed, the return rate for test reading, and the number of positive and negative tests. Patient data collected included patient demographics, TB risk factors, and reason for obtaining a TB test (e.g., immigration, school, or work).

**RESULTS:** In NM, 43 pharmacists are certified for TB testing, 25 of which are actively prescribing and performing TB tests at eight NM community pharmacies. Approximately 500 TB tests were prescribed and administered by pharmacists in NM between 2011 and 2013. Preliminary data includes 85 patients who received 87 tests. Complete results will be presented at the annual meeting. Sixty percent of the patients that received a TB test were female with a mean age of 35 ( $\pm 14$ ). Employment and school were the main reasons for obtaining a TB test. A total of 95% of patients followed up and had their test read appropriately. Two positive tests were identified and appropriate referrals were made following the NM Department of Health protocol.

**CONCLUSION:** New Mexico has expanded the scope of practice for Pharmacists. Pharmacist-performed TB testing can have a valuable public health benefit. TB testing follow-up rates at community pharmacies in NM were high, most likely due to convenient hours, accessible locations, and no required appointments. We hope to see pharmacist TB testing programs expanded within the US.

**357. Family structure predicts intensity of cocaine high in 12th graders.** Aileen Wong, Pharm.D. Candidate 2014<sup>1</sup>, Ajna Hamidovic, PharmD, MS<sup>2</sup>; (1)University of New Mexico College of Pharmacy (2)Department of Pharmacy Practice and Administrative Sciences, College of Pharmacy, University of New Mexico, Albuquerque, NM

**PURPOSE:** Intensity of cocaine high may be an important factor associated with addictive potential. Progression from cocaine use to DSM-IV dependence is a multi-faceted phenomenon not fully understood. In this study, we evaluate potential predictors of cocaine high intensity as a proxy for dependence.

**METHODS:** Using data from the Monitoring the Future Study (1995–2011) we described trends in cocaine use among adolescents and evaluated potential predictors of intensity of cocaine high in 12th graders that self-reported having first used cocaine in the 10th grade. Outcome of intensity of cocaine high (*howhigh*) was coded as two categories: none-moderate and very high. Variables of interest included substances of abuse and demographic variables. Both  $\chi^2$  and t-tests were run as first-level bivariate analyses. Variables of  $p < 0.25$  were placed in a multivariate logistic regression model. Mother living in the household was a significant predictor and was analyzed in a log-odds model (logit) and predictive margin for probability of high intensity was also analyzed.

**RESULTS:** Among 12th graders that first used cocaine in the 10th grade ( $n=228$ ), having a mother in the household was associated with intensity of cocaine high (OR=0.14, 95% CI=0.0342–0.5839,  $p=0.007$ ). Students with a mother in the household were less likely to report intense highs compared to students without a mother in the household (OR=0.28, 95% CI=0.1271–0.6294,  $p=0.002$ ). Predictive margin of the probability of *howhigh* was 30% lower for those with a mother in the household versus those without a mother in the household (0.3282 vs. 0.6333).



**CONCLUSIONS:** Students from households without a mother are self-reporting more intense highs. Studies have shown that pleasurable effects are linked to increased consumption. Increased consumption has also been shown to increase the probability of becoming dependent. Therefore, the more intense highs that these 12th grade students are experiencing may be a predictor of dependence.

**358. Comparison of warfarin dosing requirements between a Hispanic and non-Hispanic white population.** *Melissa Polasek, Pharm.D. Candidate 2014<sup>1</sup>, Joe Anderson, PharmD<sup>1</sup>, James Nawarskas, Pharm.D.<sup>1</sup>, Shannon Dyke, PharmD<sup>2</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Anticoagulation Center, University of New Mexico Hospital, Albuquerque, NM*

**PURPOSE:** Significant inter-patient differences in warfarin dose requirements can exist, and the role of ethnicity as a factor influencing warfarin dosing has yet to be adequately explored. The objective of our study is to examine if initial and maintenance warfarin dosing requirements vary within Hispanic and non-Hispanic White patients treated at The University of New Mexico Anticoagulation Center.

**METHODS:** A retrospective cohort study is being conducted at The University of New Mexico Hospital anticoagulation clinic. Patients will be included if they are  $\geq 18$  years, newly initiated on warfarin therapy for an indication with a desired therapeutic international normalized ratio (INR) range of 2–3 between the dates of 1/1/2009 and 9/30/2012, and were self-identified as either Hispanic or non-Hispanic White. The co-primary endpoints are the mean initial warfarin dose required to achieve consecutive INR values  $\geq 2$ , and the mean maintenance dose over the subsequent 3 month period of follow-up. Secondary endpoints will include the time to achieve initial anticoagulation, time within the therapeutic range, and number of bleeding events. Additional patient variables such as age, gender, body mass index, comorbid conditions, and concomitant medications will be collected and analyzed by logistic regression to determine the impact on warfarin dosing requirements.

**RESULTS:** From an available 985 patients, 300 patients met the inclusion criteria. Ultimately, 140 Hispanic and 140 non-Hispanic White patients were matched according to gender and age. Within the two groups, there is an equal distribution of males and females ( $n=70$ , respectively). The mean age of the Hispanic patients is  $55.5 \pm 15.0$ , and  $55.6 \pm 14.7$  years in the non-Hispanic White patients. Within the Hispanic group, 38 patients (13.6%) had Spanish listed as their preferred language.

**CONCLUSION:** Data collection is ongoing and is expected to be completed by July 31st with data analysis completed by August 31st, 2013.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**359. Pharmacokinetic/pharmacodynamic evaluation of once-daily ceftaroline dosing in renally impaired patients.** *Andrea Boyce, Pharm.D. Candidate<sup>1</sup>, Douglas N. Fish, PharmD, BCPS<sup>2</sup>; (1) Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus, Aurora, CO (2) University of Colorado Anschutz Medical Campus, Aurora, CO*

**PURPOSE:** Ceftaroline is a 5th generation cephalosporin effective against a broad range of bacteria including methicillin-resistant *S. aureus* (MRSA). Approved doses in the U.S. include 300 mg Q12H in severe renal impairment [creatinine clearance ( $CL_{cr}$ ) 15–30 mL/min], and 200 mg Q12H in end-stage renal disease [ESRD,  $CL_{cr} < 15$  mL/min or hemodialysis (HD)], however once-daily administration would be preferred for increased clinical convenience. The objective of this study was to evaluate the pharmacokinetic/pharmacodynamic (PK/PD) performance of approved (Q12H) regimens versus alternative once-daily (Q24H)

regimens using similar or reduced total daily doses (TDD) in renally impaired patients.

**METHODS:** Using Monte Carlo Simulation (Oracle Crystal Ball<sup>®</sup>, 5,000-patient simulations), the following regimens were evaluated against methicillin-susceptible *S. aureus* (MSSA) and MRSA: 300 mg Q12H, 600 mg Q24H, and 300 mg Q24H in severely impaired patients; and 200 mg Q12H, 400 mg Q24H, and 200 mg Q24H in ESRD/HD patients. PK parameters and MICs for the analysis were obtained from previously published literature. The desired PD target was percent time above MIC of unbound drug ( $\%/T > MIC$ )  $\geq 50\%$  with goal probability of target attainment (PTA)  $\geq 90\%$ .

**RESULTS:** A  $\%/T > MIC \geq 50\%$  was achieved against MSSA and MRSA with PTA of 100% for all four regimens evaluated using approved TDD. Once-daily dosing regimens using the same TDD thus achieved  $\%/T > MIC$  and PTAs comparable to standard divided-dose regimens in both severely impaired and ESRD/HD patients. Furthermore, reduced TDD of 300 mg Q24H in severe impairment and 200 mg Q24H in ESRD/HD achieved predicted PTA of 97% and 96%, respectively.

**CONCLUSION:** In patients with severe renal impairment and ESRD/HD, once-daily administration of ceftaroline at the same TDD achieves PK/PD performance comparable to standard divided-dose regimens against MSSA and MRSA while improving clinical convenience. It may also be possible to further reduce the TDD, although further investigation is needed.

**360. Minocycline and candesartan: potential for interaction after stroke.** *Ami Patel, Pharm.D. Class of 2014<sup>1</sup>, Sahar Soliman, B.S.<sup>2</sup>, Susan C. Fagan, Pharm.D., BCPS, FCCP<sup>3,4</sup>; (1) University of Georgia, College of Pharmacy, Augusta, GA (2) Program in Clinical and Experimental Therapeutics, University of Georgia College of Pharmacy, Augusta, GA (3) Department of Clinical and Experimental Therapeutics, University of Georgia, College of Pharmacy, Veteran's Affairs Medical Center, Augusta, GA (4) Department of Medicine, Georgia Regents University and Veteran's Affairs Medical Center, Augusta, GA*

**PURPOSE:** Neovascularization in the penumbra and maintenance of blood brain barrier integrity are vital aspects of recovery after ischemic stroke. Candesartan, an angiotensin II receptor blocker, has been shown to be proangiogenic, increase MMP activity and improve outcome after experimental stroke. Minocycline is anti-inflammatory, anti-apoptotic and an MMP-inhibitor, which improves outcome in acute ischemic stroke patients. This investigation was undertaken to determine whether the contrasting effects on MMP activity would result in altered angiogenesis and permeability in human microvascular endothelial cells, when candesartan and minocycline are combined in a model of ischemia and reperfusion.

**METHODS:** Human microvascular endothelial cells (hUVECs and hCMECs) were exposed to 2 hour oxygen and glucose deprivation (OGD) followed by 22 hour reperfusion with or without treatment. Treatment groups included minocycline 6  $\mu\text{g/mL}$ , candesartan 0.1, 1, and 10  $\mu\text{g/mL}$  alone or a combination of minocycline with the aforementioned candesartan concentrations. Different angiogenic steps were assessed including cell proliferation by BrdU incorporation, cell migration by wound healing assay and tube formation by matrigel tube formation assay. Activity of matrix metalloproteinases (MMPs 2, 3 and 9) was measured by Western blotting and Zymography.

**RESULTS:** Candesartan enhanced endothelial angiogenic potential at higher doses (1  $\mu\text{g/mL}$ ,  $p < 0.001$  & 10  $\mu\text{g/mL}$ ,  $p < 0.005$ ). MMP-3 activity increased at candesartan 1 and 10  $\mu\text{g/mL}$  in dose dependent fashion ( $p < 0.05$ ,  $p < 0.005$ , respectively). Minocycline 6  $\mu\text{g/mL}$  alone and in combination with candesartan blunted these effects ( $p < 0.05$ ) in both cell lines.

**CONCLUSIONS:** The combination of minocycline and candesartan at clinically relevant concentrations may reduce reparative angiogenesis after ischemic stroke. Careful adjustment of administration of each agent after stroke will be needed to resolve this interaction and provide optimal outcome.

**361. Simultaneous determination of the nucleoside analogues Clofarabine and Fludarabine by Liquid Chromatography-Tandem Mass Spectrometry in low volume clinical samples: application to a pharmacokinetic study in children.** Ryan Beechinor, BS<sup>1</sup>, Janel Long-Boyle, PharmD, PhD<sup>2</sup>; (1)School of Pharmacy, University of California at San Francisco, San Francisco, CA (2)Clinical Pharmacy, University of California at San Francisco

**PURPOSE:** Fludarabine and Clofarabine are nucleoside analogs increasingly utilized in conditioning regimens for patients undergoing allogeneic hematopoietic cell transplantation (alloHCT). Currently, the combination of low dose clofarabine added to standard fludarabine and busulfan is being evaluated for safety and efficacy in a phase II dose-escalation clinical trial. Characterization of clofarabine and fludarabine pharmacokinetics (PK) will significantly advance our understanding of the optimum systemic concentrations required to elicit drug synergism with concomitant administration. This study aims to characterize the PK of both clofarabine and fludarabine in pediatric patients receiving combination nucleoside analog therapy prior to alloHCT.

**METHODS:** We have prospectively collected PK data from pediatric patients undergoing alloHCT at UCSF Benioff Children's Hospital between June 2012 and March 2013. Patients were eligible to be included in the analysis if they had undergone a related or unrelated HCT including combination nucleoside analog therapy with fludarabine and clofarabine, were between 0 and 18 years of age, and had nucleoside analog time-concentration data available for analysis. Drug levels and potential covariates influencing drug exposure will be analyzed with standard population PK methodologies using non-linear mixed effects modeling software (NONMEM). Retrospective PK data available in children receiving monotherapy of fludarabine or clofarabine will be used in the model-building process.

**RESULTS:** This study will utilize nucleoside analog time-concentration data available in 11 pediatric HCT recipients (7 males/4 females). Subjects range in age from 3 months to 12 years. Median weight is 13.2 kg (range: 7.3–50) and includes four subjects with an actual body weight less than 12 kg. A total of 134 quantifiable concentrations are available for PK modeling. The range of observed fludarabine and clofarabine concentrations are 0.313–300.0 and 0.462–137 ng/mL, respectively.

**CONCLUSION:** Data collection is complete. PK analysis is underway and will be completed with results available at the time of the ACCP Annual Meeting.

**362. Quantitative determination of d- and l- enantiomers of methylphenidate in placenta and fetal brain tissue by liquid chromatography-mass spectrometry.** Haley Trivett, B.S., PharmD Candidate, Stacy Brown, PhD, Brooks Pond, PhD; Department of Pharmaceutical Sciences, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, TN

**PURPOSE:** The purpose of this study is to quantify the amounts of both d- and l-threo enantiomers of methylphenidate in placenta and maternal and fetal brain tissue during prenatal exposure. Due to increasing rates of use of methylphenidate amongst females of childbearing age, it is important to understand the extent of exposure to the fetus.

**METHODS:** Pregnant mice were injected with 5 mg/kg methylphenidate at 18 days gestation, and tissue was collected 1, 5, 10, 30, 60, and 120 minutes following injection. Methylphenidate was extracted from tissue via solid phase extraction using Clean Screen DAU Columns. Because methylphenidate is administered as a racemic mixture of d- and l-threo enantiomers, the enantiomers were quantified separately. Chiral separation was achieved using a Chirobiotic V column with a methanol mobile phase containing 0.375 mmol/L triethylammonium acetate and flow rate of 1.0 mL/min. Mass spectrometric detection utilized a Shimadzu IT-TOF system with the APCI source running in positive mode.

**RESULTS:** Our results demonstrate that methylphenidate does cross the placenta and enter the fetal brain. Interestingly, concentrations of both d- and l- methylphenidate in fetal brain were comparable to maternal brain concentrations. Furthermore,

d-methylphenidate reached higher concentrations than l- methylphenidate in all of the matrices examined.

**CONCLUSION:** Because the d-enantiomer is believed to be predominantly responsible for the pharmacologic activity of methylphenidate, the higher concentrations detected in fetal tissues is of significance. In light of our preliminary findings, use of methylphenidate during pregnancy may pose fetal risk.

**363. Beyond-use date determination for buprenorphine buccal veterinary solution using validated high-performance liquid chromatographic method.** Loren Kirk, BS, Stacy Brown, PhD; Department of Pharmaceutical Sciences, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, TN

**PURPOSE:** This research aimed to develop and validate a stability-indicating high performance liquid chromatographic (HPLC) method with ultra-violet (UV) detection for the determination of buprenorphine in buccal veterinary solution and apply that method to determine the stability of a 3 mg/mL buprenorphine preparation at two temperatures. This study was supported by The United States Pharmacopeial Convention.

**METHODS:** The HPLC-UV assay utilized an isocratic separation on a Thermo Hypersil BDS C8 column. The method was validated according to USP Guidelines for system suitability, precision, accuracy, linearity, and robustness. Buprenorphine was compounded into a buccal formulation with a final target concentration of 3 mg/mL. Aliquots of the formulation were stored at refrigerated and room temperature for 90 days. Sample pH was recorded and samples were assayed for potency at day 0, 1,2,7,15,21,30,60,75, and 90.

**RESULTS:** System suitability measurements indicate a robust column performance (N=2100) and adequate peak resolution of 6.48. Accuracy exceeded 98% at each assay level. Intra-day precision was less than 0.14% RSD (relative standard deviation) for all assay levels, and inter-day precision had a 3.70% RSD over six days. The method was shown to be linear with  $R^2 > 0.99$  for concentrations ranging from 75 to 375 mcg/mL. Mean buprenorphine concentrations for all samples were assessed immediately after compounding and were within 90–110% of the labeled potency, remaining in this range throughout the 90-day study period. The pH for the refrigerated sample remained within the 4.0–4.8 target range; however, the pH of the room temperature sample fell below 4.0 after 30 days.

**CONCLUSION:** Potency of buprenorphine buccal solution 3 mg/mL remains within the 90–110% target range for 90 days; however, the pH of the preparation at room temperature is not consistent. These data indicate that refrigerated storage should be recommended for this product if kept longer than 30 days.

**364. Comparison of stability profiles of three generic vancomycin HCl for injection products.** Loren Kirk, BS<sup>1</sup>, Stacy Brown, PhD<sup>1</sup>, Paul Lewis, PharmD<sup>2</sup>; (1)Department of Pharmaceutical Sciences, Bill Gatton College of Pharmacy at East Tennessee State University, Johnson City, TN (2)Johnson City Medical Center, Johnson City, TN

**PURPOSE:** The objective of this investigation was to use liquid chromatography-mass spectrometry (LC-MS) to evaluate the refrigerated stability of generic vancomycin HCl for injection products from three different manufacturers (Hospira, APP, Pfizer).

**METHODS:** Triplicate samples of vancomycin HCl products were reconstituted with sterile water for injection as indicated on the package label. The LC-MS method included a gradient elution on a Kinetex C18 column (2.1 × 50 mm, 5 micron particle size). The mass spectrometer was operated in +ESI (electrospray) mode, acquiring data on the target mass for vancomycin at m/z 724.72. Samples were removed from the manufacturer vials on days 0, 1, 2, 4, 7, 10, and 14 following reconstitution and assayed for vancomycin B concentration. Stability profiles over 14 days were compared using an analysis of variance (ANOVA) with a Tukey's Multiple Comparison Post-Test and a Bartlett's Test for Equal Variances.

**RESULTS:** The data indicate that the concentration of vancomycin B in the samples fell below 90% of labeled amount after 4 days of refrigerated storage for all three manufacturers tested. Furthermore, the profiles of these products showed no statistically significant differences over 14 days. Each product conveyed a peak concentration of vancomycin B after 2 days post-reconstitution, indicating a solubility lag time for these injectable products. After 14 days of storage, all products showed a vancomycin B concentration of <80% of the labeled amount.

**CONCLUSION:** The results of this stability investigation indicate that a BUD of 96 hours, when the products are kept refrigerated, is applicable to all three generic products tested. The use of LC-MS to conduct stability investigations of vancomycin products provides added assurance that the API is being quantified as opposed to closely related impurities.

**365. An evaluation of twice daily versus three times daily tobramycin dosing in pediatric cystic fibrosis patients experiencing acute pulmonary exacerbations.** *Kristen Alspaugh, Pharm.D. Candidate 2014, Stephanie Hoge, Pharm.D. Candidate 2014, Megan Patch, Pharm.D. Candidate 2014, Kalen B. Manasco, Pharm.D., BCPS, AE-C; University of Georgia College of Pharmacy, Augusta, GA*

**PURPOSE:** The objective of this study is to compare the safety and efficacy of twice daily versus three times daily dosing of tobramycin in pediatric cystic fibrosis patients admitted for acute pulmonary exacerbations. Twice daily dosing of tobramycin has the potential to maintain the concentration dependent killing ability as seen with once daily dosing, while also reducing the adverse effects seen with three times daily dosing.

**METHODS:** This study is a retrospective chart review of cystic fibrosis patients (age 5–18 years old) admitted to the Children's Hospital of Georgia from January 1, 2008 – December 31, 2012 for an acute pulmonary exacerbation. Patients who received both twice daily and three times daily dosing of tobramycin will be self-compared during subsequent admissions for exacerbations. Our primary outcome is changes in FEV1 from baseline to discharge. Secondary outcomes will assess changes in Cmax/MIC, time to next exacerbation, renal function and changes in microbial resistance.

**RESULTS:** Project is in progress and expected to be completed by date of presentation.

**CONCLUSION:** Project is in progress and expected to be completed by date of presentation.

**366. Metered Dose Inhalers: Varying the time between multiple actuations could influence the emitted dose.** *Julia Hautmann, Pharm.D. Candidate 2014<sup>1</sup>, Sebastian E. Godoy, MS, Patricia Mars-hik, Pharm.D., Ramesh Chand, Ph.D., Jason McConville, Ph.D., Sanjay Krishna, Ph.D., Sanchita Krishna, Ph.D., Pavan Muttill, Ph.D.<sup>3</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Department of Pharmaceutical Sciences, University of New Mexico College of Pharmacy, Albuquerque, NM*

**PURPOSE:** This study demonstrated the variations in emitted dose when the time interval between individual actuations was altered for commonly used pressurized metered dose inhalers (pMDI's). This variability could potentially affect the quality, handling, use, efficacy and compliance of pMDIs.

**METHODS:** The fine particle mass (FPM) of the aerosol droplets discharged from three pMDI's (Proventil® HFA, Proair® HFA, Ventolin HFA®) was assessed using a next generation cascade impactor. The studies were performed with and without a valved holding chamber (VHC) after varying the time between multiple actuations. After 10 actuations (each actuation separated by 15, 30, 60 or 120 seconds) the deposited particles were quantified spectrophotometrically. The temperature and velocity (of the leading edge) of the aerosol plume was measured using a high-speed longwave IR Camera for the three inhalers after varying the time between actuations. Three black-body sources at different temperatures were utilized to perform a three-point calibra-

tion of the collected imagery in order to measure the plume temperature.

**RESULTS:** A significant increase in the FPM was observed when the time between actuation was increased from 15 s to 120 s for ProAir HFA (without VHC), Proventil HFA (VHC) and Ventolin HFA (VHC and no VHC). ProAir HFA (0.22 s) is the softest plume followed by Proventil HFA (0.18 s) and Ventolin HFA (0.11 s). The spray velocity showed that Ventolin HFA and Proventil HFA were at their highest velocity at 60 s between actuations.

**CONCLUSIONS:** Our *in vitro* studies indicate that the emitted dose can vary significantly for commercial pMDI's by changing the time between actuations. We also showed subtle temperature and spray velocity alterations in the emitted aerosol by using an IR camera. These changes could be due to either the differences between the formulation and/ or the actuator portion of individual inhalers.

**367. Optimization of spray drying parameters using a factorial design for pulmonary bcg vaccine against tuberculosis.** *Avni Patel, Pharm.D. Candidate 2016<sup>1</sup>, Dominique N. Price, Ph.D. Candidate<sup>2</sup>, Alaa Elmaoued, M.S.<sup>3</sup>, Pavan Muttill, Ph.D.<sup>2</sup>; (1) University of New Mexico College of Pharmacy, Albuquerque, NM (2) Department of Pharmaceutical Sciences, University of New Mexico College of Pharmacy, Albuquerque, NM (3) College of Pharmacy, Department of Pharmaceutical Sciences, University of New Mexico College of Pharmacy, Albuquerque, NM*

**PURPOSE:** Bacille Calmette Guerin (BCG) is an attenuated live vaccine against tuberculosis. The current vaccine, administered via the intradermal route, has a variable efficacy ranging from 0% to 80%. Our lab has recently shown BCG administered via the pulmonary route may provide consistent efficacy. This project aims to determine an optimal protocol for preparing a live, inhalable, spray-dried BCG vaccine.

**METHODS:** Combinations of leucine, mannitol, and trehalose were spray dried using the following variable factors: excipient mixture ratios, as well as spray drier feed rate and inlet temperature. Powders were then characterized for the following outcome variables: yield, particle size, residual water content, and water uptake during storage. Particle size and span were observed using laser diffraction. Residual water content was determined by looking at weight loss of powders after drying in an oven at 110 °C for 24 hours. Water uptake was determined by weight gain after exposing to 90% relative humidity for 24 hours. Data was analyzed using the program Design Expert®.

**RESULTS:** With all excipient mixtures, a lower feed rate of 10% gives smaller particle sizes. Inlet temperature appears to depend on the formulation mixture being spray dried. For example, the high mannitol formulations produced smaller particles at a lower temperature of 140 °C compared to high leucine formulations producing smaller particles at a higher temperature of 160 °C. High mannitol mixtures had the lowest residual water content and narrowest particle size distribution of all mixtures. Both high leucine and mannitol powders had similar yields whereas high trehalose mixtures had the lowest yield and the largest particle sizes.

**CONCLUSION:** Based on trends in the current study, the carrier particle for our BCG vaccine will be a mixture of 70% mannitol, 20% leucine and 10% trehalose, using a 10% feed rate and an inlet temperature of 140 °C.

**368. Enteric-coating of HPC capsules prepared by injection-molding.** *Elena Macchi, Bachelor's of Science<sup>1</sup>, Lucia Zema, PhD<sup>2</sup>, Andrea Gazzaniga, Master of Science<sup>1</sup>, Linda Felton, PhD<sup>3</sup>; (1) Sezione di Tecnologia e Leg. Farmaceutiche, Università degli Studi di Milano, Milano, Italy (2) Sezione di Tecnologia e Leg. Farmaceutiche "Maria Edvige Sangalli", Dipartimento di Scienze Farmaceutiche, Università degli Studi di Milano, Milano, Italy (3) Department of Pharmaceutical Sciences, University of New Mexico, Albuquerque, NM*

**PURPOSE:** To evaluate injection molded (IM) hydroxypropyl cellulose (HPC)-based capsules as cores for the application of a



pH-dependent soluble coating, in comparison with conventional capsules.

**METHODS:** IM (BabyPlast 6/10P, Cronoplast S.L.) formulation consisted of a 90:10 HPC (Klucel<sup>®</sup> LF, Ashland):polyethylene glycol 1500 blend. Size 0 gelatin and hydroxypropyl methylcellulose (HPMC) capsules (Capsugel) and the IM HPC-based capsules were filled with 80 mg of acetaminophen. Aqueous solutions of the same materials were used for sealing the capsule shells. Capsules were coated (Hi-coater, Vector Corporation LDSC, equipped with a perforated pan) with a Eudragit<sup>®</sup> L 30 D55 (64.10):TEC (3.85):deionized water (32.05) suspension. Samples of sealed and unsealed capsules with theoretical weight gains of 0, 4, 6, 8, 10 mg of dry polymer/cm<sup>2</sup> were withdrawn and imaged by scanning electron microscopy (SEM). The *Dissolution Test for Delayed-Release Dosage Forms* (USP 34) was used for evaluating the release performance and the amount of drug released was determined by UV/Vis spectrophotometry at 248 nm.

**RESULTS:** Initially gelatin, HPMC and HPC were coated simultaneously in a single pan; actual polymer deposition was not linear to theoretical weight gain likely due to different capsules shell weight and so HPC ones were coated separately (same coating parameters). The release performance demonstrated no need for sealing the HPC-based cores. Different from gelatin and HPMC capsules, the lag time (time to 10% drug release) from HPC ones increased as a function of the amount of polymer applied, up to ~168 min; moreover, samples with the maximum level of coating were able to withstand the acidic medium and release the drug after the pH change within a time analogous to the lag time of uncoated IM cores.

**CONCLUSION:** Molded HPC-based capsules could successfully coated with an enteric polymer; this gastroresistant pulsatile-delivery device has promise for further developing into a colonic delivery system.

**369. Literature review of protamine dosing strategies for the reversal of heparin after cardiopulmonary bypass (CBP).** *Andrew Orsa, Pharm. D. Candidate<sup>1</sup>, Justin Miranda, Bachelors of Science Pharm. D. Candidate<sup>2</sup>, Roy Hendley, M.S., Pharm. D. BCNSP<sup>3</sup>, (1) School of Pharmacy, Texas Tech University Health Sciences Center School of Pharmacy, Lubbock, TX (2) School of Pharmacy, Texas Tech University Health Sciences Center, Lubbock, TX (3) Lubbock Heart Hospital*

**PURPOSE:** Reoperation is required for 3 – 5% of cardiovascular patients undergoing CPB to stop excessive hemorrhage. The effects of hemorrhage include increase hospital length of stay, administration of blood products, and incidence of sepsis. Hemorrhage following CPB is known to be a result of excessive heparinization, inadequate heparin reversal with protamine, protamine overdose, and/or heparin rebound. Correct dosing of protamine can limit these adverse affects; however, current literature describes several different dosing strategies. The optimal strategy still remains unknown. Traditionally, clinical pharmacists do not play a role in drug monitoring for CPB but their knowledge and focus on pharmacotherapy may be useful. Current practice guidelines recommend pharmacists to: evaluate the appropriateness of drug therapies, provide background primary information, and establish a rapport with other healthcare professionals. This literature review aims to describe the protamine dosing strategies and to evaluate which method may be optimal.

**METHODS:** A literature search with Pubmed using the keywords: cardiopulmonary bypass, protamine, and heparin revealed 564 search results. Based on exclusion criteria, five different dosing strategies were identified which include: weight based (WB), Hepcon<sup>®</sup> assisted (HD), continuous infusion (CI), standard dosing using heparin:protamine ratio (SD), and dose response curve (DR).

**RESULTS:** In each study the group size, heparin protocol, patient monitoring, and design of the trials varied considerably. These studies reported outcomes such as: hemorrhage, heparin rebound, and amount of protamine administered. Preliminary analysis of these studies shows a reduction in the total protamine

administered if WB and HD dosing are used to initially reverse heparin at the conclusion of CPB. CI dosing after initial heparin reversal has shown to significantly reduce bleeding after CPB. A more thorough analysis will be completed.

**CONCLUSION:** By reviewing primary literature and pharmacotherapeutic background, clinical pharmacists can assist in protamine dosing to reduce post operative bleeding and drug costs.

**370. Preformulation development of polymorphic rifampicin particles for pulmonary delivery.** *Kai Berkenfeld, Pharmacist, Kybran Lamkin, PharmD Student, Alf Lamprecht, PhD, Jason McConville, Ph.D.; Pharmaceutics, University of New Mexico, Albuquerque, NM*

**PURPOSE:** Rifampicin (RF) is an antibiotic drug used in first line tuberculosis therapy. A daily dose of 10 mg/kgBW (adults, 600 mg max.) is administered via oral route. In order to avoid certain side effects, to limit therapy costs and to increase patient compliance, our goal is to develop a formulation that can be administered via pulmonary route. RF polymorphs show specific physicochemical properties so purposive manipulation is a promising approach for formulation development.

**METHODS:** Suspensions or solutions of rifampicin (RF) crystalline Form I in: (i) ethanol, (ii) 2-propanol, (iii) acetone and (iv) acetone + 2-pyrrolidone were spray dried using a Bÿchi Mini Spray Dryer B-290 (BUCHI Corporation, New Castle, DE). Samples were characterized by X-ray powder diffractometry (XRPD), scanning electron microscopy (SEM), differential scanning calorimetry (DSC) and Laser diffractometry (LD).

**RESULTS:** XRPD data showed that recrystallization from ethanol or acetone (i, iii) created different crystalline solvates with characteristic peaks at 8.1, 11.7, 16.2, 18.4 °2θ and 7.8, 8.0, 10.0, 20.1, 21.1, 21.8 °2θ respectively but different grades of crystallinity. Spray drying of ii and iv formed the Form-II polymorph or amorphous particles respectively. DSC experiments showed characteristic thermograms for i and iii, equivalence of ii with Form II and no distinct events for iv. SEM images confirmed three different types of particle shapes: flake-like (i), spherical (iii) and rectangular (ii, iii), the rectangular shapes differed in smoothness. LD experiments showed median particle sizes of 6.96 ± 0.19 μm (i), 5.09 ± 0.14 μm (ii), 7.56 ± 0.17 μm (iii) and 2.29 ± 0.06 μm (iv).

**CONCLUSION:** Distinct polymorphic rifampicin structures were successfully prepared and characterized as a precursor for development of a respirable dosage form.

## Pulmonary

**371. Triciribine, a selective akt inhibitor, ameliorates idiopathic pulmonary fibrosis and pulmonary hypertension.** *Maha Abdalla, Pharm.D., Ph.D. Candidate<sup>1,2</sup>, Alanna Pruitt, B.S.<sup>1,2</sup>, Anna Goc, Ph.D.<sup>1,2</sup>, Lakshman Segar, Ph.D.<sup>1,2</sup>, Advije Ergul, M.D., Ph.D.<sup>1,2</sup>, Susan C. Fagan, Pharm.D., BCPS, FCCP<sup>1,2</sup>, Somanath P.R. Shenoy, Ph.D.<sup>1,2</sup>; (1) Department of Clinical and Experimental Therapeutics, University of Georgia, College of Pharmacy, Veteran's Affairs Medical Center, Augusta, GA (2) Department of Medicine, Georgia Regents University, Veteran's Affairs Medical Center, Augusta, GA*

**PURPOSE:** Idiopathic pulmonary fibrosis (IPF) is an incurable, chronic and progressive disease with severely poor prognosis and often leads to pulmonary hypertension (PH). Persistent myofibroblast (MFs) differentiation, marked by *de novo* expression of αSMA stress fibers, is the central orchestrator of tissue fibrosis and vascular remodeling that occurs in IPF and PH. Here we investigated the role of protein kinase B (Akt) in mediating MF differentiation and the efficacy of Triciribine (TCBN), a selective Akt inhibitor, currently in clinical trials for cancer therapy, as a potential therapeutic option for IPF and PH.

**METHODS:** Mouse embryonic fibroblasts (MEFs), primary human lung fibroblasts (HLF) and MEFs transfected with hyperactive and inactive Akt variants (Myr-Akt and DN-Akt, respectively) were used *in vitro*. To evaluate the severity of IPF and

PH, *in vivo*. Wild Type mice were subjected to the following insults: intratracheal adenovirus TGF $\beta$  (adTGF $\beta$ ) gene delivery or chronic hypoxia, respectively. Mice were treated with placebo, insult alone, and insult plus TCBN or Rapamycin.

**RESULTS:** Hyperactivation of Akt resulted in a 6-fold increase in  $\alpha$ SMA expression, an effect that was blunted in dominant negative (DN)-Akt cells despite TGF $\beta$  stimulation. In TGF $\beta$ -stimulated MEFs and HLFs, treatment with TCBN blunted  $\alpha$ SMA expression. Additionally, TCBN markedly attenuated MFs contraction as evident by a marked decrease in collagen gel contraction assay. Furthermore, *in vivo*, TCBN (0.5 mg/kg/day) reversed adTGF $\beta$ - and hypoxia-induced IPF and PH, respectively, compared to Rapamycin. Mice treated with TCBN had markedly lower tissue dense infiltration and fibrosis, lower adventitial and medial remodeling, lower  $\alpha$ SMA, fibronectin and collagen assembly, and marked vasodilation.

**CONCLUSION:** We are the first group to demonstrate the anti-fibrotic and anti-remodeling effects of Triciribine at a dose 50% lower than that utilized in preclinical cancer studies.

**TRANSLATIONAL IMPACT:** Triciribine could potentially be a therapeutic option for IPF and PH.

**372. Effects of smoking cessation in asthmatic patients: a systematic review.** *Giannina Richelle Chan*, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Precious Bagazin, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Maureen Bautista, Bachelor of Science in Pharmacy Major in Clinical Pharmacy, Christine Beatrice Gison, Bachelor of Science in Pharmacy Major in Clinical Pharmacy; Department of Pharmacy, University of Santo Tomas, Manila, Philippines

**PURPOSE:** This study aimed to determine the effects of smoking cessation in asthmatic patients, with regards to pharmacologic and non-pharmacologic interventions.

**BACKGROUND:** Smoking is associated with a higher incidence of asthma and is strongly predictive of the development of new-onset asthma in allergic adults. Compared to nonsmoking asthmatic patients, smoking asthmatic patients are at risk of more severe symptoms and worse asthma-specific quality of life. There is a wide variety of approaches to smoking cessation from pharmacologic therapy to behavioral interventions.

**METHODS:** Systematic study. Only studies relating smoking cessation or smoking to asthma were included in this study. The following electronic databases, namely EBSCO Integrated Search, ScienceDirect and Scopus were used. For each trial, the following data were extracted using a standardized form: (1) year of publication (2) comparisons studied (3) study methods (setting, randomization, length of follow-up) (4) study population (number randomized and diagnostic criteria used); and (5) intervention(s).

**RESULTS:** The results of this systematic review indicate that both pharmacologic and behavioral interventions are effective in smoking cessation but the significant statistical difference between the two cannot be established.

**CONCLUSION:** It seems more useful that pharmacological therapies supplement behavioral interventions in approaching patients who want to quit smoking. Overall smoking cessation has positive effects in improving the condition of asthmatic patients.

**373. Dasatinib inhibits alpha-sma assembly in myofibroblasts differentiation: a potential role in pulmonary fibrosis.** *Erin Gurley*, Pharm.D. Candidate<sup>1</sup>, LeeAnn Thompson, Pharm.D. Candidate<sup>1</sup>, Maha Abdalla, Pharm.D., Ph.D. Candidate<sup>2,3</sup>, Somanath P.R. Shenoy, Ph.D.<sup>2,3</sup>; (1)University of Georgia, College of Pharmacy, Augusta, GA (2)Department of Clinical and Experimental Therapeutics, University of Georgia, College of Pharmacy, Veteran's Affairs Medical Center, Augusta, GA (3)Department of Medicine, Georgia Regents University, Veteran's Affairs Medical Center, Augusta, GA

**PURPOSE:** Idiopathic Pulmonary Fibrosis (IPF) represents the most common cause of death from progressive lung disease. Currently the only effective treatment option is lung transplant, which highlights the need for an effective pharmacologic alterna-

tive. Myofibroblasts (MFs), the hallmark of IPF, are characterized by *de novo* alpha smooth muscle actin ( $\alpha$ SMA) stress fibers assembly and excess extracellular matrix (ECM) fibronectin secretion and assembly. Here we investigate the role of Src in mediating MF differentiation through  $\alpha$ SMA and ECM assembly. Furthermore, we study the efficacy of dasatinib, a Src inhibitor with a multifactorial mechanism of action, as a pharmacologic option in the treatment of IPF.

**METHODS:** Mouse Embryonic Fibroblasts (MEFs) and Fibrotic Human Lung Fibroblasts (FHLFs) were used *in vitro*. Cells were plated on an eight well chamber, MEFs in the absence or presence of transforming growth factor  $\beta$ 1 (TGF $\beta$ 1) for 48 h and concomitant dasatinib or PP2 (a selective Src inhibitor) for 24 h (total 72 h); FHLFs directly treated with dasatinib or PP2 for 48 h. The fixed cells were incubated with primary anti- $\alpha$ SMA and primary anti-fibronectin antibodies (Abcam). The immuno-fluorescence staining images were taken by Zeiss fluorescent microscope.

**RESULTS:** We first determined optimal TGF $\beta$ 1-induced MF differentiation to occur at 72 h as evident by marked increase in  $\alpha$ SMA and was associated with increased fibronectin expression and assembly. Intriguingly, the stimulatory effects of TGF $\beta$ 1 were blunted upon targeted Src inhibition using dasatinib and PP2 as evident by decreased  $\alpha$ SMA and fibronectin assembly. At a dose of 10 nmol/L, dasatinib markedly attenuated MF differentiation. Similar trends were observed in FHLFs.

**CONCLUSION:** Our results demonstrate that targeted Src inhibition using dasatinib has effective anti-fibrotic potential at a dose 10 fold less than that used in current cancer studies.

**TRANSLATIONAL IMPACT:** Dasatinib can be a pharmacologic option for IPF management.

**374. Dasatinib, a Src inhibitor, attenuates alpha-SMA synthesis: role in pulmonary fibrosis.** *LeeAnn Thompson*, Pharm.D. Candidate<sup>1</sup>, Samantha Burke, Pharm.D. Candidate<sup>1</sup>, Erin Gurley, Pharm.D. Candidate<sup>1</sup>, Robert C. Newsome, Pharm.D.<sup>1</sup>, Maha Abdalla, Pharm.D., Ph.D. Candidate<sup>2,3</sup>, Somanath P.R. Shenoy, Ph.D.<sup>2,3</sup>; (1)University of Georgia, College of Pharmacy, Augusta, GA (2)Department of Clinical and Experimental Therapeutics, University of Georgia, College of Pharmacy, Veteran's Affairs Medical Center, Augusta, GA (3)Department of Medicine, Georgia Regents University, Veteran's Affairs Medical Center, Augusta, GA

**PURPOSE:** Idiopathic pulmonary fibrosis (IPF), a progressive and generally fatal disease, is incurable and characterized by hypertrophic scarring. Persistent myofibroblast differentiation is the hallmark of IPF and is characterized by neo-expression of alpha smooth muscle actin ( $\alpha$ SMA) and excess extracellular matrix (ECM) fibronectin deposition. A well established trigger, transforming growth factor  $\beta$  (TGF $\beta$ ) has also been shown to activate Src signaling pathway. Dasatinib, an anti-cancer medication, targets Src kinases as well as c-Abl kinases, and PDGF receptors. Therefore, here we investigated the mechanism by which dasatinib modulates myofibroblast differentiation and its potential repurposing for the management of IPF.

**METHODS:** Mouse embryonic fibroblasts (MEFs; NIH3T3) and fibrotic human lung fibroblasts (FHLF) were utilized *in vitro*. A dose study was conducted in MEFs under serum starvation. Cells were subjected to TGF $\beta$  treatment for 48 hour, plus dasatinib or PP2 at respective doses for an additional 24 hour. After 72 hour, cells were lysed, and Western-blot analysis for expression of  $\alpha$ SMA, phospho-Src, and total Src was performed. Once the dose was determined, both MEFs and FHLF were subjected to dasatinib or PP2 to investigate the mechanism of cell differentiation.

**RESULTS:** Maximum TGF $\beta$ -induced myofibroblast differentiation occurred at 72 hour as evident by marked increase in  $\alpha$ SMA expression that was associated with increased fibronectin. Interestingly, targeted Src inhibition using dasatinib and PP2 attenuated myofibroblast differentiation as evident by blunted  $\alpha$ SMA and fibronectin expressions. Mechanistically, our data suggests that dasatinib modulates the transcription factor SRF via  $\beta$ -catenin pathway independent of GSK pathway. FHLFs exhibited similar trend.

**CONCLUSION:** Our results show that myofibroblast differentiation is mediated through Src pathway.

**TRANSLATIONAL IMPACT:** Dasatinib could potentially be a therapeutic option in patients with IPF at a dose much lower than that used in cancer therapy.

**375. Conversion of Veterans Affairs Patients to Combivent RespiMat: A patient follow-up to evaluate adherence, appropriate use, and symptom control.** Amy Higginson, B.S.<sup>1</sup>, Michelle Pfeifer, B.S.<sup>1</sup>, Angie Roberti, B.S.<sup>1</sup>, Stellar Yi, B.S., B.A.<sup>1</sup>, Jessica C. McGregor, PhD<sup>1</sup>, Jane Manning, PharmD<sup>2</sup>, Kristina Hinton, PharmD<sup>3</sup>, Harleen Singh, PharmD, BCPS<sup>1</sup>; (1) Oregon State University/Oregon Health Science University, College of Pharmacy, Portland, OR (2) Portland Veterans Affairs Medical Center, Portland, OR (3) Portland Veterans Affairs Medical Center, Vancouver, WA

**PURPOSE:** In March 2013, the Portland Veterans Affairs Medical Center (PVAMC) Pharmacy began a phased transition to Combivent RespiMat, the new chlorofluorocarbon-free alternate to Combivent MDI. Converted patients were sent an instructional DVD and handout. The purpose of this project was to evaluate patient adherence and understanding of the new inhalation device and degree of symptom control.

**METHODS:** Chart review was used to collect patient demographics, smoking status, COPD stage, relevant medications, and comorbidities for all patients converted to Combivent RespiMat. Phone interviews were conducted to assess knowledge of RespiMat use and severity of symptoms following conversion (exacerbations and subjective ratings). Patients were excluded if not started on RespiMat, unable to be contacted, died, or no longer followed by PVAMC.

**RESULTS:** Of 364 patients converted, 90 have been screened to date and 52 met inclusion criteria. Forty-seven patients had a diagnosis of COPD and five had asthma. Following conversion, 16/52 patients watched the DVD, but only 3/52 were unclear how to prepare and prime the device. At follow-up, four patients had discontinued RespiMat leaving 48 patients for a detailed review. Among these patients Combivent RespiMat was used for an average of 82 days. The device was used as prescribed (one puff four times daily) by 17/48 (35%) patients, 36/48 (75%) stated following the recommended inhalation technique, and 42/48 (88%) reported holding their breath for ten seconds following inhalation. Compared to the MDI, 42/48 (88%) patients stated feeling the same or less breathless and reported sleeping the same or better, since switching to RespiMat.

**CONCLUSION:** Only 35% of patients reported using Combivent RespiMat as prescribed and thus required additional phone consultation on dosage directions. Still, the majority of patients converted at PVAMC demonstrated appropriate inhalation technique and symptom control was generally maintained or improved in these patients.

## Substance Abuse/Toxicology

**376. Buprenorphine versus methadone in opioid dependant patients.** William Ballough, BBA, PharmD.Candidate, Rachel Crowe, PharmD. Candidate, Jennifer Elbert, PharmD. Candidate; School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, FL

**PURPOSE:** Illicit opioid use is a global problem both socially and economically. Illicit opioids such as heroin represent an illegal class of drugs that is characterized with negative outcomes including mortality, criminal behavior, and the spread of blood borne illness. Treating an opioid dependent individual with a prescription drug delivers therapeutic affects that offer patients an opportunity to not depend on illicit opioids. Methadone has been the gold standard in treatment, but with nearly identical chemical properties to heroin, the "cure" may be worse than the "disease". Buprenorphine has been integrated into therapy more recently in the hopes of offering a medication that is not only effective in treating opioid dependence but also a drug less prone to abuse.

**METHODS:** In these three randomized controlled trial, we thoroughly reviewed primary literature that examined the effectiveness

of buprenorphine compared to methadone in opioid dependant patients. The primary outcomes were as follows: The LEEDS trial, for patients to remain abstinent from illicit drugs for 6 months; The SUMMIT trial, for retention in treatment at 6 months or total opioid detoxification, and in the "double-blind randomized trial comparing buprenorphine and methadone in opiate dependence" for retention with either treatment drug, or illicit opioid use.

**RESULTS:** The LEEDS trial showed no statistically significant findings. The SUMIT trail showed that significantly fewer of those patients selecting buprenorphine achieved retention compared to methadone.  $P < 0.001$ ; OR 0.34 [95% CI: 0.20–0.59]. In the "double-blind randomized trial comparing buprenorphine and methadone in opiate dependence", a statistically significant number of patients were retained on methadone compared to buprenorphine ( $p = 0.002$ )

**CONCLUSION:** When used in patients with illicit opioid dependency, methadone is significant in retaining patients on the medication with less patients reverting back to illicit drug use. Buprenorphine is clinically significant and can be successfully used in patients desiring total detoxification.

**377. Effect of prenatal alcohol co-exposure and other factors on neonatal abstinence syndrome in infants born to opioid-dependent mothers.** Christine Kreitinger, PharmD Candidate 2015<sup>1</sup>, Hilda Gutierrez, BS<sup>2</sup>, Ajna Hamidovic, PharmD, MS<sup>2</sup>, Preeyaporn Sarangarm, PharmD<sup>3</sup>, Eve Wohlert, RN<sup>4</sup>, Emily Stephens, RN<sup>5</sup>, Lawrence Leeman, MD, MPH<sup>6</sup>, Ludmila Bakhireva, MD, MPH, PhD<sup>2</sup>; (1) College of Pharmacy, University of New Mexico, Albuquerque, NM (2) Department of Pharmacy Practice and Administrative Sciences, College of Pharmacy, University of New Mexico, Albuquerque, NM (3) Inpatient Pharmacy, University of New Mexico Hospital, Albuquerque, NM (4) Milagro Outpatient Clinic, University of New Mexico Hospital, Albuquerque, NM (5) Clinical and Translational Science Center, University of New Mexico Health Sciences Center, Albuquerque, NM (6) Department of Family and Community Medicine, School of Medicine, University of New Mexico, Albuquerque, NM

**PURPOSE:** Neonatal abstinence syndrome (NAS) has seen rising incidence, resulting in extended newborn hospital stays and more costly postnatal care. This study examined the effects of prenatal alcohol exposure (PAE) and other risk factors on the incidence and severity of NAS.

**METHODS:** For this prospective cohort study, 73 pregnant women on opioid maintenance therapy (OMT) were recruited from a perinatal substance abuse clinic. PAE was assessed at enrollment and delivery through structured maternal interviews and ethanol biomarkers evaluated in the mother (GGT, %CDT, PEth, EtG, EtS) and infant (PEth in dry blood spots). If the mother or infant was positive for any of the biomarkers at delivery, they were categorized as alcohol exposed. Information on maternal OMT, urine drug screens, and NAS outcomes were abstracted from electronic medical record.

**RESULTS:** Alcohol exposure was found in 21.9% of the sample, and 75.3% of the newborns required pharmacologic treatment for NAS. In univariate analyses, PAE trended towards a greater need for pharmacologic treatment of NAS (81.3% vs. 73.7%), longer duration of hospital stay ( $19.5 \pm 15.7$  vs.  $16.3 \pm 9.8$  days), and higher cumulative methadone dose received by the newborn ( $14.2 \pm 16.2$  vs.  $9.9 \pm 6.8$  mg); however, none of these differences were statistically significant ( $p > 0.05$ ). In multivariate analysis, PAE was not an independent predictor; however, lack of breastfeeding was associated with longer hospital stay ( $\beta = 7.6$ ,  $p = 0.008$ ) and greater cumulative methadone dose received by the newborn ( $\beta = 6.7$ ,  $p = 0.03$ ). In addition, the use of buprenorphine rather than methadone predicted later initiation of NAS treatment, while co-exposure with amphetamines predicted earlier initiation ( $p < 0.01$ ).

**CONCLUSION:** PAE was not associated with NAS outcomes possibly due to moderate levels of alcohol consumption in this cohort and stronger effects of other maternal factors. The effect of amphetamines on earlier initiation of NAS treatment requires examination in future studies.



## Transplant/Immunology

**378. Early experience with 3-Month ciprofloxacin prophylaxis for BK infection in renal transplantation.** Amy Lehnert, B.S., Samir Patel, Pharm.D.; University of Houston College of Pharmacy, Houston, TX

**PURPOSE:** BK polyomavirus (BKV) is an infection affecting renal transplant recipients. Previous data suggests possible activity of fluoroquinolones against BKV, although their role in prevention is unknown. Our objective was to review 6-month experience using a ciprofloxacin protocol specifically aimed at preventing BKV.

**METHODS:** Beginning in 03/2012 at The Methodist Hospital, renal transplant recipients were discharged on prophylactic ciprofloxacin (CIP) 500 mg once daily for 90 days. Medical records were reviewed to compare CIP patients to a consecutive cohort of patients transplanted from 01/2011 to 03/2012 who did not receive CIP prophylaxis. Statistical methods used include Student *t*-test, Fisher's exact test, Chi-squared test, and Kaplan-Meier curves.

**RESULTS:** A total of 327 patients (80-CIP and 247-noCIP) were reviewed. There were no differences in age, race, gender, and tacrolimus use. There was a slightly higher rate of rATG induction (74% vs. 61%;  $p=0.04$ ) and mycophenolate use (100% vs. 97%,  $p=0.05$ ) in the CIP arm, and a lower percentage of living donors (24% vs. 36%,  $p=0.03$ ) and prednisone use (79% vs. 89%;  $p=0.02$ ). Though not statistically significant, a 27% reduction in BKV was seen at 6 months. No differences were seen in UTI rates, although 9 bacteremias occurred in noCIP patients compared to 0 in CIP patients ( $p=0.02$ ). Several antibiotic susceptibility rates were decreased in CIP patients.

**CONCLUSIONS:** Preliminary data suggests a modest reduction in BKV at 6 months with CIP prophylaxis, but this may be at the expense of increased antibiotic resistance.

**379. Clostridium difficile following solid organ transplantation.** Jennifer Miao, Pharm.D. Candidate, Jaelyn Powell, Pharm.D., Spencer Martin, Pharm.D., BCPS, Shreya Shah, Pharm.D., Keith Fester, Pharm.D., Jenna Scheffert, Pharm.D., Demetra Tsapepas, Pharm.D., BCPS; NY-Presbyterian Hospital-Columbia University Medical Center, New York, NY

**PURPOSE:** *Clostridium difficile* infection (CDI) is a common cause of nosocomial antibiotic-associated diarrhea. CDI is of concern among solid organ transplant (SOT) recipients whom possesses innate risk factors for CDI such as increased immunosuppression, antibiotic exposure, and prolonged hospitalizations.

**METHODS:** This single center, retrospective study included all SOT recipients (heart, liver, lung, and renal) diagnosed with CDI between Sept2009-Dec2012. CDI was detected by *C. difficile* gene B PCR testing of stool specimens obtained from SOT recipients with diarrhea. Demographics, laboratory data, antibiotic exposure, and patient outcomes were recorded. The objective of this study was to describe the incidence and clinical profiles of SOT recipients developing CDI post-transplant.

**RESULTS:** Of 1,663 patients receiving organ transplants at Columbia University Medical Center (816 renal, 395 liver, 199 lung, 253 heart), 94 were diagnosed with CDI. Of these patients, 85 developed CDI following their first transplant and were included in this study. Patients had a median age of 57.1 (IQR 46.6–64.3) at the time of transplant and were predominantly Caucasian (52.9%). Laboratory assessments indicate 41.2% of patients experienced leukopenia, 7.1% underwent a gastrointestinal procedure within 3 months of CDI, and 42.4% were diabetic. 70.6% of recipients received antibiotics in the 3 months prior to CDI with penicillins (33%) and cephalosporins (29%) being the most common. Patients had a cumulative and restricted antimicrobial exposure in days of 12 (IQR 0–26.5) and 8 (IQR 0–17), respectively. CDI was classified as mild-to-moderate in 64.7% and severe in 35.3% of cases. Patient and allograft survival at a median follow-up of 909 (IQR 591.5–1456) days was 76.5% and 67.1% respectively.

**CONCLUSION:** Our single center experience demonstrates that transplant recipients with diabetes, leukopenia, and antibiotic exposure – particularly penicillins and cephalosporins are at

increased risk for developing CDI. Clinicians should have heightened awareness for CDI risk among recipients with these characteristics.

**380. Everolimus maintenance immunosuppression for acute rejection following liver transplantation.** Fiona Cheung, Pharm.D. Candidate, Hanlin Li, Pharm.D. Candidate, Demetra Tsapepas, Pharm.D., BCPS, Spencer Martin, Pharm.D., BCPS, Jaelyn Powell, Pharm.D.; NY-Presbyterian Hospital-Columbia University Medical Center, New York, NY

**PURPOSE:** Conventional therapies utilized for the treatment of acute rejection following orthotopic liver transplantation (OLT) include high dose corticosteroids and anti-thymocyte globulin. Patients experiencing persistent rejection despite these therapies, or those with relative contraindications to receiving these agents, have limited immunosuppressive options. Herein we describe our experience using everolimus, an inhibitor of mammalian target of rapamycin (mTOR), to successfully manage acute rejection in OLT recipients refractory or intolerant to conventional therapy.

**METHODS:** This single center, retrospective study included all OLT recipients treated with everolimus following an episode of acute rejection between November 2012 and April 2013. Demographics, laboratory data, biopsy data, and patient outcomes were recorded. The objective of this study was to describe the clinical course of this patient cohort after everolimus was incorporated into their immunosuppressive strategy.

**RESULTS:** Six OLT recipients experiencing seven episodes of acute rejection received everolimus following high dose corticosteroids and/or anti-thymocyte globulin. Etiologies of primary liver disease included hepatitis C viral infection (50%) or autoimmune disease (50%). The median time to rejection after liver transplantation was 4.2 months; all biopsies were interpreted as moderate or severe rejection (mean rejection activity index=6.5). Following non-response to standard rejection therapies, everolimus was initiated at a mean starting dose of 1.6 mg/day and added to patient's maintenance immunosuppressive regimen consisting of a calcineurin inhibitor, mycophenolic acid, and corticosteroid taper. Overall, addition of everolimus provided (1) reduction of rejection activity index score, (2) improved hepatic enzyme tests, and (3) stable renal function.

**CONCLUSIONS:** In the setting of refractory acute rejection after OLT, the addition of everolimus to patients' standard maintenance immunosuppression resulted in resolving acute rejection.

**381. Restless legs syndrome in lung transplant recipients and relationship with immunosuppressant medications.** Kalynn A. Rohde, Pharm.D. Candidate<sup>1</sup>, Zachary W. Schlei, Pharm.D. Candidate<sup>1</sup>, Ashley K. Weber, Pharm.D.<sup>1</sup>, Krista M. Katers, Pharm.D.<sup>1</sup>, Donald S. Hawes, R.N.<sup>2</sup>, Kelly L. Radford, RN<sup>2</sup>, Mary L. Francois, RN, MSN<sup>2</sup>, Mary S. Hayney, PharmD, MPH<sup>1</sup>, John M. Dopp, Pharm.D., M.S.<sup>1</sup>; (1) University of Wisconsin School of Pharmacy, 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 (RLS). Recent data suggests up to 50% of lung transplant recipients have RLS symptoms, however, its pathophysiology after lung transplantation is unclear. We sought to evaluate the prevalence of RLS and the relationship with immunosuppressant medications following lung transplantation.

**METHODS:** To date we have enrolled 65 subjects who did not have sleep problems prior to transplant and who had undergone lung transplantation at least six weeks prior to study entry. RLS was assessed using the four standard diagnostic criteria for RLS, and RLS severity was assessed using the International Restless Legs Syndrome Rating Scale (IRLS). Exposure to tacrolimus for each subject was estimated 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, 23 out of 65 subjects report positive diagnostic criteria for RLS (35%). Mean  $\pm$  SEM tacrolimus AUC

was higher in patients with positive RLS diagnostic criteria ( $15376 \pm 2217$  ng-days/mL) compared to those without RLS criteria ( $11144 \pm 1536$  ng-days/mL). RLS symptoms were relatively mild (mean IRLS score  $13.3 \pm 1$  out of 40) in the RLS subjects. Subject enrollment is ongoing and statistical analyses will be performed on the subsequent larger sample size.

**CONCLUSIONS:** In our cohort, RLS is common after lung transplantation, with prevalence greater than in the general population. RLS complaints are associated with greater exposure to tacrolimus. Future research should investigate the relationship between immunosuppressant therapy and development of sleep disorders.

**382. A retrospective review of fall risk factors in the bone marrow transplant inpatient service.** *Cory Vela, BS<sup>1</sup>, Lisa Savage, PharmD, BCOP, BCPS<sup>1</sup>, Allison Wehr, MS<sup>2</sup>, Ali McBride, PharmD, MS, BCPS<sup>3</sup>, Leslie Andritsos, MD<sup>1</sup>;* (1) The James Cancer Hospital and Solove Research Institute, The Ohio State University Wexner Medical Center, Columbus, OH (2) Center for Biostatistics, The Ohio State University, Columbus, OH (3) Department of Pharmacy, The University of Arizona Cancer Center, Tucson, AZ

**PURPOSE:** Falls are the largest reported adverse event within a hospital, with over one-million falls occurring annually; moreover, they are associated with increased costs, decreased quality of life, and premature death. This study aimed to identify risk factors in patients who have experienced a fall during hospitalization in the Bone Marrow Transplant (BMT) setting at The James Cancer Hospital.

**METHODS:** A retrospective, case-controlled analysis reviewed data from reported fall events and patient electronic medical records. One hundred sixty-eight adult BMT inpatients with hematological malignancies, treated from January 2010 through September 2012, were evaluated. Chemotherapy history, inpatient medication administration history, patient specific characteristics, and details of the fall event were recorded 24 hours prior to a fall event for fallers, and matched date for control patients.

**RESULTS:** Univariate analysis revealed that the administration of anticonvulsants ( $p=0.0211$ ) and antidepressants ( $p=0.0019$ ) increased a patient's fall risk. Multivariate analysis revealed that a leukemia diagnosis (OR 1.443, CI 2.398–28.443,  $p=0.0229$ ), age greater than 65 years (OR 8.238, CI 0.36–5.783,  $p=0.0008$ ), or recent steroid administration (OR 6.793, CI 2.543–18.142,  $p=0.0001$ ) were at higher risk of experiencing an inpatient fall. For patients who fell ( $n=59$ ), 49% fell while in the bathroom (not including patients using the shower) or using the bedside commode. This was consistent with data which showed that 37% of fallers experienced incontinence ( $p=0.029$ ).

**CONCLUSION:** Our findings are consistent with previous studies which found that the use of benzodiazepines, anticonvulsants, and antidepressants placed patients at a higher risk of experiencing a fall. Contrary to prior studies, opioid use was not a risk factor in the BMT population ( $p=0.1389$ ). The BMT nursing staff, physicians and pharmacists have begun to identify high risk patients to mitigate awareness of fall risks in the inpatient setting.

## LATE BREAKERS

### Adult Medicine

**383. Medication discrepancies captured during post-discharge phone calls to patients on the hospitalist service at a large academic hospital.** *Tran Tran, PharmD, BCPS<sup>1</sup>, Hanlin Li, Pharm.D. Candidate<sup>2</sup>, Jennifer Miao, Pharm.D. Candidate<sup>2</sup>;* (1) College of Pharmacy and Health Sciences, St. John's University, NY (2) NY-Presbyterian Hospital-Columbia University Medical Center, New York, NY

**PURPOSE:** This study describes medication discrepancies caught by pharmacy students while performing phone calls to patients after discharge from the hospitalist service at a large academic hospital.

**METHODS:** Pharmacy students called patients within 72 hours of discharge from the hospitalist service. Patients discharged to nursing home, prison, or shelters were excluded. Patients were

asked to describe name, dose, and frequency of medications they were currently taking. Patients' responses were compared to discharge medication lists from electronic health records. Discrepancies were documented and discussed with the pharmacist and medical team to determine the most appropriate action.

**RESULTS:** Phone calls were made to 71 patients discharged from the hospitalist service over 34 days. Forty-eight patients (67.6%) were reached. Twenty-three were not reached due to lack of response after three attempts or wrong numbers. An average of 1.48 calls per patient were made. Of those reached, nearly 40% ( $n=21$ ) had a drug discrepancy. Six patients reported taking one or more drug(s) of the wrong dose or frequency. Two patients claimed they did not have prescriptions for all of their medications. One patient reported taking a duplicate drug which was part of a combination product. Three patients were taking medications not listed in hospital records. Six patients were taking medications that had been discontinued while in the hospital. Two patients denied taking medications due to cost. One patient was unsure of their medications. Post-discharge phone calls gave students the opportunity to reiterate the importance of medication adherence, clarify side effects to patients and relay experienced adverse effects to the medical team. Students confirmed follow up appointments and identified patients in need of additional counseling or follow up.

**CONCLUSION:** Pharmacy students can have a significant impact on patient care by performing post discharge phone calls to detect medication discrepancies on the hospitalist service.

### Ambulatory Care

**384. Evaluation of the measurement of Vitamin D levels and risk factors associated with deficiency at a veterans affairs medical center.** *Kaitlyn Adams, PharmD, Jim Lichauer, PharmD, Crystal Burkhardt, PharmD;* Pharmacy Practice Residency Program, Kansas City VA Medical Center, Kansas City, MO

**PURPOSE:** The primary objective is to determine the percentage of Vitamin D levels drawn in patients with defined risk factors for Vitamin D deficiency. The secondary objectives of the study are to determine the percentages of patients with sufficient, insufficient and deficient Vitamin D levels in the entire population, and percentage of patients with or without risk factors. A sub-analysis will be completed to define the five most prevalent risk factors for Vitamin D deficiency in this patient population.

**METHODS:** This is a retrospective, single-center study consisting of an electronic data extraction. The study population includes both outpatient and inpatient veterans between the ages of 18 and 89 years at the KCVAMC who had a Vitamin D level drawn in the period of January 1st, 2011 to December 31st, 2011. The following data was collected: age, race, risk factors for Vitamin D deficiency and Vitamin D (25(OH)D) levels.

**RESULTS:** A total of 6450 patients were included in the study. Vitamin D levels were drawn appropriately in accordance with the Endocrine Society guidelines in 67% of these patients. The average Vitamin D level was insufficient at 28 ng/mL. Fifty-nine percent of the study population's Vitamin D levels were insufficient or deficient. Of those patients without defined risk factors, only 15% of the levels drawn resulted in sufficient levels.

**CONCLUSION:** The majority of Vitamin D levels measured are associated with a risk factor for Vitamin D deficiency and result in deficient or insufficient values. The most prevalent risk factors in this patient population parallel identified risk factors defined in current practice guidelines.

### Education/Training

**385. Evaluation of implementation and assessment of PCOA data as part of a SEP at a state-college of pharmacy.** *Justine S. Gortney, PharmD, BCPS<sup>1</sup>, Francine Salinitri, PharmD<sup>2</sup>, Lynette R. Moser, Pharm.D.<sup>3</sup>, Richard Lucarotti, PharmD<sup>2</sup>, Richard Slaughter, B.S., Pharm M.S.<sup>4</sup>;* (1) Pharmacy Practice, Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI (2) Pharmacy Practice, Eugene Applebaum

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**PURPOSE:** 1) To evaluate the implementation and the administration of a summative evaluation plan (SEP) including the Pharmacy Curriculum Outcomes Assessment (PCOA) during the second year of the Pharm.D. curriculum and 2) to assess curriculum effectiveness and student learning.

**METHODS:** IRB approval was obtained. A comprehensive evaluation of resources required for development and implementation of a SEP was conducted through review of faculty records and documentation of processes used for preparation and communication. Curricular effectiveness was assessed using received P2 PCOA data, student performance against other established indicators of student knowledge (GPA and self-assessment), and curricular markers. A survey of student perception of confidence in pharmacy content areas relative to coursework studied to date reflected on exam content was administered following the completion of PCOA. Exam content areas were mapped to curricular topics studied to date. The survey scale for each content area ranged from 1 to 10 (1=low confidence, 10=high confidence). Descriptive statistics and Pearson's correlation were performed.

**RESULTS:** Developing a SEP required significant resources including 30 meetings, 354 plus faculty-hours, 110 student-hours, and base exam cost to implement. P2 students PCOA performance had a significant moderate correlation ( $r=0.472$ ,  $p<0.01$ ,  $n=96$ ) to their GPA at time of exam. The mean perception of student confidence for PCOA topics related to coursework studied to date was  $5.7 \pm 1.17$  (confident). Moderate correlation ( $r=0.554$ ,  $p=0.061$ ,  $n=12$ ) was seen between PCOA content area score relative to coursework studied and perception of confidence scores. Based on comparison of college PCOA scores and reference sample, 4 areas of curricular excellence were identified and 3 potential areas for improvement.

**CONCLUSION:** Though the implementation of a new SEP requires substantial college effort, utilization of a standardized evaluation tool provides the college with a valuable assessment of the curriculum. PCOA exam performance related to student markers of knowledge.

## Hematology/Anticoagulation

**386. A matched case-control evaluation of the risk of upper extremity deep vein thrombosis in patients with peripherally inserted central catheters.** Julia L. Reffert, PharmD, BCPS<sup>1</sup>, Winter J. Smith, PharmD, BCPS<sup>1</sup>, Matthew L. Bird, PharmD, BCPS<sup>1</sup>, Donald L. Harrison, PhD, FAPhA<sup>1</sup>, Omar L. Esponda, MD<sup>2</sup>, Susan W. Rathbun, MD, MS, FACP, RVT<sup>2</sup>; (1) College of Pharmacy, University of Oklahoma Health Sciences Center, Oklahoma City, OK (2) College of Medicine, University of Oklahoma Health Sciences Center, Oklahoma City, OK

**PURPOSE:** Upper extremity deep vein thrombosis (UE DVT) accounts for as many as 10% of all deep vein thromboses, and is associated with both acute and long-term morbidity. It has been reported that 45–93% of UE DVTs occur in patients with central venous catheters. The objective of this study was to assess the clinical characteristics associated with UE DVT in patients with peripherally inserted central catheters (PICCs).

**METHODS:** This retrospective, cross-sectional study was conducted at a 400-bed academic institution. Adult patients who received a PICC between 1/1/2011 and 12/31/2011 were included; case patients were defined based on documented UE DVT and/or SVT (superficial vein thrombosis) confirmed with vascular ultrasound imaging, and controls were matched to cases by age and sex in a 2:1 ratio. Patients' demographic characteristics, comorbid disease states, reason for admission, medications, devices, laboratory results, and PICC characteristics were captured.

**RESULTS:** UE DVT and/or SVT occurred in 124 patients with PICCs (30% of all UE DVT and SVT diagnosed during the same period); 248 control patients were also evaluated. The mean age

was 52.2 years for case patients and 52.7 years for control patients (with respective standard deviations of 17.4 and 17.3), and 45% in both groups were female. Characteristics significantly associated with UE DVT and SVT ( $p<0.05$ ) included: history of DVT, use of vancomycin, lack of enoxaparin prophylaxis or treatment, lack of antiplatelet medication, blood glucose greater than 200 mg/dL, and hospital length of stay.

**CONCLUSION:** This large, matched case-control study identified novel risk factors for UE DVT and SVT in patients with PICCs. Future research should include methods to modify risk and identify preventative strategies.

## Infectious Diseases

**387. Influenza susceptibility to neuraminidase inhibitors.** Scot E. Walker, PharmD, MS, BCPS, BCACP; Facts & Comparisons/Lexicomp/Medi-Span, St. Louis, MO

**PURPOSE:** The neuraminidase inhibitors oseltamivir and zanamivir are the primary antivirals used to treat influenza. Because of widespread resistance the CDC does not recommend use of adamantanes. This study will look at end of season surveillance data published by the CDC on the susceptibility of influenza viruses to neuraminidase inhibitors and any changes over time.

**METHODS:** Data on influenza virus susceptibility to neuraminidase inhibitor will be used from the CDC Flu Activity and Surveillance Reports from 2008 to 2013. The CDC designation for influenza severity for selected years will also be obtained from the 2013 report.

**RESULTS:** Oseltamivir has maintained its activity for influenza viruses. While virus susceptibility for the H1N1 virus was less than 1% during the an H1Ni strain in 2009, it rebounded to 98.6% to 100% susceptibility in the past 4 influenza seasons. This included the 2009–2010 season which was classified as a pandemic influenza season. The susceptibility of the H3N2 virus and Influenza B has remained at or near 100% for the all 6 seasons that susceptibility data is available. When available, susceptibility data on zanamivir have indicated no resistance.

**CONCLUSIONS:** Influenza virus susceptibility to neuraminidase inhibitors appears to be unique each year, with large decreases in susceptibility occurring primarily due to certain strains of the virus. Because of shifts in the circulating virus strains, susceptibility appears to change each year.

## Neurology

**388. Uncontrolled seizures and bone health among adult epilepsy patients.** Mikiko Yamada, MS, PharmD<sup>1</sup>, Timothy Welty, PharmD<sup>2</sup>, Sue Min Lai, PhD<sup>3</sup>; (1) Department of Pharmacy Practice and Administrative Sciences, University of New Mexico College of Pharmacy, Albuquerque, NM (2) College of Pharmacy and Health Sciences Department of Clinical Sciences, Drake University, Des Moines, IA (3) Department of Preventive Medicine and Public Health, University of Kansas Medical Center, Kansas City, KS

**PURPOSE:** Uncontrolled seizures negatively impact the quality of life among epilepsy patients, and bone health represents one of the more serious adverse outcomes due to epilepsy and its treatment. The objective of this study was to determine the association between seizure status (well-controlled vs. uncontrolled) and bone damage.

**METHODS:** A retrospective case-controlled study was conducted. Patients' data were collected at the Comprehensive Epilepsy Center at the University of Kansas Medical Center. Adult patients with a positive diagnosis of epilepsy (age range: 21–50 years old) who were treated with at least one antiepileptic drug (AED) for more than 6 months were included in the study sample. Patients with a diagnosis of psychogenic non-epileptic seizures, obesity, abnormal liver transaminases (AST and ALT), comorbidities and concomitant medications that alter bone remodeling status were excluded for participation. Alkaline phosphatase (ALP) level was used as a biomarker for bone damage.



Logistic regression was used to assess the association and account for potential confounders.

**RESULTS:** Among 2607 patients, 161 patients were eligible for this study; 85 cases and 76 controls were identified. Patients with uncontrolled seizures demonstrated 1.964 times higher odds with ALP elevation relative to the odds of patients with well-controlled seizures (95% CI: 1.049–3.680,  $p=0.0341$ ). Number of comorbidity, length of epilepsy, serum Ca levels, number of AEDs, and proportion of high dose of AEDs were considered potential confounders. The degree of ALP elevation became higher among patients who took vitamin D supplementation.

**CONCLUSION:** Uncontrolled seizure status is a significant risk factor for ALP elevation, which implies bone damage when liver transaminases are normal. Seizure control is a significant factor to maintain healthy bones. Further investigation is necessary to determine the influences of vitamin D intake, serum Ca and vitamin D levels, and proportion of enzyme-inducing AEDs on ALP elevation and uncontrolled seizures.

## Pharmacoepidemiology

**389. Assessment of doctor shopping for zolpidem in insomnia outpatient in Taiwan.** *Tzu-Hsuan Lu, MS<sup>1</sup>, You-Meei Lin, MS<sup>2</sup>, Chung-Hsuan Chiu, PhD<sup>1</sup>*; (1) School of Health Care Administration, Taipei Medical University, Taipei City, Taiwan (2) Department of Pharmacy, Taipei Medical University-Shuang Ho Hospital, New Taipei City, Taiwan

**PURPOSE:** The zolpidem listed as a restricted drug evokes a common problem with its overuses in Taiwan. This problem is deemed as doctor shopping behavior (DSB) which could lead to the possible overutilization and resource spendthrift. National Health Insurance Bureau sets the new policy to regulate the physician's prescription behavior, instead of patient's shopping behavior. This study aims to analyze doctor shopping for zolpidem of insomnia outpatients and assess the related factors in doctor shopping behavior retrospectively.

**METHODS:** Data was extracted from the Taiwan Longitudinal Health Insurance Database. Individuals with  $\geq 1$  dispensing for zolpidem in 2008 were followed-up for 24 months. DSB was defined as  $\geq 2$  prescriptions by different doctors with  $\geq 1$  day of overlap. The doctor-shopping indicator (percentage of zolpidem obtained through doctor-shopping) were used as an indicator to access the intensity of shopping behavior for each patient.

**RESULTS:** Among the 6,947 insomnia patients were prescribed zolpidem, 1,652 of them exhibited DSB (23.78%). Average drug dispensing from pharmacy was 244.21 (s.d.=680.87), the doctor-shopping indicator was 0.2 (s.d.=0.23) among patients with DSB. The most striking characteristics of DSB patients were younger, with chronic disease, suffering numbers of diseases, higher premiums, and high socioeconomic status.

**CONCLUSION:** Doctor shopping for zolpidem appears to be an important issue in Taiwan. Implementing a proper referral system with efficient data exchange might reduce the doctor shopping behavior by physician or pharmacist-led medication reconciliation process.

**390. Knowledge and attitude of healthcare professionals toward adverse drug reaction reporting system in Saudi Arabia.** *Zuhair Alqahtani, PharmD<sup>1</sup>, Mohammed Almoslem, PharmD<sup>1</sup>, Shuroug Alowais, PharmD<sup>1</sup>, Hisham Aljadhey, PharmD, PhD<sup>1</sup>, Thamir Alshammari, PhD, M.S., RPh<sup>2</sup>*; (1) College of Pharmacy, King Saud University, Riyadh, Saudi Arabia (2) College of Pharmacy, Hail University, Hail, Saudi Arabia

**PURPOSE:** Investigating the knowledge and attitude of healthcare professionals (HCPs) toward Adverse drug reaction (ADR) reporting and determine if there is a need for programs and system to be applied to enhance patient safety. Make the proper recommendations to the Saudi Drug and Food Authority (SFDA) to enhance HCPs knowledge and awareness on ADR reporting.

**METHODS:** A cross sectional self-administered survey has been conducted in five governmental hospitals in Riyadh and Dam-

am, Saudi Arabia in the period between January and February 2013. The questionnaire comprised from 24 questions assessing the knowledge and attitude of HCPs toward ADRs Reporting System. It was adopted from published study and was validated. All statistical analyses were conducted using SAS version 9.2.

**RESULTS:** A total of two hundred thirteen HCPs responded to the survey with response rate of 65%. The type of HCPs who participated in this survey was comparable (physicians 15%, pharmacists 41%, nurses 36% and others 8%). The majority of the responders experience is from 1–5 years (41%). Around 70% of HCPs were not aware of the existence of a National Pharmacovigilance Center (NPC) in Saudi Arabia. In addition, 68% were aware of reporting ADR system in their hospitals (39% of them did submit ADRs) and 32% were not. The common factor discouraging reporting of ADR was concern that the report may be wrong (49%).

**CONCLUSION:** The knowledge of ADR reporting is inadequate among HCPs in Saudi Arabia. More training and education should be conducted to all HCPs.

**391. The health care professional's awareness and attitude toward influenza vaccines in Saudi hospitals.** *Lama Alfehaid, PharmD<sup>1</sup>, Joud Alfraih, PharmD<sup>1</sup>, Zuhair Alqahtani, PharmD<sup>1</sup>, Thamir Alshammari, PhD, M.S., RPh<sup>2</sup>*; (1) College of Pharmacy, King Saud University, Riyadh, Saudi Arabia (2) College of Pharmacy, Hail University, Hail, Saudi Arabia

**PURPOSE:** Is to scrutinize attitude, awareness and knowledge of HCPs toward influenza vaccination. Also determine of voluntary immunization with influenza vaccine among healthcare professionals (HCPs) in Saudi Arabia, and to know reasons for why HCPs did not to get vaccination.

**METHODS:** A cross-sectional observational study conducted in 6 (four governmental and two privates) major hospitals in Saudi Arabia. A two hundred and forty five anonymous self-completed survey distributed to the staff members in a voluntary manner during the influenza season 2012–2013. The questionnaire was composed of five sections. All statistical analyses were conducted using SAS version 9.2.

**RESULTS:** A total of 242 questionnaires were received with response rate of 98%. The percentage of HCPs who get the vaccine was 38%. The reasons for noncompliance were: the fear of contracting illness 16%, being young and healthy or they don't know where to get the flu shot 13%. Some of the barriers that prevent the practice from providing the influenza vaccine were the vaccine safety concern in HCPs and patients (35%, 37%) respectively, and the unavailability of vaccine 39%. Nevertheless, almost 75% of the HCPs were not aware of the published guidelines ACIP or CDC for influenza immunization.

**CONCLUSION:** Despite the recommendations, the percentage of HCPs who get the vaccine was low 38% in Saudi Hospitals. HCPs believe that influenza vaccination is important. However, they were not aware of published guidelines ACIP or CDC for influenza immunization. More efforts by health authorities and regulatory in Saudi Arabia are needed to enhance the compliance of all healthcare worker towards influenza vaccination.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**392. Formulation of a dry powder vaccine containing *Listeria monocytogenes* for immunization against tularemia.** *Alaa Elmaoued, M.S.<sup>1</sup>, Pavan Muttil, Ph.D.<sup>2</sup>*; (1) Department of Pharmaceutical Sciences, College of Pharmacy, University of New Mexico College of Pharmacy, Albuquerque, NM (2) Department of Pharmaceutical Sciences, University of New Mexico College of Pharmacy, Albuquerque, NM

**PURPOSE:** Dry powder vaccines provide several advantages compared to liquid vaccines including minimal cold-chain storage requirement, improved sterility, and elimination of degradation

pathways. We show the formulation and optimization of dry powders containing a recombinant *Listeria monocytogenes* (Lm) bacterial strain by the process of spray drying. The resulting dry powder vaccine is investigated for its stability for oral and pulmonary delivery.

**METHODS:** A variety of formulations containing different amounts of selected sugars and an amino acid (L-leucine) were spray dried to encapsulate Lm in dry powders. The ratio of the excipients was selectively chosen to enhance the dry powder properties including the powder yield, their size, and the viability of encapsulated bacteria. Particle sizing techniques including dynamic light scattering (DLS), next generation cascade impactor (NGI), and laser diffraction were used to determine the hydrodynamic, aerodynamic, and spherical diameters for the powders, respectively. Differential scanning calorimetry (DSC) was used to investigate the stability of several of the formulations. Scanning electron microscopy was used to examine the topography and morphology of the powders and the encapsulated bacteria. The viability of the encapsulated Lm was also determined. Simulated gastric and intestinal fluid stability studies will be performed for Lm containing powders.

**RESULTS:** The percent yield for these formulations after spray drying was between 44% and 72%. The median particle size for most of the powders was around 2.5  $\mu$ m. DSC has shown a stable powder based on a high glass transition temperature. Lastly, viability of Lm in powder has been observed for 12 weeks at room temperature, 4°C, and 37°C, thus far.

**CONCLUSION:** Spray drying is a one-step process that allows engineering of dry powders from a liquid bacterial suspension for stable live-bacterial vaccinations. These stable dry powder vaccines could be delivered via the pulmonary or oral route.

## Psychiatry

**393. Impact of psychiatric hospital readmission rates through pharmacist intervention—a retrospective analysis.** G.S. Shankar, MS (Public Hlth), MS (Psych), PharmD, BCPP; Department of Pharmacy Practice, College of Pharmacy, Western University of Health Sciences, Pomona, CA

**PURPOSE:** Mental illnesses, such as Schizophrenia, do not have a routine objective marker that can be measured like blood pressure. Previous studies have shown that pharmacist interventions can reduce hospital readmission rates. The goal of this study was to investigate if pharmacist consultations could improve psychiatric hospital readmission rates.

**METHODS:** Pharmacists provided consultations as part of their daily responsibilities. This study analyzed 46 adult patients with a diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder or major depression, who were discharged between February 2013 and March 2013 and had history of high admission rates. Group assignment was determined by acceptance of consultation services. Patients were placed in the study group if they accepted consultation services. The primary outcome was the number of hospital readmission within 30 days after patient discharge. The secondary outcome was days between readmission and previous discharge. This retrospective study was IRB approved.

**RESULTS:** There were 16 patients in the control group and 30 patients in the study group. The control and study groups showed

an average number of hospital readmissions of 2.6 (95% C.I. 2.28–2.92) and 2.2 (95% C.I. 2.05–2.35) respectively;  $p=0.02$ . The time for readmission was longer in the study group compared to the control group, 9.1 days (95% C.I. 7.5–11.7) versus 2.1 days (95% C.I. 1.8–3.6) respectively;  $p<0.01$ . Lastly, the length of stay was longer in the control group, 10.0 days (95% C.I. 8.7–11.3) compared to the study group, 6.1 days (95% C.I. 5.3–6.9) respectively;  $p<0.01$ .

**CONCLUSION:** Patients with high psychiatric hospital readmissions rates may benefit from a pharmacist consultations. In patients that received pharmacist consultation, the number of readmission was lower and length between two hospitalizations was longer. The limitations of this study included: length of study, number of participants and patient recruitment. Further studies are required to show the full impact of pharmacist consultations

**394. Retrospective analysis of QT interval monitoring in hospitalized patients prescribed antipsychotics.** D. Dickerson, Pharm.D., J. Twilla, Pharm.D., BCPS, L. Hutchison, Pharm.D., BCPS, CGP, A. Negrete, Pharm.D., BCPS, C.S. Oliphant, Pharm.D., BCPS, (AQ, Cardiology); Methodist University Hospital, Memphis, TN

**PURPOSE:** Antipsychotic medications can cause many adverse reactions; ventricular arrhythmias are some of the more serious including Torsades de Pointes (TdP) and sudden cardiac death. Despite the known risk of QT prolongation, there are no formalized guidelines on electrocardiogram (ECG) monitoring for these agents. This study examines the frequency of ECG monitoring and the incidence of these cardiac effects with antipsychotic use.

**METHODS:** A retrospective review of adults prescribed antipsychotics at Methodist Healthcare between August 1, 2007 through August 31, 2012 was conducted to include 200 patients. Patients were assigned to one of three groups: (i) newly initiated antipsychotics, (ii) home antipsychotic dose increased or new interacting/QT prolonging medication added or (iii) new antipsychotic with dose increase or interacting/QT prolonging medication added. Adult patients were included if they received three or more doses of antipsychotic and were admitted at least three days.

**RESULTS:** A total of 594 patients were screened to meet goal inclusion. The antipsychotic most commonly prescribed was haloperidol ( $n=21$ ) and 27 patients were prescribed more than one antipsychotic. ECG monitoring occurred in 69% of patients overall while ECG monitoring at baseline occurred in 62%. Baseline QTc change occurred in 10% of patients, respectively while the incidence of QTc greater than 450 msec was 36%. Interventions due to QTc prolongation occurred in 32% of patients. The highest percentage of ECG monitoring occurred in Group 2, with 40%, 83%, and 52% in Groups 1, 2, and 3 respectively.

**CONCLUSIONS:** The majority of patients receiving antipsychotic agents had ECG monitoring, with QTc prolongation identified in about one-third. We identified a lack of ECG monitoring, particularly in hospitalized patients newly initiated on antipsychotics. This study highlights the need for a standardized process surrounding cardiac monitoring in patients receiving not only antipsychotics but also other QT prolonging medications.

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