accp

American College of Clinical Pharmacy
2010 Annual Meeting
October 17–20 • 2010
Austin • Texas

**Presentation Abstracts and
Index of Authors
Are Available Online at
*www.pharmacotherapy.org***

ABSTRACTS

2010 ACCP ANNUAL MEETING

October 17–20, 2010

Austin, Texas

ORIGINAL RESEARCH

ADR/Drug Interactions

1. A Phase 1, Single-Center, Open-Label, Randomized, Two-Period Cross-Over Study, to Investigate the Pharmacokinetics, Pharmacodynamics, Safety and tolerability of Sanctura XR and Glucophage.

Michael G. Oefelein, M.D., FACS[1], Warren Tong, Pharm.D.,[1] Sam Kerr, Pharm.D.,[1] Kavitha Bhasi, Pharm.D.,[1] Rina Patel, M.S.[1], Dale Yu, Ph.D.[2]; (1)Allergan, LLC, Irvine, CA; (2)Clinical Pharmacology Department, Allergan, Irvine, CA

Purpose: Sanctura XR® (Trospium Chloride) and Glucophage® (Metformin hydrochloride) are both dependent on renal elimination, which may theoretically result in a drug-drug interaction (DDI). The purpose of this study was to investigate the pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of co-administration of Sanctura XR® with Glucophage®.
Methods: Healthy male and female subjects (n=44) were randomly assigned in a 1:1 ratio to Group A or Group B. A two-period, steady-state, cross-over study (AB, BA) was conducted with either Glucophage® 500 mg twice daily, Sanctura® XR 60 mg daily or in combination. PD measurements (Glucose, 4-hrs post-prandial) were performed with each drug alone or in combination.
Results: Co-administration of Sanctura XR® did not alter the steady-state PK or PD of Glucophage®. When administered with Sanctura XR®, the mean steady-state C_{max} and AUC_{0-12} values of metformin were bioequivalent to when metformin was administered alone. The percentage of dose excreted in urine and renal clearance of metformin were comparable, with values ranged from 28.3% to 31.9% and 33.0 to 33.7 L/hr, respectively. Converesly, Glucophage® reduced the steady-state C_{max} and AUC_{0-24} values of trospium by approximately 34% and 29%, respectively. The percentage of dose excreted in the urine was reduced by 30%. Nonetheless, the renal clearance of trospium with or without co-administered metformin was unchanged.
Conclusion: A drug-drug interaction study was conducted to evaluate the PK of trospium and metformin when Sanctura XR® 60mg QD was co-administered with Glucophage® 500mg BID under steady state conditions in 44 subjects. The steady-state PK and PD of Glucophage® was not affected by the concomitant use of Sanctura XR®. Therefore, no dosage adjustment is necessary for Glucophage® when it is co-administered with Sanctura XR®.

2. Clopidogrel and proton pump inhibitor co-prescribing (CLAP COP) study.

Charles F. Seifert, Pharm.D.; Texas Tech University Health Sciences Center School of Pharmacy, Lubbock, TX

Background: Publications quoting clopidogrel resistance have attributed decreased clopidogrel effectiveness to several factors including a drug interaction with proton pump inhibitors (PPIs). The mechanism is thought to be PPI inhibition of CYP2C19, the enzymes responsible in the metabolism and activation of the prodrug, clopidogrel. In response, the FDA released a safety alert notifying health care providers and urged them to re-evaluate this combination.
Purpose: Analyze and evaluate the prescribing trends of clopidogrel concurrently with PPIs in inpatients.
Methods: Retrospective chart review conducted on a randomized collection of 200 charts meeting inclusion criteria. Charts were grouped into a BEFORE group (n=100), those prescribed clopidogrel prior to the FDA safety alert release and an AFTER group (n=100). Charts were reviewed for demographic data, initiation of a PPI, hospital and discharge medications. Primary outcome is percentage of patients on a PPI with clopidogrel during the 8 months prior and 8 months after the FDA alert release. Secondary outcomes evaluated PPI indications for appropriateness, and percentage of patients who were discharged on both medications.
Results: In the BEFORE group 58% (58/100) of patients prescribed clopidogrel were also on a PPI and for those patients in the AFTER group 55% (55/100) were on both, difference found to be insignificant using a χ^2 test (p=0.104). Secondary outcomes found that 41.3% (38/92) of the BEFORE group and 43.5% (37/85) in the AFTER group were discharged on the combination. There was a poor documentation of appropriate PPI indication.
Conclusion: Data indicates that regardless of the FDA safety alert, ordering physicians fail to re-evaluate the use PPIs in patients on clopidogrel. As pharmacists, we can provide education and perform interventions to help decrease the potential for adverse outcomes associated with this drug combination.

Adult Medicine

3. The incidence of hypoglycemia: a comparison of two insulin protocols in a community hospital.

Krisan Anderson, Pharm.D.,[1] Amy R. Donaldson, Pharm.D., BCPS[2], Cara L. Léos, Pharm.D., BCPS[3], Christine Cicci, Pharm.D., BCPS[4]; (1)East Alabama Medical Center and Auburn University Harrison School of Pharmacy, Opelika, AL; (2)Auburn University Harrison School of Pharmacy, Auburn, AL; (3)Auburn University Harrison School of Pharmacy, Auburn University, AL; (4)East Alabama Medical Center, Opelika, AL

Purpose: The American Diabetes Association recommends that all hospitalized patients with diabetes receive both scheduled basal insulin, scheduled prandial doses of fast-acting insulin, and correctional insulin doses as needed. Fear of hypoglycemia is a common barrier to the use of basal/bolus/correction insulin protocols in hospitals nationwide. The purpose of this study was to compare the efficacy and safety of a basal/bolus/correction insulin protocol as compared to sliding scale insulin in non-critical patients with type 2 diabetes admitted to a community hospital.
Methods: A prospective analysis followed non-critical adult patients with type 2 diabetes receiving basal/bolus/correction insulin to analyze the incidence of hypoglycemia, nursing adherence to the hypoglycemia protocol, and level of glycemic control. These patients were matched retrospectively to similar patients who had received sliding scale insulin under the care of the same physicians, and data between the two groups was compared using χ^2 and t-test analysis.
Results: Ninety-four patients were analyzed. Baseline characteristics were similar except for higher home insulin use in the basal/bolus group (p<0.05). There were four more incidents of hypoglycemia with basal/bolus (p=0.505), the majority of which were attributable to the continuation of home insulin doses. The sliding scale group experienced more readings <60 mg/dL (15 vs. 9, p=0.22), more D50W administration (3 vs. 0, p=0.08), and more symptomatic episodes (6 vs. 3, p=0.32). Nursing adherence to the hypoglycemia protocol was low (15-25%) for both groups. The basal/bolus group did experience a higher number of elevated blood glucose readings, defined as >250 mg/dL (p<0.05).
Conclusion: Reduction of home insulin doses at the time of admission may be appropriate for some patients to reduce the risk of hypoglycemia. Nurse education regarding correction of hypoglycemia must be ongoing. Basal/bolus/correction insulin doses should be readjusted throughout the hospital stay if needed to maintain appropriate glycemic control.

4. Evaluation of pneumococcal vaccination rates after vaccine protocol changes.

Jennifer G. Smith, Pharm.D.,[1] Nicole L. Metzger, Pharm.D.[2]; (1)Emory Healthcare, Atlanta, GA; (2)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

Purpose: Eligibility screening and administration of the pneumococcal vaccine prior to discharge in qualified patients is evaluated by the Joint Commission as part of core quality measures. The average reported pneumococcal vaccination rate for our institution was 56% in

2008. This study sought to determine whether implementing a revised electronic screening tool, nursing education, and automatic vaccine orders would improve pneumococcal vaccine screening and administration rates.

Methods: Electronic medical records for 150 randomly selected patients were retrospectively reviewed for the 4-month interval before and after the implementation of vaccine protocol changes. The study included adult inpatients admitted to two internal medicine units during the specified periods. Patient demographic data, presence of vaccine screening, vaccine indication, vaccine administration, vaccine rescheduling, and vaccine refusal were collected. The primary outcome compared pneumococcal vaccination rates before and after implementation of vaccine protocol changes.

Results: Vaccine screening was similar in the pre-implementation group (n=150) compared to the post-implementation group (n=150) (96% vs. 99.3%, P=0.06). The primary endpoint, vaccine administration, significantly improved in the post-implementation group compared to the pre-implementation group (74.2% vs 19.1%, P<0.001). Vaccine refusal was also significantly increased the post-implementation group (87.1% vs 27.7%, P=0.02).

Conclusion: Implementation of vaccine protocol changes improved pneumococcal vaccination rates in eligible medicine patients. Protocol changes were relatively easy to implement in a large institution and resulted in significant improvement in pneumococcal vaccination rates. A similar approach may be implemented at other institutions as an effective and inexpensive way to improve pneumococcal vaccination rates.

5E. Risk of hypoglycemia in hospitalized patients prescribed a sulfonylurea.
Christina M. Hedrick, Pharm.D.[1], Amy C. Donihi, Pharm.D., BCPS[2], Kim Coley, Pharm.D.[2]; (1)University of Pittsburgh Medical Center Presbyterian, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

Purpose: To identify the incidence of and risk factors associated with hypoglycemia in hospitalized patients taking sulfonylureas.
Methods: A nested case-control study of adult patients who received a sulfonylurea while hospitalized at a tertiary care hospital between November 1, 2008 and October 31, 2009 was performed. Case patients included those who experienced hypoglycemia (BG <70 mg/dL) during sulfonylurea treatment. Control patients included those who never experienced hypoglycemia. Controls were matched 1:1 with cases based on gender and number of days treated with a sulfonylurea. Potential risk factors for the development of hypoglycemia, including patient age, renal insufficiency, NPO status, concomitant use of insulin and beta blockers, and hospital location were compared. Covariates with p values ≤0.1 in univariate regressions were included in a multivariate logistic regression model.
Results: Overall 16% of patients who received a sulfonylurea experienced ≥1 episode of hypoglycemia. Cases (n=117) were more likely than controls (n=117) to be ≥65 (74% vs 53%, p<0.001), have renal insufficiency (18% vs. 7%, p=0.013), and receive basal insulin (28% vs. 14.5%, p=0.012), and less likely to receive glipizide (44% vs 57%, p=0.05). Variables included in the multivariate regression were age ≥65, renal insufficiency, and treatment with glipizide, glyburide, or basal insulin. Age ≥65 (OR = 3.07, p<0.001), basal insulin (OR = 3.01, p=0.002), and renal insufficiency (OR = 3.64, p=0.006) were predictors of hypoglycemia and use of glipizide (OR = 0.44, p=0.005) was found to be protective in the multivariate logistic regression model.
Conclusions: These results can be used to identify hospitalized patients for whom sulfonylurea agents should be avoided due to their high risk for sulfonylurea-related hypoglycemia.
Presented at 29th Annual Eastern States Conference for Pharmacy Residents and Preceptors, Hershey, PA, April 2010.

6. An assessment of the compliance with standards of care for erythropoeisis-stimulating agents.
Tara E. Gleason, Pharm.D., Julie A. Murphy, Pharm.D., BCPS; St. Louis College of Pharmacy, St. Louis, MO

Purpose: The objective of this study was to determine the impact of computerized physician order entry (CPOE) on the compliance with evidence-based standards of care for prescribing, dosing, and monitoring of erythropoeisis-stimulating agents (ESAs).
Methods: Patients eighteen years of age and older who received epoetin alfa, the only ESA on formulary at St. John's Mercy Medical Center (SJMMC), were included. Data including medical history, hospital course, medication profile, and laboratory parameters was collected on patients admitted to SJMMC during March 2009 (pre-CPOE implementation) and March 2010 (post-CPOE implementation). Differences were evaluated using the Fisher's exact test, χ^2 test, and unpaired t-test.
Results: Baseline characteristics were similar between the pre-CPOE implementation group (n=59) and post-CPOE implementation group (n=68). Eighty-five percent of the pre-CPOE implementation group received epoetin alfa for an FDA-approved indication [chronic kidney disease (CKD) on hemodialysis, n=40; CKD, n=7; chemotherapy-induced anemia, n=3] versus 93% in the post-CPOE implementation group [CKD on hemodialysis, n=56; CKD, n=6; chemotherapy-induced anemia, n=1] (p=0.17). Twelve patients (8%) in the pre-CPOE implementation group received a dose of epoetin alfa despite that day's documented Hgb level greater than 12 g/dl versus eight patients (5%) in the post-CPOE implementation group (p=0.25). Ninety-three percent of patients in the pre-CPOE implementation group had a documented Hgb level on the day of epoetin alfa administration versus 95% in post-CPOE implementation group (p=0.47).
Conclusion: CPOE did not significantly improve compliance with evidence-based standards of care for prescribing, dosing, and monitoring of ESAs. Other methods of intervention are needed to optimize the use of ESAs at SJMMC. These may include prescriber education, pharmacist education, or a revised CPOE order entry screen for ESAs.

Allergy

7E. Bepreve™ 1.5% reduces rhinorrhea for at least 16 hours: An integrated analysis of two phase 3 conjunctival allergen challenge (CAC) clinical trials.
Timothy R. McNamara, Pharm.D.[1], Jon I. Williams, Ph.D.[1], James A. Gow, M.D.[1], Paul J. Gomes, M.D.[2], Mark B. Abelson, M.D.[3]; (1)ISTA Pharmaceuticals, Inc., Irvine, CA; (2)ORA Clinical Research & Development, Inc., Andover, MA; (3)Harvard Medical School, Boston, MA

Purpose: To establish the efficacy and safety of Bepreve™ 1.5% compared to placebo in reducing rhinorrhea using the CAC clinical model of allergic conjunctivitis.
Methods: Two double-masked, randomized, placebo-controlled clinical trials were approved by an IRB. Eligible subjects provided written consent to participate and were assigned to either Bepreve™ (bepotastine besilate ophthalmic solution) 1.5% or placebo according to a computer-generated randomization list. Test agents were instilled onto both eyes of enrolled subjects 15 minutes, 8 hours or 16 hours pre-CAC and rhinorrhea was self-evaluated by subjects at 7, 15, and 20 minutes post-challenge using a 0–4 standardized unit scale (0=none, 4=severe).
Results: A total of 157 subjects were enrolled, of whom 140 subjects (N = 70 for placebo, N = 70 for Bepreve™ 1.5%) were in the protocol-compliant population. Clinical superiority (0.5 units or greater improvement, placebo – active) and statistical significance by t-test or Wilcoxon rank sum test (P≤0.01) was seen in the integrated trial population for reduced rhinorrhea with Bepreve™ 1.5% treatment in challenges conducted 15 minutes, 8 hours, and 16 hours post-dosing. *Post hoc* subject-by-subject analysis shows a correlation between relief of CAC-induced rhinorrhea and of nasal congestion with Bepreve™ 1.5% compared to placebo.
Conclusion: Bepreve™ 1.5% provides rapid and sustained reduction in rhinorrhea for at least 16 hours after dosing that is correlated with relief provided for nasal congestion as judged using the CAC model of allergic conjunctivitis.
Presented at The American Academy of Allergy, Asthma & Immunology (AAAAI), New Orleans, LA, February 26–March 2, 2010

Ambulatory Care

8. ACCP ambulatory care practice and research network (PRN): Assessment of membership needs and diversity 2009 update.

Andrew Smith, Pharm.D.[1], Jennifer N. Clements, Pharm.D.[2], Daniel S. Longyhore, Pharm.D., BPS[3], Lea DelaPena, Pharm.D.[4], Beth Bryles Phillips, Pharm.D.[5], Marissa Quinones, Pharm.D.[6], Tiffany C. Rodgers, Pharm.D.[7]; (1)UMKC School of Pharmacy, Kansas City, MO; (2)Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA; (3)Wilkes University, Wilkes Barre, PA; (4)Midwestern University, Downers Grove, IL; (5)University of Georgia, Athens, GA; (6)Parkland, Dallas, TX; (7)Oklahoma City VA Medical Center, Oklahoma City, OK

Purpose: The ACCP Ambulatory Care PRN completed a membership diversity and needs survey in 2003. Objectives of this project were to update the diversity within this PRN and to assess members' perceptions of value of PRN activities.
Methods: An internet-based questionnaire (Survey Monkey™) was sent via email to PRN members which queried them regarding background/training, practice setting, research, and networking. Descriptive analysis was performed of PRN members practice, research, and networking activities and needs in comparison to 2003 results.
Results: Of 10,914 ACCP members (on 07/31/09), 1066 (9.8%) were enlisted in the Ambulatory Care PRN. A total of 170 surveys were completed (15.9% response) after two email solicitations. The age distribution was similar to the 2003 results with the median age group being 31–35 years. The percentage of members who are Board Certified Pharmacotherapy Specialists (BCPS) drastically increased (91% in 2009 versus 42% in 2003). Members practice in various environments including ambulatory care (78%), community pharmacies (6%), geriatrics (3%), Veterans Affairs Medical Centers (11%), and managed care settings (3%). Members reporting research related activity increased from 74% in 2003 to 83% in 2009. Networking activities that occur during ACCP meetings have continued to be rated as highly valuable/valuable for business meetings (73% in 2009 vs 77% in 2003) and networking forums (77% in 2009 vs 74% in 2003). The list-serve continues to be the most common reason people join the PRN (86% in 2009 vs 89% in 2003).
Conclusion: The Ambulatory Care PRN is large and diverse, with members spanning a broad range of practices and employment affiliations without much change from 2003. There was a dramatic increase in the percent of BCPS pharmacists from 2003 to 2009. Members continue to be satisfied with PRN-related educational and networking activities.

9. Comparison of physician and pharmacist inquiry into ambulatory patients' use of complementary, alternative, and over-the-counter medicine.

Kelly M. Summers, Pharm.D.[1], Rachel A. Boyer, Pharm.D.[2], Patricia Uber, Pharm.D.[3], Mandeep Mehra, M.D.[3]; (1)Food and Drug Administration, Silver Spring, MD; (2)CVS, Baltimore, MD; (3)University of Maryland School of Medicine, Baltimore, MD

Purpose: National Patient Safety Goals recommend that providers "accurately and completely reconcile medications across the continuum of care;" however, the extent to which providers routinely document alternative or non-prescription medicines is not well studied. The purpose of this study was to compare how often physicians and pharmacists ask ambulatory care patients about complementary and alternative medicine (CAM) and over-the-counter (OTC) drug use.
Methods: In this prospective, IRB-approved observational study, researchers directly observed physicians' and pharmacists' patient visits in ambulatory care clinics. Providers were blinded regarding the reason for observation. Researchers recorded whether providers inquired about CAM/OTC use and what CAM/OTC products providers documented. At visit conclusion, researchers interviewed patients independently to record actual CAM/OTC use. The primary outcome was to determine how many patients pharmacists asked about CAM/OTC use compared to physicians. Secondary outcome measures included number of providers inquiring about use, detected prevalence

of use, and percentage of actual use detected.
Results: Twenty-one physicians (N=78 patients) and 15 pharmacists (N=67 patients) were observed. Significantly more patients in the pharmacist group (N=59) than the physician group (N=54) used CAM/OTC (P=0.01) but total products used did not differ significantly (P=0.86). Pharmacists asked significantly more patients (N=25) about use than physicians (N=7) (p<0.01). Also, significantly more pharmacists (N=11) than physicians (N=5) asked about use (P<0.01). Pharmacists detected significantly more actual CAM/OTC users than physicians (40/59 patients versus 24/54 patients, respectively, P=0.01). Pharmacists also detected significantly more products actually used than physicians (70/147 products versus 44/131 products, respectively, P=0.02).
Conclusion: In this study, pharmacists were more likely than physicians to ask patients about CAM/OTC use. Also, pharmacists detected a greater degree of actual use in their patients. However, neither pharmacists nor physicians detected all actual users or products. These results indicate that making CAM/OTC medication reconciliation routine practice needs continued improvement and emphasis.

10. Oral Anticoagulation Knowledge of Patients at a Veterans Affairs Healthcare System.

Jennifer W. Baker, Pharm.D., BCPS, Kristi L. Pierce, Pharm.D., Casey A. Ryals, Pharm.D.; Veterans Affairs Tennessee Valley Healthcare System, Nashville, TN

Purpose: This study evaluated 1) the current level of warfarin knowledge in our patient population by using the validated Anticoagulation Knowledge Assessment (AKA) instrument and 2) the potential correlation between anticoagulation knowledge and International Normalized Ratio (INR) control.
Methods: A single center cross-sectional retrospective analysis of all outpatient anticoagulation clinic patients seen during their routine visit within the 8 week recruitment period. Upon voluntary consent, the AKA instrument was completed with demographic data and the four most recent INR values manually extracted from the patients' records. A score of 70% was required on the AKA questionnaire to be considered passing. A sample size of at least 182 patients allowed for 80% power to detect a 15% increase or decrease in passing rate versus the 35% mean pass rate reported in the literature.
Results: One hundred eighty-five patients participated in the study (age 68 ± 0.74 years). The majority of patients were undergoing anticoagulation treatment for atrial fibrillation (n=112) and had been treated for at least one year (87.5%). One hundred thirty-eight patients (74.6%) achieved a 70% or better on the AKA questionnaire. Eight questions were identified as potential deficiencies in patient education including several covering dietary modifications and side effects. There were no statistically significant differences between patients in the passing and failing categories as they correlated to INR control.
Conclusions: Overall, this patient population demonstrated a significant improvement over previous literature in warfarin knowledge. However, adequate knowledge was not determined to correlate with therapeutic goal achievement. Areas for improvement in patient education have been identified and procedures for education modification are underway.

11. Comparison of health spending resources and therapeutic outcomes of a pharmacist-managed anticoagulation service compared to usual medical care.

Deanne L. Hall, Pharm.D.[1], Julianne Buchanan, M.S.[2], Bethany E. Helms, Pharm.D.[3], Matthew W. Eberts, Pharm.D., M.B.A.[3], Yushu Liu, Ph.D.[2], Donald Yoder, B.S.[2], Pamela Peele, Ph.D.[2], Chronis Manolis, R.Ph.[2], Scott M. Mark, Pharm.D., M.S.[1], Anne B. Docimo, M.D., M.B.A.[2]; (1)University of Pittsburgh School of Pharmacy/University of Pittsburgh Medical Center, Pittsburgh, PA; (2)UPMC Health Plan, Pittsburgh, PA; (3)University of Pittsburgh Medical Center, Pittsburgh, PA

Purpose: To evaluate the differences in health care expenditures and therapeutic outcomes of patients receiving warfarin therapy management by a pharmacist-managed anticoagulation service as compared to usual care.

Methods: A retrospective, matched case-control study was conducted on patients of the pharmacist-managed UPMC Anticoagulation Service which were also members of the UPMC Health Plan. Patients were followed for at least 2 months between October 2007 and September 2008 (case group) and were matched to UPMC Health Plan members receiving warfarin management via usual care (comparison group). Medical claims data compared direct anticoagulation cost and overall medical care costs; anticoagulation related adverse events; hospital and ER visits; frequency of INR lab draws and warfarin refills. Operational costs of the anticoagulation service were also calculated. INR results and time within therapeutic range was assessed through Anticoagulation Service reports and lab results.

Results: One-hundred and seventy-five patients met inclusion criteria for the case group and were matched to 175 comparison patients. The direct anticoagulation care cost was $35,456 vs $111,586, and the overall medical care cost was $754,191 vs $1,480,600, for case versus comparison groups, respectively. Accounting for operational cost, this resulted in a cost savings of $694,416. The case group had significantly less anticoagulation related adverse events (14 vs 41, p<0.0001); less hospital admissions (30 vs 85; p<0.0001) and ER visits (60 vs 143; p<0.0001). The percent of results and percent of time in range of INR readings were significantly higher in the case group (67.2% vs 54.6%, p<0.0001) and (73.7% vs 61.3%, p<0.0001). The case group had significantly more INRs drawn. No difference was found in medication refills.

Conclusion: After accounting for operational cost, pharmacist-managed anticoagulation leads to reduced health care expenditure, while improving therapeutic outcomes as compared to usual medical care.

12. Retrospective evaluation of prescription ergocalciferol dosing for vitamin D repletion.
Joseph P. Vande Griend, Pharm.D., Robert B. McQueen, M.A., Sunny A. Linnebur, Pharm.D., FCCP, Sheryl F. Vondracek, Pharm.D., FCCP; University of Colorado School of Pharmacy, Aurora, CO.

Purpose: Maintaining 25(OH) vitamin D (25-OH vitD) levels ≥30ng/mL is important for disease prevention. Ergocalciferol 50,000 units is frequently utilized for vitamin D repletion. There are no standard dosing guidelines and limited data exist regarding the efficacy of repletion regimens. The objective of this study is to describe the prescribing patterns for prescription ergocalciferol 50,000 units at the University of Colorado. Secondary objectives include evaluating the efficacy of various ergocalciferol regimens for raising 25-OH vitD levels and to evaluate predictors for attainment.

Methods: This retrospective study identified 1446 patients age 18–89 years within the University of Colorado system who had a new prescription for ergocalciferol between 1/1/07 and 12/31/08. Of this cohort, 589 patients had a 25-OH vitD level within 120 days prior to the first prescription date and a follow-up level between 60 and 180 days after the prescription date. The ergocalciferol regimens in this cohort were evaluated for efficacy and predicting attainment of levels ≥30ng/mL (sufficiency).

Results: Thirty unique ergocalciferol regimens were prescribed in the overall cohort. The majority (54%) of regimens utilized a dose of 50,000 units/week. For those with follow-up 25-OH vitD levels, the mean (SE) initial level was 17.8 (0.33) ng/ml, which increased to 32.8 (0.73) ng/ml with ergocalciferol. Overall, 55.5% of patients attained sufficiency with a prescription regimen. Compared to patients taking <50,000 units/week, a significantly higher number of patients attained sufficiency taking 50,000–100,000 units/week (57.6% vs 49.5%, P<0.001). Significant predictors of sufficiency were dosing of 50,000–100,000 units/wk (OR 1.61, 95% CI 1.01–2.5) and body mass index ≥30 kg/m^2 (OR 0.42, 95% CI 0.29–0.60).

Conclusion: Many different dosing regimens for ergocalciferol were utilized to replace vitamin D. Overall attainment of 25-OH vitD levels ≥30ng/mL was moderate, suggesting it may be difficult to increase vitamin D levels in some patients, especially those who are obese.

13. Implementation and evaluation of a health literacy workshop for medical residents.
Jessica E. Wilhoite, Pharm.D., Alison M. Walton, Pharm.D., BCPS, Karie A. Morrical-Kline, Pharm.D.; St. Vincent Joshua Max Simon Primary Care Center, Indianapolis, IN

Purpose: The American Medical Association recommends developing education programs that train physicians to communicate with patients having limited health literacy skills; however, an optimal program has yet to be determined. The primary study objective was to estimate the effect of a health literacy workshop on medical residents' ability to evaluate patient health literacy. Secondary objectives included assessing health literacy of an outpatient clinic population and determining the relationship, if any, between health literacy and medication adherence.

Methods: An IRB approved prospective study design was used to evaluate the study objectives. Researchers collected patient demographics and assessed adherence and health literacy through standardized questioning. Following the patient – physician encounter, the internal medicine resident was asked to evaluate the patient's health literacy by answering the following question: "Do you feel your patient has a literacy problem?" Data collection occurred one month prior and two months post a physician-based health literacy workshop. Patients without medications at the time of clinic visit, documented cognitive impairment, or primary language other than English or Spanish were excluded.

Results: Medical residents were "correct" in the assessment of patient literacy, when compared to the Newest Vital Sign (NVS) assessment, in 47.1% of the patients prior to the health literacy workshop. Two months following the workshop, residents were "correct" in the assessment in 61% of the patients (p = 0.069). Of the overall study population (n=179), 58% of patients failed the health literacy screening. Elderly, male, non-Caucasian, and patients with a high school education or less were significantly more likely to have limited health literacy. No relationship between NVS assessment and patients' adherence was identified.

Conclusion: Medical residents' ability to assess health literacy improved two months following the health literacy workshop. Following suggested improvements, a health literacy workshop will be included in the Internal Medicine resident curriculum.

14. Bleeding incidence and risk evaluation with concomitant use of antidepressants and warfarin.
Kelly A. Cochran, Pharm.D., Jeffrey R. Bishop, Pharm.D., M.S., Larisa H. Cavallari, Pharm.D., Nancy L. Shapiro, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL

Purpose: Bleeding is the major complication associated with warfarin. Antidepressants, particularly selective serotonin reuptake inhibitors (SSRIs), are also associated with increased risk of bleeding. Warfarin and antidepressants are used frequently in combination, but it is not known if concomitant therapy with these agents increases the risk of bleeding beyond that seen with warfarin alone. This study compared the incidence of any bleeding and major bleeding between patients on concurrent warfarin and antidepressant therapy with those on warfarin alone. A secondary analysis identified the antidepressant class most associated with bleeding.

Methods: This was a retrospective, single-center, cohort study of patients (n=46 on an antidepressant, n=54 no antidepressant) anticoagulated with warfarin between January 2007 and November 2009. Medical records over six months were reviewed for data on INR values, bleeding risk, bleeding incidence and hospitalization due to bleeding.

Results: Concurrent use of any antidepressant and warfarin was not significantly associated with increased risk of bleeding (p=0.10). However, use of an SSRI, was associated with an increased risk of any bleeding (OR 2.55, 95% CI, 1.01–6.4 p=0.03), major bleeding (OR 4.44, 95% CI, 1.09-18 p=0.04,) and hospitalization due to bleeding (OR 7.0 95% CI 1.2–40 p=0.03). Use of a SSRI remained associated with any bleeding and major bleeding (both p=0.04) after accounting for other factors associated with bleeding risk.

Conclusions: Use of an SSRI was associated with increased risk of bleeding and hospitalization due to bleeding among patients on warfarin. These data suggest that patients on concomitant warfarin and SSRI therapy should be vigilantly monitored for signs of bleeding.

15. Seasonal variation in venous thromboembolism incidence: the influence of specific risk factors in ambulatory patients.
Holly H. Chiu, Pharm.D., Jennifer L. Clemente, Pharm.D.; Harper University Hospital, Detroit, MI

Purpose: Several studies report that venous thromboembolism (VTE) incidence exhibits seasonal periodicity. In contrast, others failed to find any variation; however, differences in study populations and risk factors have not been evaluated and hence, may explain the apparent discrepancies. Thus, we sought to determine if seasonal VTE variation occurred in ambulatory patients and examine the potential influence of specific demographic characteristics and risk factors.

Methods: Our retrospective chart-review examined patients, identified from VTE-specific ICD-9 codes, presenting to the Emergency Department with suspected VTE from 2004 to 2008: subsequently confirmed by CT-scan or sonography (n=1,066). All in-hospital VTE cases were excluded. Demographic data, co-morbidities and the month of the VTE-event were tabulated. We plotted VTE frequency versus month for the entire patient population and for subgroups based on potential influencing factors: ethnicity, gender, age, body mass index above and below 30 kg/m^2, and also risk factors including previous VTE, malignancy, and recent surgery/trauma. We compared observed distributions to corresponding uniform monthly distributions using Kuiper's test—designed to assess periodic data.

Results: Although the entire population had a uniform VTE distribution, our analysis revealed a non-uniform distribution in patients of African ancestry (n=739; $P<0.05$) with a peak in spring/summer. Specifically, during April-August, VTE-incidence was 25% higher than the average of the other months. In contrast, patients of European ancestry had uniform VTE distributions (n=327; $P>0.5$). The only other subgroup with non-uniform monthly distribution was patients with malignancies and, or, recent surgery/trauma (n=349; $P<0.005$): they had a spring/summer peak with a 37% increase in April–August versus other months.

Conclusions: Ambulatory patients of African ancestry and those with malignancy and, or, recent surgery/trauma appear at increased risk of VTE in the spring/summer. Although the reasons are unknown, our observation suggests that VTE awareness should be heightened for these groups between April and August.

---

16. Outcomes of a pharmacist-cardiologist collaborative care model for hypertension management in patients with cardiovascular disease.

Sherry V. Laguardia, Pharm.D.[1], Brian K. Irons, Pharm.D.[1], Gary E. Meyerrose, M.D.[2], Kavita Dalal, Pharm.D.[3], Charles F. Seifert, Pharm.D.[1]; (1)Texas Tech University Health Sciences Center School of Pharmacy, Lubbock, TX; (2)Texas Tech University Health Sciences Center School of Medicine, Lubbock, TX; (3)Texas Tech University Health Sciences Center School of Pharmacy, Dallas, TX

Purpose: To compare the effectiveness of hypertension management using a physician-pharmacist collaborative care model versus usual care by a university based outpatient cardiology group, in patients with established coronary artery disease (CAD) or at high CAD risk.

Methods: A retrospective chart review was performed. The study populations evaluated consisted of hypertensive persons with CAD, or CAD risk equivalent, followed in a pharmacist-cardiologist collaborative drug therapy management hypertension clinic (experimental group) or by an outpatient cardiology group (control group). The primary outcome was percent of patients at their goal blood pressure (BP) < 130/80 mm Hg.

Results: At the last clinic visit evaluated, the percentage of patients at their goal BP in the control vs experimental group was 31.0% vs 49.2% respectively (p=0.0456). Median follow-up SBP was 136.0 vs 126.0 mm Hg (p=0.0077) and percent of SBP <130 mm Hg was 32.8% vs 57.6% respectively (p=0.0069). At baseline, both group's median DBP was <80 mm Hg. Final clinic visit pulse pressure (PP) was 67.0 vs 58.0 (p=0.0153). Median number of hypertension medications was 2.0 vs 3.0 (p<0.0001). The number of visits/year was 3.4 vs 10 (p<0.0001).

Conclusion: Compared to usual care, the pharmacist-cardiologist model had a higher percent of patients at their BP goal or with a SBP <130 mm Hg, a lower absolute SBP, and a lower PP. DBP did not differ between the two groups. The pharmacist-cardiologist model had more frequent clinic visits and medications prescribed. The physician-pharmacist collaborative drug therapy management model is an effective way to manage hypertension in patients with cardiovascular disease.

---

17. Effect of Pharmacy Student Interventions in a Family Medicine Setting.

Regina Ginzburg, Pharm.D.[1], Wendy B. Barr, M.D., M.P.H., MSCE[2]; (1)St. John's University, Queens, NY; (2)Beth Israel Residency in Urban Family Practice, New York, NY

Purpose: Students obtaining their Doctor of Pharmacy (Pharm.D.) degree undergo various experiential clerkships prior to graduation, including an ambulatory care clerkship. Pharm.D. students are directly involved in various patient care activities which include patient counseling, drug therapy evaluation, drug therapy recommendations, adverse drug reaction (ADR) reporting, and providing drug information. Extensive evidence exists on the impact and cost savings of pharmacists' interventions in patient care, but little is known about the benefit of pharmacy student interventions in the outpatient setting.

Methods: We performed a prospective observational study documenting students' clinical interventions in a family medicine clinic. An electronic database (MedKeeper) was used to track students' interventions and assign a cost value. Our primary objective was to determine the number of interventions presented by pharmacy students and the acceptance rate of these recommendations by the healthcare providers. Secondary endpoints included examining potential cost savings and prevention of potential adverse events from these interventions.

Results: Eighteen students underwent this experiential site in the 8 student-months studied. A total of 718 interventions were performed with 77% being accepted. Physicians accepted 58% of the 200 interventions that required immediate action. Other interventions included patient counseling, answering drug information questions, and reporting adverse drug reactions. Projected cost savings was calculated at $61,855.

Conclusion: Pharmacy students play an important role in our family medicine clinic. Their interventions resulted in significant cost savings and were generally well received. Future direction is to determine reasons for intervention acceptance/rejections

---

18. Vitamin K supplementation for anticoagulation control: do some patients respond better than others?

Jennifer L. Clemente, Pharm.D.[1], Peter Whittaker, Ph.D.[2]; (1)Harper University Hospital, Detroit, MI; (2)Wayne State University School of Medicine, Cardiovascular Research Institute and Dept of Emergency Medicine, Detroit, MI

Purpose: AHA/ACCP guidelines suggest vitamin K (VK) supplementation to stabilize anticoagulation control in patients with unidentified causes of instability. However, VK supplementation trials have produced conflicting results; possibly because optimal patient characteristics have not yet been examined. We previously found that VK consumption profoundly influenced stability: patients who consumed either minimal or significant amounts (>3 servings/week) of VK-containing food exhibited greater stability than those who consumed intermediate amounts (2–3 servings/week). VK supplementation would reduce these three groups to two: patients with minimal VK intake shift to intermediate, while those in the intermediate group shift to significant consumption. Therefore, we hypothesized that VK supplementation would be more effective in patients with intermediate or significant dietary VK consumption versus those with minimal intake.

Methods: Eight patients in our pharmacist-managed anticoagulation clinic identified as unstable, received VK (100 μg/day) in addition to their normal dietary intake (486 ± 51 days follow-up). Our retrospective chart-review assessed four anticoagulation stability and management parameters: (A) percent time in therapeutic range (TTR), (B) INR standard deviation, (C) proportion of emergent clinic visits (ECVs); defined as visits <7 days in response to a significantly out-of-range INR, and (D) proportion of visits which required warfarin dose manipulation. We divided patients into two groups (both n=4) on the basis of dietary VK consumption: (1) minimal and (2) intermediate-significant.

Results: TTR was higher (68 ± 3 vs. 53 ± 4%; $P=0.024$, t-test) and INR standard deviation lower (0.56 ± 0.04 vs. 0.85 ± 0.04; $P=0.002$) for patients with intermediate-significant dietary VK. Furthermore, this group had fewer ECVs (1 ± 1 vs. 11 ± 4%; $P=0.04$) and fewer

dose manipulations (30 ± 2 vs. 48 ± 2%; *P*=0.001): results consistent with stable anticoagulation and effective control.

Conclusions: Response to VK supplementation is non-uniform: it is more effective in enhancing anticoagulation stability and reducing required clinical management in patients who have intermediate-significant dietary VK versus those with minimal dietary consumption.

19. A retrospective evaluation of potentially inappropriate medications in the elderly.
Caroline L. Pitney, Pharm.D., Amy M. Drew, Pharm.D., BCPS; St. Louis College of Pharmacy and St. John's Mercy Medical Center, St. Louis, MO

Purpose: In the elderly, certain classes of medications have the potential to cause harm and are therefore often considered potentially inappropriate medications (PIMs) in this population. The objectives of this study were to evaluate prescriptions written for PIMs in the elderly with regards to 1) number of prescriptions per class, 2) number of prescriptions per stratified age group, and 3) evaluation of specific benzodiazepine prescriptions.
Methods: Patients sixty-five years of age and older were included if prescribed at least one prescription for one of the following PIMs: benzodiazepines, tricyclic antidepressants, anticholinergic antihistamines, skeletal muscle relaxants, and propoxyphene. Data were collected using the electronic patient medical record system. Prescriptions were included if written for one of the aforementioned PIMs from September 2008 through August 2009.
Results: PIMs were prescribed for 19% of the population (n=1,470). Of these prescriptions, approximately 60% were benzodiazepines, 14% tricyclic antidepressants, 11% anticholinergic antihistamines, 9% skeletal muscle relaxants and 6% propoxyphene. The proportion of prescriptions for PIMs increased with age (p=0.02). A further analysis of the benzodiazepine prescriptions indicated that over 89% were long acting agents and 11% were short acting agents. Higher than recommended doses were ordered in 16.3% of the benzodiazepine prescriptions.
Conclusion: Prescriptions written for PIMs in the elderly at this facility were less than expected, given previous national estimations that 20–36% of elderly patients are prescribed PIMs. The number of prescriptions for these medications appeared to increase with age, which may be due to survivorship bias. Benzodiazepines appeared to be the most frequently prescribed PIM in the elderly and should be an area of future focus for this practice setting.

20. The VA INITIAL PRE-Visit Planning TRIAL: The V.I.P. TRIAL.
Michael Katzourakis, Pharm.D., Ravindra Pathak, Pharm.D., Ph.D., M.B.A., BCPS, Debra Macdonald, B.S., Pharm; VA Salt Lake City Health Care System, Salt Lake City, UT

Purpose: To evaluate the impact of pharmacist mediated pre-visit planning on patient healthcare in the Salt Lake VA Medical Center.
Methods: This study is a single center retrospective chart review of 203 patients (intervention; N=53, Control; N=150) aged >18 at the Salt Lake Veterans Affairs Medical Center. Patients included were on >10 medications or >7 medications and >2 disease states. The intervention group met with a clinical pharmacist for a pre-visit planning appointment 2–3 weeks prior to their primary care physician appointment. The control group included randomly selected patients who had a primary care appointment with the same physicians prior to initiation of the intervention, and did not see a clinical pharmacist. The primary outcome looked the percent change in the mean Medication Appropriateness Index (MAI) scores in the intervention vs. control group. Secondary outcomes include: Percent of labs completed by physician appointment, pharmacist recommendations made vs. accepted, number of medications pre vs. post physician appointment, and a net year-to-date cost analysis.
Results: Medication regimen appropriateness increased significantly more in the intervention group compared to the control group (76% vs. 14% respectively, p<0.05). The mean number of medications/patient decreased by 1.8 in the intervention group compared to an increase of 0.3 in the control group (p< 0.05). An average of 6.3 pharmacist recommendations/patient were made, with 59% acceptance

rate. The intervention group had 96% of labs completed by physician appointment, compared to 43% in the control group (p< 0.05). A net medication cost savings of $1,680.50 was seen in the intervention group.
Conclusion: Pharmacist/physician collaboration when compared to standard of care showed an increase in appropriateness of patient's medication regimen, decreased the number of medications/patient, increased the number of labs completed before physician appointment, with a net savings in medication costs.

21. Effect of daily vitamin D supplementation on hemoglobin A1c in patients with uncontrolled type 2 diabetes mellitus.
Mate M. Soric, Pharm.D.[1], Elizabeth Renner, Pharm.D.[1], Steven R. Smith, M.S., R.Ph.[1], Stephen Thomas, Pharm.D., BCPS[2]; (1)The Toledo Hospital Family Medicine Residency, Toledo, OH; (2)Flower Hospital Family Medicine Residency, Sylvania, OH

Purpose: Vitamin D is typically understood to support musculoskeletal health when administered concomitantly with calcium. A number of recent studies suggest, however, that this important nutrient may play a significant role in several pathophysiological processes, including diabetes mellitus. Though the exact mechanism is unclear, it is hypothesized that vitamin D may improve insulin secretion and sensitivity. The few clinical trials prospectively examining the effects of vitamin D on diabetes have been of insufficient duration or power to detect a clinical effect.
Methods: In this prospective, single blind study, patients between the ages of 21 and 75 years with uncontrolled type 2 diabetes mellitus (hemoglobin A1c >7%) were randomized to receive either vitamin D3 2,000 IU daily or placebo. Patients with renal insufficiency (creatinine clearance <30mL/min), gestational diabetes, malabsorption syndrome or treated with high dose (>400IU daily) vitamin D in the previous year were excluded from the study. Follow up occurred at weeks 4 and 8 via telephone calls to assess adverse events. Hemoglobin A1c was measured at baseline and after 12 weeks of treatment.
Results: A total of 37 patients were randomized, and the two groups were similar at baseline. Overall, mean hemoglobin A1c was reduced to a greater extent in the vitamin D group as compared to treatment with placebo (-0.41% ± 1.2% vs. +0.10% ± 0.58%) but this difference was not statistically significant (p=0.16). When adjusted for baseline A1c, however, patients with a baseline hemoglobin A1c ≥9.0% had a statistically significant reduction in A1c (-1.4% ± 1.2% in the vitamin D group vs +0.2% ± 0.5% in the placebo group, p=0.013).
Conclusion: Daily supplementation with 2,000 international units of vitamin D3 was associated with a significant decrease in hemoglobin A1c in patients with baseline hemoglobin A1c values greater than 9.0% when compared to a vitamin C-containing placebo.

22. Implications on vaccine compliance rates with the implementation of a pharmacist driven vaccination protocol: phase 1.
Jamie M. Pitlick, Pharm.D.[1], Abigail M. Yancey, Pharm.D.[2], Alicia B. Forinash, Pharm.D.[1], Thomas Myles, M.D.[3]; (1)St. Louis College of Pharmacy, St. Louis, MO; (2)St. Louis College of Pharmacy, St Louis, MO; (3)Saint Louis University, St Louis, MO

Purpose: To determine if a pharmacist driven immunization protocol influences compliance with 2009 CDC immunization recommendations for hepatitis A, hepatitis B, influenza, tetanus/diphtheria/pertusis, human papillomavirus (HPV) and pneumococcal disease at a community teaching hospital internal medicine (IM) and obstetrics and gynecology (Ob/Gyn) clinic.
Methods: Phase 1 of this study included a retrospective chart review of IM and Ob/Gyn patients seen in the clinic during a 4-week period in October–November 2009. The chart review included baseline demographics and patient specific indications for the various vaccines. Compliance was defined as having an indication for the vaccine and receiving at this visit or previously within the appropriate time frame. This baseline analysis was completed prior to pharmacist intervention. Phase II will include a re-analysis of compliance 12 months after initiation of a pharmacist driven immunization protocol and will occur late 2010.
Results: A total of 311 patients were eligible to be included in phase 1 of the study, 194 from IM and 117 from Ob/Gyn. Overall compliance

with the 2009 CDC immunization recommendations was low for hepatitis A (24.4%), hepatitis B (12.2%), influenza (19%), tetanus/diphtheria/pertusis (3.9%), HPV (6.8%) and pneumococcal disease (29.6%). Significant differences were found between the IM and Ob/Gyn clinics for the pneumococcal (39.6% vs. 0%; p<0.0001) and HPV vaccines (28.6% vs. 1.7%; p=0.0041). No other significant difference was found between the two clinics for individual vaccine compliance.

Conclusion: The baseline compliance with the 2009 CDC immunization recommendations was low showing the potential benefit for pharmacist intervention.

23. Performance of internal medicine and obstetrics and gynecology residents on a case based vaccine quiz.
Alicia B. Forinash, Pharm.D., BCPS[1], Jamie M. Pitlick, Pharm.D., BCPS[1], Abigail M. Yancey, Pharm.D., BCPS[1], Thomas Myles, M.D.[2]; (1)St. Louis College of Pharmacy, Saint Louis, MO; (2)Saint Louis University, St. Louis, MO

Purpose: To assess the baseline knowledge of internal medicine (IM) and obstetrics and gynecology (Ob/Gyn) medical residents on the 2009 CDC vaccine indications.
Methods: A 5 vignettes quiz was developed to assess baseline vaccine knowledge for indications of the following vaccines: influenza injection, influenza nasal spray, hepatitis A, hepatitis B, human papillomavirus (HPV), pneumococcal, tetanus/diphtheria/pertussis (Tdap), and tetanus/diphtheria (Td). Additionally, the quiz surveyed demographic and personal vaccine usage. The quiz was piloted and revised based on feedback from pharmacists. The quiz was administered to IM and Ob/Gyn residents during required discipline-specific educational programs.
Results: The survey was completed by 66% IM and 58% Ob/Gyn residents. Overall, vaccine recommendation knowledge was low. The mean correct recommendation rates were influenza (83.3%), hepatitis A (25.5%), hepatitis B (58.9%), HPV (56.7%), pneumococcal (15%), and Tdap (41.7%). Ob/Gyn residents were more likely to correctly recommend Tdap in both cases (p<0.003 and p<0.0006) and correctly recommend influenza injection vaccine during pregnancy (p<0.003) compared to IM residents. No other difference existed between the residency programs. As for personal vaccine usage, residents had received 2008 influenza (70.0%), hepatitis A (36.7%), hepatitis B (90.0%), Tdap (33.3%), Td (66.7%), and human papillomavirus (70.0%) excluding males and females >32 years old with no significant differences between programs.
Conclusion: Overall, significant gaps in resident's baseline knowledge of the 2009 CDC vaccine indications were observed showing the need for pharmacist intervention. Personal vaccine rates were surprisingly low.

24. A description of medication discrepancies found after hospital discharge of primary care patients.
Shara Elrod, Pharm.D.[1], Kim Coley, Pharm.D.[2], Melissa Saul, MSc[1], John Donehoo, RPh[1], Gary Fischer, M.D.[1], Wishwa N. Kapoor, M.D., M.P.H.[1], Deanne L. Hall, Pharm.D.[3]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (3)University of Pittsburgh School of Pharmacy/University of Pittsburgh Medical Center, Pittsburgh, PA

Purpose: To describe the number and type of medication discrepancies found after hospital discharge of primary care clinic patients.
Methods: This study compared medication lists from the inpatient discharge summary to the outpatient electronic medical record in patients recently discharged from the hospital after primary care physician follow-up to identify possible medication discrepancies over a five-month period. A medication discrepancy is defined, for the purposes of this study, as any difference in the name, dosage, frequency, or route between the two medication lists. Patients were included if they were discharged home and if they followed-up with their primary care physician within fifteen days of date of discharge. Patient characteristics such as demographics, number of medications at discharge, and length of hospital stay will also be described.
Results: A total of 136 patients were identified for inclusion, with 135 patients considered to have some type of medication discrepancy.

Patients were discharged from the hospital on an average of 10.4 medications. A total of 885 discrepancies were found for all patients with an average of 6.5 per patient and a range of 0 to 25 discrepancies. Differences between the name of a product or complete omission of a product entirely accounted for the vast majority of discrepancies (n=667). In addition, 130 discrepancies in dose, 68 discrepancies in frequency and two discrepancies in route were found. A total of 559 discrepancies were found for prescription medications, while 306 were for over-the-counter medications.
Conclusion: This study revealed that a patient is likely to experience a medication discrepancy after hospital discharge even after follow-up with their primary care physician. A description of these medication discrepancies will aid in the design and improvement in transitional care programs in primary care, potentially allowing for an interdisciplinary approach to medication reconciliation after hospital discharge.

25. An evaluation of patients with type 2 diabetes followed by a pharmaceutical care clinic.
Cari Cristiani, Pharm.D., BCPS, Prathima Reddy, Pharm.D., Jun-Yen Yeh, Ph.D., Lisa Potts, Pharm.D., BCPS; Cleveland Clinic, Cleveland, OH

Purpose: Pharmacist-managed diabetes care services have been offered at Cleveland Clinic since 2002. A retrospective study in 2004 assessed these services, though had limitations including a lack of control group. The objective of this study was to evaluate the impact of pharmacist intervention on glycemic control in patients with uncontrolled type 2 diabetes previously managed by a primary care physician (PCP).
Methods: A retrospective chart review included patients with type 2 diabetes previously managed by their PCP ≥ 6 months prior to pharmacist intervention, with baseline A1c ≥7.5% upon referral. Change in A1c from baseline to 3, 6 and 12 months; and the percentage of patients with A1c < 7% within 12 months following first visit with the pharmacist were obtained. A conservative sample size calculation suggested 59 samples were required with 80% power to detect a change of 1% in A1c from baseline. Paired t-test and fisher's exact test were used for statistical analysis.
Results: Fifty patients with type 2 diabetes were evaluated with a mean age of 60 years and mean duration of diagnosis of 3.3 years. The mean reduction in A1c from baseline to 6 months was -2.3% [95% CI: -1.27 to -3.66 %, p=0.001]. The change in HbA1c from baseline was -2.3% [95% CI: -1.54 to -2.80 %, p=0.001] at 3 months and -2.5% [95% CI: -1.50 to -4.53 %, p=0.001] at 12 months. Forty-two percent of the patients had at least one A1c < 7% within 12 months.
Conclusions: Pharmacist-managed diabetes care resulted in significant A1c reductions in patients with uncontrolled type 2 diabetes in a primary care setting.

Cardiovascular

26. Use and Predictors of Erythropoietin in Heart Failure Patients with Anemia of Chronic Kidney Disease.
Cynthia Jackevicius, B.Sc.Phm, Pharm.D., M.Sc., FCSHP, BCPS[1], Alberta Warner, M.D.[2]; (1)Western University of Health Sciences, Pomona, CA; (2)VA Greater Los Angeles Healthcare System, Los Angeles, CA

Purpose: Anemia often develops in both heart failure (HF) and chronic kidney disease (CKD). These three conditions appear to be interconnected, and have been coined the cardio-renal-anemia syndrome (CRAS). Therapy for anemia in HF is still under investigation. Anemia of CKD has been routinely treated with erythropoietin (EPO), however, there have been recent concerns about increased cardiovascular events with EPO use. This study examines the rates and predictors of EPO use, specifically in patients with CRAS.
Methods: We conducted a retrospective, observational cohort study using administrative data from the Greater Los Angeles VA Healthcare System. Patients were identified for the study if they had an inpatient or ambulatory HF diagnosis based on ICD-9-CM code 428.x and 425.x, an estimated glomerular filtration rate (eGFR) <60mL/min

based on the MDRD 4-variable equation on 2 occasions at least 3 months apart and a hemoglobin <12 g/dL. Patients were considered EPO users if they were dispensed an EPO prescription ± 1 month of the CRAS index date. Multivariate stepwise logistic regression was used to identify potential predictors for the receipt of EPO.
Results: Of 2074 CRAS patients identified between 2003 and 2006, 213 (10.3%) were prescribed EPO. EPO patients were younger (71.9 vs 73.2 years) but had a higher rate of diabetes (53.1% vs 47.4%), hypertension (76.1% vs 68.4%) and dialysis (5.2% vs 1.1%). Predictors for EPO use were iron use (OR 30.69 [95% CI 7.36–127.92]), outpatient nephrology consult (OR 2.76 [1.95–3.90]), malignancy (OR 1.65 [1.18–2.31]), use of hydralazine/nitrates (OR 1.52 [1.18–1.96]), index hemoglobin (per unit increase) (OR 0.59 [0.52–0.68]), and eGFR (per unit increase) (OR 0.96 [0.95-0.97]).
Conclusion: In CRAS patients, EPO was not commonly prescribed, although indicated by CKD anemia guidelines at the time of the study. Severity of anemia, severity of CKD, and concomitant malignancy were predictors for EPO use.

27E. Nesiritide Cohort Study in Total Artificial Heart Patients.
Mihaela Popescu, Pharm.D., Jodie Fink, Pharm.D., BCPS, Michael Militello, Pharm.D., BCPS; Cleveland Clinic, Cleveland, OH

Purpose: Endogenous B-type natriuretic peptide (BNP) is produced by the ventricular cardiomyocytes. When the ventricles are replaced by a total artificial heart (TAH) in severe heart failure patients, it is hypothesized that there is inadequate BNP production to maintain renal function and volume homeostasis. Case reports have supported nesiritide administration to attenuate the effects of abrupt BNP withdrawal. The current study was conducted to assess the use of nesiritide in patients with a TAH at the Cleveland Clinic (CC).
Methods: A retrospective medical record review of adult patients who received a TAH at CC was conducted. The objectives were to assess the change in urine output (UOP) in patients with a TAH who received nesiritide, and secondarily assess: 1) average daily nesiritide dose 2) average daily diuretic dose 3) change in serum creatinine (SCr) 4) incidence of hypotension. Patients who received CVVHD or did not receive nesiritide infusion were excluded. Data was analyzed using descriptive statistics.
Results: Between July 2005-February 2010, 16 patients received a TAH at CC. Seventeen episodes of nesiritide use were observed in 11 patients. Five patients were excluded. Small doses of nesiritide were utilized (mean 0.005mcg/kg/min) for a median duration of 12–17 days. Loop diuretics confounded the benefit expected with nesiritide as UOP coincided with the dose of diuretic administered. Clinically, the average change in SCr was unremarkable (baseline 1.7mg/dl and post-nesiritide 1.3mg/dl). The higher baseline SCr was likely multifactorial in the post-operative period. Although 6 patients received nesiritide and vasopressors concomitantly, symptomatic hypotension was not documented.
Conclusion: In the small cohort of TAH patients at CC, the majority received low doses of nesiritide. Overall, UOP was related to the administration of loop diuretics rather than nesiritide. Neither hypotension nor change in renal function was observed with nesiritide use.
Presented at Ohio College of Clinical Pharmacy Spring Meeting, Beachwood, OH, May 21, 2010

28. Comparative effects of nesiritide and nitroglycerin on renal function, and incidence of renal injury by traditional and RIFLE criteria in acute heart failure.
Kimberly A. Ackerbauer, Pharm.D., Tien M.H. Ng, Pharm.D., Alifiya F. Hyderi, B.A., Uri Elkayam, M.D.; University of Southern California, Los Angeles, CA

Purpose: Renal insufficiency or a decrease in glomerular filtration rate (GFR) is associated with poorer outcomes in acute heart failure (AHF). The renal effects of vasodilators in AHF are inconclusive. We hypothesized that nesiritide and nitroglycerin would be associated with differing effects on the incidence of acute renal injury and changes in GFR.
Methods: A retrospective cohort study was conducted in AHF patients at the Los Angeles County+USC Medical Center on aggressive

diuretic regimens who received intravenous nesiritide or nitroglycerin for at least 6 hours. Acute renal injury was assessed by the RIFLE classification system and an acute rise in creatinine of 0.3mg/dL or 25%. Secondary endpoints included absolute change in estimated GFR, serum creatinine, BUN, blood pressure, and hourly urine output.
Results: A total of 131 patients (age 57 ± 12 y, 67% male, LVEF 38 ± 35%, 30% ischemic etiology) received nesiritide (N=37) or nitroglycerin (N=94). Diuretic regimen and doses were similar in both groups. Mean duration of therapy was not different (nesiritide 39 ± 36 vs nitroglycerin 31 ± 23 h, p=0.13). No differences were detected in incidence of renal injury using either criteria, however GFR declined and BUN increased to a greater degree in the nitroglycerin group (table). The nesiritide group had lower mean hourly blood pressures and a higher incidence of systolic blood pressure < 80 mmHg.

Mean dose	Nesiritide 0.01 ± 0.002	Nitroglycerin 128 ± 120	p-value
% change at 24h:			
Scr	5.9 ± 25	14.6 ± 28	0.10
BUN	-0.2 ± 9.8	4.2 ± 9.1	0.015
GFR	-0.5 ± 25	-9.5 ± 21	0.04
Renal Injury:			
RIFLE	18.9%	22.2%	0.88
Traditional	21.6%	34.4%	0.16
SBP<80 mmHg	26%	8%	0.01
Mean SBP:			
Baseline	114 ± 24	123 ± 23	0.07
1h	110 ± 20	125 ± 24	<0.01
6h	110 ± 21	120 ± 21	0.02
24h	102 ± 18	119 ± 20	0.01

Conclusion: The incidence of renal injury was not different between nesiritide and nitroglycerin, however, nitroglycerin was associated with a decline in GFR and increase in BUN despite higher blood pressures.

29E. Inflammatory biomarkers in left ventricular remodeling under stem cell and pharmacological treatment in a rat model of myocardial infarction.
Sheryl L. Chow, Pharm.D., BCPS[1], Arezoo Campbell, Ph.D.[2], Istvan Kovanecz, PhD[3], Judy Wang, M.D.[4], Dolores Vernet, Ph.D.[3], George Kopchock, M.S.[3], Rodney White, M.D.[4], Nestor Gonzalez-Cadavid, Ph.D.[4]; (1)Western University of Health Sciences and LA BioMed at Harbor-UCLA, Pomona, CA; (2)Western University of Health Sciences, Pomona, CA; (3)LA BioMed at Harbor-UCLA, Torrance, CA; (4)UCLA Geffen School of Medicine, Torrance, CA

Purpose: Minimally invasive methods are becoming increasingly important to predict efficacy of treatments where biopsy testing may not be feasible. Measuring the time course of circulating levels of inflammatory biomarkers may provide insight into heart failure progression and detect therapeutic response to novel heart failure treatments such as muscle derived stem cell (MDSC) therapy and continuous long-term oral sildenafil.
Methods: 19 Fisher rats underwent permanent ligation of the LAD artery and only those demonstrating impaired ejection fractions after 1 week were assigned to 1 of 3 treatment groups: (1)control (Saline cardiac injection);(2) rat MDSC (10^6 cardiac injection); and (3) rat MDSC injection + low-dose sildenafil in drinking water (3 mg/kg/day) (LDS). Serum samples were collected following infarction at 30 minutes, 24 hrs, 1 wk (treatment and injection), 2 wks, and 4 weeks and measured by ELISA for CRP, TGF-β, IL-6, and IL-10 concentrations. Echocardiography for ejection fraction was also measured at week 1 and 4.
Results: Concentrations of CRP, TGF-β, and IL-10 showed no significant elevations above normal values. IL-6 concentrations at 24 hours following myocardial infarction were found to be 16-fold higher than those of normal healthy rats and elevated throughout the entire time course of the study. After 1 week of treatment, the MDSC and MDSC + LDS groups demonstrated a trend in attenuating early rises in IL-6 levels compared to control (246.7 and 253.7, respectively, vs. 425.7, p=0.072). Improvements in mean ejection fraction were observed in the fraction of rats with the least elevations in IL-6 compared to the others (31.2 vs. 10.9%, p=0.019).

Conclusion: Assessing the time course of circulating serum IL-6 concentrations following myocardial infarction may be useful to predict functional response to novel stem cell and/or pharmacologic therapy. Correlating markers in this rat model with cardiac histological changes are warranted to predict clinical translation.

Presented at the Annual Heart Failure Society of America, San Diego, CA, September 14, 2010.

30. The effectiveness of the utilization of a heparin nomogram for the prevention of filter thrombosis in patients undergoing ultrafiltration therapy.

Kathy M. Makkar, Pharm.D., BCPS, Kathleen M. Nissley, R.N., MSN, Amanda E. Prusch, Pharm.D., BCPS, Jeffrey M. Hardin, M.D., FACC; Lancaster General Health, Lancaster, PA

Purpose: Suboptimal anticoagulation in patients undergoing ultrafiltration (UF) therapy for acute decompensated heart failure (ADHF) increases the risk of filter thrombosis. Data evaluating the effectiveness of a heparin nomogram for the maintenance of filter patency in patients undergoing UF therapy is minimal.
Methods: A retrospective, case-control study of patients undergoing UF therapy was performed. Excluded, were patients actively receiving anticoagulation therapy with intravenous (IV) heparin or direct thrombin inhibitors prior to the initiation of UF. Patients were included within the heparin nomogram group if the nomogram was initiated without any provider deviation from the protocol. Patients included in the control group received heparin per provider-guided dosing. The primary outcome was the incidence of filter thrombosis. Secondary outcomes included the incidence of premature discontinuation of UF therapy, bleeding, and length of stay (LOS).
Results: Of the 48 patients evaluated, 12 patients met exclusion criteria. The median age of the study population was 68 (62–76) years. Baseline characteristics were similar between the two groups. The incidence of filter thrombosis was 18.6% in the heparin nomogram group as compared with 35% in the control group (p=0.279). The incidence of premature discontinuation of UF therapy did not occur as frequently in patients in patients receiving nomogram-guided dosing (29% vs. 40%, p=0.207). The median length of stay in patients in the nomogram group was 14.5 days vs. 11 days in the control group (p=0.493). Bleeding complications occurred in 0% of patients in the heparin nomogram group as compared with 10% of patients receiving provider-guided dosing(p=0.497).
Conclusion: Utilization of a heparin nomogram is associated with a clinically but non-statistically significant reduction in the incidence of filter thrombosis and premature discontinuation of UF therapy in patients with ADHF. Further investigation via large, randomized, controlled trials is needed.

31. Evaluation of hemorrhagic complications in post-percutaneous coronary intervention patients.

Abigail A. Dee, Pharm.D.[1], Beth Devine, PharmD[2], Kenneth Kenyon, Pharm.D., BCPS[3]; (1)University of Washington Medicine, Seattle, WA; (2)University of Washington School of Pharmacy, Seattle, WA; (3)University of Washington Medical Center, Seattle, WA

Purpose: To determine the incidence of hemorrhagic complications in a post-PCI population in relation to peri-procedural anticoagulant and antiplatelet agent utilization. Secondary outcomes include 30-day all-cause mortality, cardiovascular mortality, need for urgent revascularization, 30-day readmission rates, and length of stay.
Methods: Retrospective review of cardiac catheterization lab databases from 2/2008 to 9/2009 identified 198 evaluable PCI patients. Patients received either unfractionated heparin (UFH) or bivalirudin as primary anticoagulant therapy with provisional GP IIb/IIIa inhibitor at the discretion of the interventional cardiologist. Electronic medical records were reviewed for additional pertinent data extraction including demographics, diagnosis, as well as baseline and post-procedure laboratory data.
Results: The majority of patients (74%) undergoing PCI received UFH as monotherapy (41%) or in combination with a GP IIb/IIIa inhibitor (33%); the remainder received bivalirudin (24%) or bivalirudin with a GP IIb/IIIa inhibitor (2%). Hemorrhagic complications occurred in 53 (27%) of the patients, and were most

prevalent in the non-ACS population, followed by STEMI, NSTEMI, and UA patients. Patients within all diagnosis groups experienced more hemorrhagic complications with UFH in combination with a GP IIb/IIIa inhibitor, compared to the other comparators. In both the non-ACS and NSTEMI groups these differences were statistically significant (p = 0.002, 0.01, respectively).
Conclusion: Hemorrhagic rates were greatest amongst the cohort of patients receiving UFH in combination with a GP IIb/IIIa inhibitor, the addition of the latter was primarily initiated post-stent deployment. Secondary outcomes were similar for all groups which raises the question whether risk stratification would better identify those patients for which a GP IIb/IIIa inhibitor should be avoided.

32. Identification of factors associated with early readmission of cardiothoracic surgical patients in a community hospital.

Estella M. Davis, Pharm.D., BCPS[1], Pamela A. Foral, Pharm.D., BCPS[2], Thomas M. Baker, DNP, APRN-BC[3], Amanda M. Herdzina, Pharm.D.[3], Christopher J. Destache, Pharm.D., FCCP[2], Karen M. Hardy, RHIA[3]; (1)Creighton University Medical Center - School of Pharmacy and Health Professions, Omaha, NE; (2)Creighton University School of Pharmacy and Health Professions, Omaha, NE; (3)Alegent Health Bergan Mercy Medical Center, Omaha, NE

Purpose: Early hospital readmissions after cardiothoracic surgery are costly and a burden to the healthcare system, however few published studies are available evaluating this problem. The purpose of this study was to identify risk factors associated with early readmission following cardiothoracic surgery in a community hospital.
Methods: A retrospective, matched case-control study was completed on cardiothoracic patients from January 2009 to April 2010. Patients readmitted within 30 days after discharge following a cardiothoracic procedure were matched based on surgical procedure to patients who did not require readmission. Data was obtained from the Society of Thoracic Surgeons Adult Cardiac Surgery Database and analyzed using appropriate univariate statistical techniques to identify factors associated with early readmission following a cardiothoracic surgical procedure. Mean ± SD was determined as appropriate.
Results: One hundred and fourteen patients were included; 57 in the Readmit group and 57 in the No Readmit group, with a mean age of 67 ± 13 years and mean weight of 88 ± 23 kg. Coronary artery bypass graft alone was performed on the majority of patients (63%) and 36% of all patients had an off-pump cardiac procedure. Patients in the Readmit group had significantly more discharge medications (p=0.009), higher STS algorithm risk score (p=0.003), longer hospital length of stay (p=0.017), lower hematocrit value prior to discharge (p<0.001) and more days between discharge and first documented cardiac rehabilitation visit (p=0.031). Patients having chronic lung disease (p<0.001) and peripheral vascular disease (p=0.01) were identified as risk factors for early readmission. The severity of chronic lung disease was associated with longer hospital length of stay (p=0.029).
Conclusion: Numerous factors were identified with early readmission and risk factors include chronic lung disease and peripheral vascular disease. Based on these results, further research using multivariate analysis is warranted to determine predictors for readmission.

33. Implementation of a glycemic control protocol in a cardiothoracic intensive care and step-down unit.

Bradley E. Hein, Pharm.D.[1], Terri S. Cook, Pharm.D.[2]; (1)The Christ Hospital/The University of Cincinnati, Cincinnati, OH; (2)Lexington VA Medical Center, Lexington, KY

Purpose: This study evaluated the effectiveness of a glycemic control protocol in cardiac surgery patients at a large community-teaching hospital. The primary objective was assessment of glycemic control of cardiac surgery patients before and after the implementation of a pharmacist-directed glycemic control protocol. The secondary objective was to evaluate average compliance rates with current surgical care improvement project (SCIP) measures for glucose control in cardiac surgery patients.
Methods: Following institutional review board approval, medical records of 522 patients undergoing cardiac surgery between 6/1/2008 and 5/31/2009 were reviewed. Diabetic status, hemoglobin A1C, 72-

hour postoperative glucose levels and length of stay (LOS) were recorded. The objectives were evaluated prior to (PRE) and after (POST) implementation of the glucose control protocol (12/2008).

Results: The PRE and POST groups were well matched. The average 72 hour postoperative blood glucose was 144 mg/dL in the PRE group and 136 mg/dL in the POST group (p<0.05). The percentage of patients in the PRE group with the average 72 hour postoperative blood glucose in the range of 70–150 mg/dL was 70.3% and after implementation, it improved to 80.3%. Hypoglycemia rates in the PRE and POST groups were low and not significantly different (0.72% vs 1.11%, respectively). Average LOS was not significantly different between the groups. Of note, the LOS of diabetic patients was reduced from 9.84 to 9.11 days. In the PRE group, compliance with the SCIP measures averaged 79%. After implementation, compliance improved to 97%.

Conclusion: A pharmacist-directed glycemic control protocol effectively optimized blood glucose control without significantly increasing hypoglycemia rates. Compliance with SCIP blood glucose measures improved as well.

34. Therapeutic anticoagulation with enoxaparin and associated Anti-Xa monitoring in patients with morbid obesity.

Eli N. Deal, Pharm.D., *James M. Hollands, Pharm.D.*, Jennifer N. Riney, Pharm.D., Lee P. Skrupky, Pharm.D., Jennifer R. Smith, Pharm.D., Richard M. Reichley, R.Ph.; Barnes-Jewish Hospital, Saint Louis, MO

Purpose: The optimal dose of enoxaparin in patients with morbid obesity is not well-established. Our purpose was to describe the Anti-Xa levels, dose requirements, and subsequent complications associated with enoxaparin in this population.

Methods: Inpatients with a BMI > 40 kg/m^2 at an academic medical center from 2004–2010 prescribed enoxaparin targeting therapeutic anticoagulation and an associated Anti-Xa level were included in this retrospective evaluation. Steady-state peak Anti-Xa levels from 0.5–1 IU/mL were considered at goal. A bleeding event was defined as requiring ≥2 units of blood for transfusion with a ≥2gm/dL drop in hemoglobin.

Results: Twenty-six patients were identified having median weight of 162 kg (range 106–243), median BMI of 49.5 (range 40.1–98.1), and median enoxaparin duration of 4 days (range 1–32). Venous thromboembolism was the most common reason for anticoagulation (n=19, 73%). The median starting dose was 0.8mg/kg (range 0.51–1; absolute dose 80–150mg) every 12 hours. Twelve patients (46%) achieved goal Anti-Xa level; 10 (38%) were above goal and 4 (15%) were uninterpretable. Goal anticoagulation was reached in 55% (11/20) with a peak serum creatinine (PSCr)1.4 mg/dL (p>0.05). Among the 10 patients with Anti-Xa levels above goal, median initial dose was 0.85 mg/kg (range 0.75–1) vs. 0.74 mg/kg (range 0.51–1) for patients at goal with similar PSCr values between these two groups (p>0.05). No bleeding events occurred among patients achieving goal anticoagulation vs. 4/10 (40%) with high Anti-Xa levels (p=0.033) with similar median PSCr between these two groups. No repeat thrombotic events were identified.

Conclusion: The majority in this cohort with morbid obesity achieved Anti-Xa levels at or above goal at doses less than the recommended 1mg/kg every 12 hours. Bleeding events were more frequent among patients with Anti-Xa levels above goal.

35. Ranolazine for the treatment of refractory angina in a Veterans population.

Ronald Shane Greene, Pharm.D.[1], Robert M. Rangel, Pharm.D.[1], Krystal L. Edwards, Pharm.D.[1], Lisa M. Chastain, Pharm.D.[1], Sara D. Brouse, Pharm.D.[1], Carlos A. Alvarez, Pharm.D., M.Sc.[1], Laura J. Collins, M.D.[2], Emmanouil S. Brilakis, M.D., Ph.D.[2], Subhash Banerjee, M.D.[2]; (1)VA North Texas Health Care System; Texas Tech University Health Sciences Center School of Pharmacy, Dallas, TX; (2)VA North Texas Health Care System; University of Texas Southwestern Medical Center at Dallas, Dallas, TX

Purpose: Pivotal ranolazine trials did not include patients with refractory angina on optimal anti-anginal medications. The purpose of this study was to evaluate the efficacy and safety of ranolazine for the treatment of angina refractory to maximal medical treatment in a Veterans population following coronary revascularization.

Methods: The study was a retrospective cohort of patients experiencing ≥ 3 angina episodes per week despite treatment with maximally tolerated anti-anginal medications (β blockers, long-acting dihydropyridine calcium channel blockers and long-acting nitrates). We assessed change in the number of self-reported weekly angina episodes and of sublingual nitroglycerin utilization. Change in the QTc interval was evaluated as a safety endpoint. All comparisons were made from baseline to endpoint using a Wilcoxon signed rank test for paired data.

Results: A total of 18 subjects were enrolled. All subjects were white males with a median age of 66.0 years. At baseline, anti-anginal use consisted of β blockers (94%), long-acting nitrates (83%) and long-acting dihydropyridine calcium channel blockers (61%). Systolic blood pressure (116.2 mmHg), diastolic blood pressure (60.3 mmHg) and pulse (65.0 bpm) were controlled. Median baseline angina episodes and sublingual nitroglycerin doses per week was 14.0 and 10.0, respectively. At study end, a significant decrease in angina episodes (-8.0; p<0.0001) and sublingual nitroglycerin doses per week (-5.0; p=0.002) was observed. Of the 18 subjects enrolled, 44% had complete resolution of angina episodes. There was no significant median change in the QTc interval (-8.0; p=0.78).

Conclusion: Addition of ranolazine to maximally tolerated anti-anginal therapy post-coronary revascularization significantly decreased both angina episodes and sublingual nitroglycerin utilization. Ranolazine may provide a safe and effective treatment option for refractory angina.

36. Assessment of the long-term anticoagulation of patients with left-ventricular assist devices: A pilot study.

Douglas L. Jennings, Pharm.D., BCPS, (AQ, Cardiology), Jane McDonnell, Pharm.D., Jessica Schillig, Pharm.D.; Henry Ford Hospital, Detroit, MI

Purpose: Left-ventricular assist devices (LVAD) represent a life-saving modality in patients with advanced heart failure (HF). These patients usually require life-long anticoagulation due the risk of device thrombosis. The average time in therapeutic INR range for our anticoagulation clinics is 68 percent. Data describing the long-term anticoagulation of LVAD patients is extremely limited. The purpose of the study is to describe the outpatient anticoagulation in LVAD patients at our institution.

Methods: All patients implanted with the HeartMate II LVAD from June 2008 to June 2009 and received warfarin were included. Data collection for 1 year post-implantation included patient demographics, comorbities, concomitant medications, INR values and warfarin dose. The primary endpoint was time within the therapeutic INR range (2–3), which was calculated using the Rosendaal Method for linear interpolation. Secondary endpoints were warfarin dosage requirement, time above the therapeutic INR range, rates of bleeding (TIMI criteria), and incidence of thromboembolism.

Results: A total of 16 patients (average age = 53 years, race = 62% African American, gender = 81% male, bridge to transplant = 31%) yielded 576 INR values and 5004 days of follow-up. The average time in the therapeutic range for LVAD patients was 51 percent. Average time above and below the therapeutic range for LVAD patients was 17 and 32 percent, respectively. The median weekly warfarin dose for these patients was 35 mg (range 16-70 mg). There were no bleeding episodes; one patient had a transient ischemic attack (INR 1.6 at the time).

Conclusions: Patients with LVADs appear to spend less time in the therapeutic INR range than the overall population of our anticoagulation clinic. Outpatient rates of bleeding and thrombembolism were low during the 1 year follow up period.

37. Outcomes in a novel Veterans Administration heart failure disease management program.

Shawn D. Anderson, Pharm.D.[1], Richard S. Schofield, M.D.[2], Tamarah J. Jungklaus, ARNP[1], Samantha L. Malloy, ARNP[1], Amy R. Mullikin, ARNP[1], Jose R. Perez[1], Lynnette Boyer, ARNP[1], Ashlee A. Meeker, Pharm.D. candidate[2], Juwon Yim, Pharm.D.[2], Carsten M. Schmalfuss, M.D.[2]; (1)Department of Veterans Affairs, Gainesville, FL; (2)University of Florida, Gainesville, FL

Purpose: To describe outcomes of a novel, multidisciplinary heart failure disease management program (HFDMP).

Methods: A HFDMP was recently implemented at our institution, whereby every inpatient admission for acute heart failure (HF) was screened using the electronic medical record (EMR). These patients were seen in consultation by the HFDMP prior to discharge. Adjudicated HF admissions were offered early post-discharge follow-up (2–14 days) with the HF team and remained enrolled in the program until stable. Patient demographics, labs and medications were obtained by review of the EMR for fiscal year (FY) 2009. Hospital outcomes were analyzed for all patients discharged from the institution with Diagnostic-Related Group (DRG) codes for HF for FY 2008-2010.

Results: A total of 321 patients with acute HF were identified over 1 year. Of these, 236 enrolled in the program. Mean age of enrolled patients was 71 ± 12, 98% were male, 79% were Caucasian, mean left ventricular ejection fraction was $35 \pm 14\%$, 79% had a history of hypertension, 45% were diabetic, and 64% had coronary artery disease. Mean NT-proBNP was 5218 ± 7269 pg/ml, serum sodium was 138 ± 4 mmol/L, and serum creatinine was 1.5 ± 0.9 mg/dl. Medication utilization determined on last documented visit was high for HF-approved beta-blockers (91%), ACE-inhibitors or ARBs (86%) and loop diuretics (88%). Spironolactone and digoxin use was 24% and 25%, respectively; a 60% increase from baseline. Average HF length-of-stay decreased from 6.1 days in FY 2008, 5.2 days in FY 2009, and 5.1 days in the first 2 quarters (Q1–2) of FY 2010. The number of ≤30-day HF readmissions was decreased by 53% and all-cause 30-day readmission rate was 37% lower for Q1–2 FY 2010 than for Q1–2 FY 2009.

Conclusion: A novel HFDMP is associated with increased medication utilization, reduced length of stay, and a reduction in 30-day HF and all-cause readmission rate.

38. The effect of providing loop diuretics to heart failure patients at discharge on 30-day readmission rates.
Meg L. Conger, Pharm.D., Mary Parker, Pharm.D., BCPS, (AQ, Cardiology), CPP; The Moses H Cone Memorial Hospital, Greensboro, NC

Purpose: Heart failure has become a public health burden, with a growing emphasis on using 30-day readmission rates as a quality and reimbursement benchmark. That emphasis has prompted many hospitals to evaluate their heart failure education and post-discharge interventions. This study sought to show that providing furosemide, a mainstay of heart failure therapy, to patients for free at discharge was an inexpensive way to prevent symptoms and readmissions.

Methods: Patients with heart failure who were treated at The Moses H. Cone Memorial Hospital in Greensboro, N.C., were enrolled between Jan.4 and Feb. 28, 2010. Patients had to be treated by physicians of local cardiology practice LeBauer HeartCare and appear on a core measures list. At discharge, patients were given a month supply of furosemide. Records were monitored for readmissions for 30 days, and the information was compared with the hospital's 9.4% readmission rate for heart failure. In another analysis, patients were their own controls, and their 30-day readmissions were compared against the 30 days before the primary admission.

Results: Twenty-five patients were enrolled. One patient was readmitted with a diagnosis code of heart failure within 30 days, yielding a 4% readmission rate. In all, four patients (16%) were readmitted for any reason. The control analysis showed three patients (12%) with an admission for heart failure in the 30 days prior to the primary admission. Overall, six patients (24%) had a total of nine admissions or emergency department visits in the control period. There were more admissions before the furosemide intervention, but the difference was not statistically significant.

Conclusion: Providing furosemide to heart failure patients at discharge did show a reduction in the number of admissions, although the reduction was not statistically significant. This intervention has the potential to prove effective in decreasing hospital visits, but will require a larger study to prove significance.

39. Use of a simplified nomogram to individualize digoxin dosing in heart failure patients vs. standard care.

Robert DiDomenico, PharmD[1], Kwanta Na-Thalang, Pharm.D.[1], Yvonne Tsao, Pharm.D.[2], Vicki L. Groo, Pharm.D.[1], Jeffrey R. Bishop, Pharm.D., M.S.[1], Marlos A.G. Viana, Ph.D.[1], Jerry Bauman, Pharm.D.[1]; (1)University of Illinois at Chicago, Chicago, IL; (2)Northwestern Memorial Hospital, Chicago, IL

Purpose: Serum digoxin concentrations (SDC) between 0.5–0.9 ng/ml have been associated with lower mortality in patients with heart failure. Currently, the Heart Failure Society of America (HFSA) recommends SDC < 1.0 ng/ml but dosing methods have not been updated to reflect the new target levels. The purpose of this study was to compare the frequency of achieving the lower target SDC using a simplified digoxin dosing nomogram to standard dosing practices.

Methods: Adult patients with left ventricular dysfunction treated with digoxin at our institution were eligible for inclusion. The study utilized a historical control group (HC) and a prospective study group (Nomogram). Digoxin dosing in the HC group was determined from standard dosing practices while the dose in the Nomogram group was determined from a previously developed digoxin dosing nomogram. The primary endpoint was the percentage of patients achieving a steady-state SDC of 0.5–0.9 ng/ml.

Results: 131 patients were included in the study (66 HC; 65 Nomogram). The mean age was 60 ± 15 years; 51.9% were male. Total body weight (99.8 ± 34.6 kg vs 85.5 ± 26.9 kg, p=0.009), ideal body weight (66.7 ± 10.3 kg vs 62.5 ± 11.3kg, p=0.026), and creatinine clearance (51 ± 22 ml/min vs 66 ± 26ml/min, p=0.001) were higher in the Nomogram group. In contrast, mean digoxin doses were lower in the Nomogram group (0.176 ± 0.074 mg vs 0.149 ± 0.067 mg, p=0.031) resulting in lower SDC (0.52 ± 0.3 ng/ml vs 1.11 ± 0.59 ng/ml, p<0.001). Target SDC were achieved with similar frequency in both groups [37.5% (Nomogram) vs 35.8% (HC), p=0.842]. However, more patients in the Nomogram group had SDC < 1.0 ng/ml (85.9% vs 43.3%, p<0.001).

Conclusions: Our simplified digoxin dosing nomogram resulted in lower SDC compared to standard dosing practices. Although the target SDC of 0.5–0.9 ng/ml was achieved with similar frequency between dosing methods, nearly twice as many patients dosed per the nomogram had SDC < 1.0 ng/ml as recommended by HFSA.

40. Efficacy of class III antiarrhythmic medications in a tertiary care center ambulatory care clinic.
Kacy Schulman, Pharm.D.[1], J. Michael Boyd, Pharm.D.[1], Melissa J. Snider, Pharm.D., BCPS, CLS[1], Cynthia Carnes, Pharm.D., Ph.D.[1], Kyle Porter, MAS[2]; (1)The Ohio State University Medical Center, Columbus, OH; (2)Ohio State University Center for Biostatistics, Columbus, OH

Purpose: This study compares the efficacy of the class III antiarrhythmic agents, amiodarone, dofetilide, and sotalol, in patients enrolled in an antiarrhythmic medications clinic.

Methods: A retrospective chart review was conducted for patients who underwent inpatient initiation of amiodarone, dofetilide, or sotalol for the treatment of arrhythmias. Patients had documented evidence of normal sinus rhythm upon hospital discharge and follow-up in the antiarrhythmic medications clinic between July 1, 2007 and November 25, 2009. Covariate data collected included: age, gender, past medical history, and previous use of antiarrhythmic medication. The primary endpoint was a composite of discontinuation due to recurrence of arrhythmia or toxicity. Secondary endpoints assessed the composite endpoint by arrhythmia type and time to recurrence.

Results: A total of 313 patients were included in the primary analysis: amiodarone (29%), dofetilide (25%), and sotalol (46%). After adjusting for model covariates, the rate of the primary endpoint was higher and statistically significant with amiodarone compared to dofetilide (hazard ratio 2.1; 95% CI 1.1 to 3.9; P=0.02). There was a similar percentage of the unadjusted primary endpoint for all three antiarrhythmic medications; however, the primary reason for discontinuation in the amiodarone group was toxicity whereas in the dofetilide and sotalol groups was arrhythmia recurrence. For the secondary endpoints, of the atrial arrhythmia patients, those receiving either amiodarone or sotalol had higher hazard rates for discontinuation than those receiving dofetilide (amiodarone vs. dofetilide hazard ratio 2.4; 95% CI 1.2 to 4.9; P=0.02, sotalol vs.

dofetilide hazard ratio 2.1; 95% CI 1.1 to 4.1; P=0.03). No statistically significant differences were found for time to recurrence.

Conclusions: On the basis of the composite endpoint, dofetilide is associated with less discontinuation due to arrhythmia recurrence or toxicity compared to amiodarone or sotalol.

41. Comparison of two techniques used to evaluate clopidogrel and prasugrel efficacy in patients who undergo a percutaneous coronary intervention: pilot study.

Matthew R. Browne, Pharm.D., Paul Phillips, M.D., Harminder Sikand, PharmD; Scripps Mercy Hospital, San Diego, CA

Purpose: Studies have reported clopidogrel resistance as high as 25% in percutaneous coronary intervention (PCI) patients. Few well-studied tools are available to guide the selection of antiplatelet therapy. Two techniques, thromboelastography (TEG) and VerifyNow are used at Scripps Mercy hospital. We aim to compare TEG and VerifyNow's measure of platelet inhibition, identification of clopidogrel poor responders, and changes in platelet inhibition measurement over time.

Methods: This was an IRB approved, prospective observational study. Subjects included were > 18 years of age, able to provide informed consent, scheduled for a heart catheterization, and received a thienopyridine. Subjects that received eptifibatide, a GPIIb/IIIa inhibitor, were excluded. TEG and VerifyNow labs were drawn pre-procedure, post-procedure, and with morning labs. Subjects who received eptifibatide or did not undergo a PCI only had pre-procedure labs drawn. Statistical analysis was done with Pearson's correlation and ANOVA analysis. Study was powered at 80% for an enrollment of 34 patients.

Results: Twenty-six subjects were enrolled. Seven subjects underwent a PCI without eptifibatide. There was a weak correlation between the measure of platelet inhibition by TEG and VerifyNow (r^2=0.13). Discrepancy existed in the identification of clopidogrel poor responders. Thirty-three percent of subjects identified as normal responders by VerifyNow were identified as poor responders by TEG. Forty-one percent of subjects identified as normal responders by TEG were identified as poor responders by VerifyNow. Discrepancy existed in the time comparison. VerifyNow measured platelet inhibition increased with time. TEG measured percent platelet inhibition increased initially, but decreased with morning labs. The difference was not statistically significant.

Conclusion: TEG and VerifyNow may miss-identify clopidogrel poor responders an equal number of times. These are dynamic tools that weakly correlate in measuring thienopyridine platelet inhibition. Given the lower cost and the ease of use, VerifyNow may be the preferred tool for identifying clopidogrel poor responders. Study in progress.

Clinical Research Study Design

42. A rigorous methodology for small sample clinical pharmacy research: evaluation of insulin dosing strategies in four nursing home patients with diabetes.

Deanne L. Hall, Pharm.D., CDE[1], Thomas Pineo, D.O.[2], Ty Ridenour, Ph.D.[3]; (1)University of Pittsburgh School of Pharmacy/University of Pittsburgh Medical Center, Pittsburgh, PA; (2)UPMC Horizon, Community Medicine Incorporated, Greenville Medical Center, Family Medicine, Greenville, PA; (3)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

Purpose: To demonstrate the power of combining an interrupted time series design with hierarchical linear modeling (HLM) for detecting treatment effects in small sample clinical trials. To illustrate this methodology, two insulin dosing strategies were compared in nursing home patients with type 2 diabetes requiring insulin: standard sliding scale (SSI) versus insulin sensitivity factor and carbohydrate-to-insulin ratio calculations (ISF/C:I).

Methods: Elderly nursing home patients with type 2 diabetes were switched from SSI to a basal/bolus insulin regimen utilizing ISF/C:I based dose calculation and delivered at bedside via subcutaneous injection as part of routine care. Retrospectively, blood glucose readings were collected for 100 days; fasting, pre-lunch, pre-dinner,

and bedtime. The number of baseline days (SSI period) for each patient was randomly chosen, thus an interrupted time series design was employed. Differences between SSI and ISF/C:I dosing were tested using HLM; between-patient differences were controlled at level 2 where as within-patient trends and dosing strategy were analyzed at level 1.

Results: Four patients were switched from SSI to ISF/C:I calculation for insulin dosing. All patients' glucose levels were significantly reduced using ISF/C:I compared to SSI. On average, glucose reductions were as follows; fasting 36 mg/dL, pre-lunch 94 mg/dL, pre-dinner 88 mg/dL, and bedtime 97 mg/dL (all p<0.001). Analyses also revealed that each patient had a unique time(s) at which ISF/C:I had the greatest impact on their glucose levels (p<0.001). All patients obtained a fasting blood glucose average < 130 mg/dL.

Conclusion: The methodology demonstrated herein permits a rigorous scientific analysis within a clinical trial in situations where only small samples may be available (e.g., pilot studies, testing of randomized clinical trials in local settings, treatment for rare illnesses). As shown here a novel insulin dosing strategy may be a viable option in select nursing home patients based on scientific analysis, not just clinical description.

Community Pharmacy Practice

43E. Association between Exposure to Diabetes Self Management Education and Disease State Knowledge and Hemoglobin A1c Levels.

Jonathan Newsome, Pharm.D.[1], Janel Bailey-Wheeler, Pharm.D.[2], Daniel Sarpong, Ph.D.[3]; (1)Hampton University, Newport News, VA; (2)Xavier University of Louisiana, New Orleans, LA; (3)Jackson State University, Jackson, MS

Purpose: To determine if exposure to diabetes self management education increases a patient's understanding of diabetes, its management, and its complications, and helps the patient reach a hemoglobin A1c (HbA1c) level of <7% or obtain a significant reduction in A1c level.

Methods: This retrospective study included patients who had previously participated in diabetes education and those who had not previously participated in diabetes education. A survey was utilized to compare the disease state knowledge and HbA1c levels between the two groups. Data collection was conducted at two community pharmacies and one ambulatory care clinic over a 4-month period. Two sample T-tests and analysis of covariance tests were performed for continuous measures and χ^2 tests and logistic regression analyses for categorical measures.

Results: Of the 65 participants screened, 50 completed the survey. The majority of the participants were African American (n=41) and female (n=32). It was determined that diabetes education significantly impacts disease state knowledge (p<0.0006), but there was no statistical significance between education and HbA1c levels (p<0.7927).

Conclusion: Based on the results, diabetes education improves awareness about the disease, its management and its complications. Additional studies should be conducted to determine the effect diabetes education will have on hemoglobin A1c levels.

Presented at Presented at the annual American Pharmacists Association meeting, San Antonio, TX, April 3–6,2009

44. Medicare Part D in Community Pharmacy: continued impact and related issues.

Shamima Khan, M.B.A., Ph.D., Carmela Avena-Woods, RPh., Pharm.D., CGP ; St. John's University, Jamaica, NY

Purpose: To explore community pharmacists' experiences with the economic and non-economic impact of Medicare Part D in New York

Methods: Four focus groups were conducted: 2 included pharmacists practicing in independent pharmacies (IPs); 1 included pharmacists practicing in chain pharmacies (CPs); and another was a combination of both groups. Twelve pharmacists practicing in IPs and six pharmacists practicing in CPs participated. We conducted content analysis of focus group transcripts.

Results: Pharmacists practicing in IPs reported more economic

hardship due to decreased reimbursement rates. The decline of cash paying patients (switched to Medicare Part D) along with dual eligible's being unable to afford co-pays has also economically impacted IPs more severely. Pharmacists (IPs and CPs) reported rendering MTM services as unprofitable because of inadequate reimbursement rates and selection bias. Formulary management is challenging, since Medicare Part D plans can add/remove drugs from formularies with minimal notice, and the prior approval process is tedious. Pharmacists' stated their patients and themselves find Medicare Part D technically and contextually challenging and confusing. Patients are afraid of reaching the "donut hole" and often skip/stop taking medications to delay/ avoid reaching it. Once reached, a number of patients discontinue their drug therapy completely. To avoid or lower co-pays, patients are increasingly opting to use mail order pharmacies, which may promote the use of poly-pharmacy.

Conclusion: With five years passage of Medicare Part D, pharmacies and their patients have become more aware of the program, however, the new program (Medicare Part D) has created new problems, such as decreased reimbursement rates, formulary management, "donut hole", contextual and technical issues.

Critical Care

45E. Does withholding early intravenous fat emulsions from parenteral nutrition reduce infections during critical illness?
Anthony Gerlach, Pharm.D., BCPS[1], Sheela Thomas, M.S., RD[1], Claire V. Murphy, Pharm.D., BCPS[1], Lydia Pourzanjani, M.S., R.D., L.D.[2], Melissa Whitmill, M.D.[1], Steven Steinberg, M.D.[1], Stanislaw Stawicki, MD[1], Charles H. Cook, M.D.[1]; (1)The Ohio State University Medical Center, Columbus, OH; (2)The Ohio State Unviersity Medical Center, Columbus, OH

Purpose: Withholding intravenous fat emulsion (IVFE) from parenteral nutrition (PN) for the first 7–10 days may decrease infectious complications (IC). This study compared IC in SICU patients receiving PN before and after routinely delaying IVFE.
Methods: SICU patients who received PN for >6 days were included. Patients receiving PN with IVFE prior to SICU admission or other IVFE (propofol or clevidipine) were excluded. Data collected included demographics, transfusions, laboratory/microbiology data, and nutritional assessments. Measured IC included blood infections, catheter related blood stream infections (CRBSI, defined by isolation of the same organisms from central line and peripheral cultures), pneumonia (defined as >10,000 cfu/mL by semi-quantitative cultures plus clinical symptoms), and urinary tract infections (>100,000 cfu/ml by urine culture). Statistical analysis was performed using Fisher's exact test, and Student's *t*-test.
Results: Sixty-four patients were included; 30 received IVFE at onset and 34 had delayed IVFE. Groups had comparable demographics, severity of illness, transfusions, and duration of PN. Overall hospital mortality was 64.0%, and IC occurred in 65.6% (63.3% IVFE at onset vs 67.6% delayed IVFE, p=0.79). Seventeen developed blood infections or CRBSI while on PN (26.7% IVFE group vs 26.5% no IVFE, p>0.99). Patients who developed bacteremia or CRBSI had a statistically longer duration of PN (32.5 ± 30.3 vs. 14.7 ± 8.1 days, p=0.013).

	IVFE@onset (n=30)	IVFE delayed (n=34)	p-value
% at least 1 IC	63.3	67.6	0.79
% Pneumonia	50	55.9	0.80
% UTI	30	32.4	>0.99
% Bacteremia	20	20.6	>0.99
% CRBSI	6.7	11.8	0.68
Median duration PN, days	24 [14–36.5]	32 [22.75–53.5]	0.93
Mean Total Kcal/kg IBW	25.8 ± 3.3	22.1 ± 3.9	0.0004
Mean gm AA/kg IBW	1.54 ± 0.28	1.76 ± 0.30	0.005

Conclusion: Delayed IVFE for 7–10 days does not appear to influence the rates of IC or mortality in SICU patients requiring PN. However, a longer duration of PN was associated with an increased incidence bloodstream and CRBSI.
Presented at Presented at the 30th Annual Meeting of Surgical Infection Society Las Vegas, Nevada April 17–20, 2010

46. Evaluation of corticosteroids use in septic shock (ECUSS): A retrospective multicenter study.
Marc M. Perreault, Pharm.D., BCPS[1], Patrick Bouchard, MSc[1], Zoe Thiboutot, MSc[1], David R. Williamson, M.Sc.(Pharm), BCPS[2], Salmaan Kanji, Pharm.D.[3], Lisa D. Burry, BSc, Phm, Pharm.D., FCCP[4]; (1)The Montreal General Hospital, Montreal, QC, Canada; (2)Faculté de pharmacie, Université de Montréal, Montreal, QC, Canada; (3)The Ottawa Hospital, Ottawa, ON, Canada; (4)Mount Sinai Hospital, Toronto, ON, Canada

Purpose: The diagnosis of critical illness-related corticosteroid insufficiency (CIRCI) in patients with septic shock and the associated supplementation remains controversial. Our objective was to describe our practice regarding corticosteroid use and CIRCI diagnostic assessment as well as associated outcomes in Canadian ICUs.
Methods: Adults with septic shock from the ICUs of 4 teaching institutions treated with hydrocortisone between 01/01/2004 and 01/06/2004 were included in this retrospective study. Patients were identified from pharmacy records and data were collected from the patients' medical record.
Results: 116 patients with septic shock met inclusion criteria: mean age 62 ± 15 years; 56% male; median ICU length of stay 9 ± 20 days. 48% of patients had an admitting diagnosis of sepsis or septic shock. The most common sites of infection were pulmonary (46%) and intra-abdominal (28%). At shock onset, a mean of 2 organs per patient were dysfunctional. Adrenal function was assessed by the 1 mcg ACTH test (45%), 250 mcg (19 %), random cortisol level (8%) and neither in 28 % after 43 ± 64 hours of shock onset. Non responders to the ACTH testing (a serum cortisol increment <250 nmol/L) were observed in 58 % post 1 mcg test and in 55% post 250 mcg test. 83% patients received 200 mg hydrocortisone daily and only 10% received fludrocortisone. Hydrocortisone was used during 4 ± 4.5 days after a delay of 45 hours after shock onset. Adjunctive sepsis treatments included: duration of ventilator support 9.6 ± 12.5 days, duration of vasopressor support 4.7 ± 5.5 days, 79% required insulin therapy within 48h of shock, 28% required CRRT, 13% received APC. Hospital mortality was 45.7%.
Conclusion: Within 4 major Canadian institutions, hydrocortisone 150–300 mg/day was administered to patients with septic shock for an average of 4 days. A wide heterogeneity of practice regarding assessment of adrenal function in septic shock was noted likely reflecting confusion about its proper evaluation.

47. A retrospective analysis of mortality and patient outcomes in trauma patients admitted to the ICU with elevated INR values.
Brenna A. Ferry, Pharm.D., Lee E. Morrow, M.D., FCCP, Samuel Cemaj, M.D., Tammy L. Burns, Pharm.D., BCPS, Megan B. Sorensen, RN, MHA, Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: The International Normalized Ratio (INR) is not included in existing mortality prediction tools. This analysis explored whether an elevated INR (≥1.5) regardless of pre-injury warfarin therapy is an independent predictor of mortality, length of stay, and number of procedures in trauma patients admitted to the ICU at an academic medical center.
Methods: Medical records of 651 trauma patients admitted to the ICU between January 1, 2007 and December 31, 2008 were reviewed. Data were extracted from the National Trauma Registry of the American College of Surgeons. Statistical analyses included Student's *t*-test, χ^2 analysis, and multivariate logistic regression modeling.
Results: Inclusion criteria were met in 303 patients. The study cohort consisted of 71% males. The most frequent trauma was motor vehicle accident (42.2%). Increasing INR (RR=2.48 ± 0.34; p=0.007) and APACHE II score (RR=1.19 ± 0.03; p=<0.001) were the only independent predictors of mortality. A sensitivity analysis showed that INR ≥1.2 was the lower limit for association with increased mortality (RR=3.88 ± 0.39; p=0.001). For every 1-point increase in INR, ICU stay was prolonged by 3.46 days (RR= 3.46 ± 1.23; p=005). An INR value ≥1.5 was also associated with an increased number of procedures in a separate univariate analysis (p=0.003).
Conclusion: This data suggests that an elevated INR is an independent predictor of mortality in trauma patients admitted to the

ICU regardless of warfarin therapy. Increased INR values are also predictive of prolonged ICU stay and increased numbers of procedures. Attention should be given to a trauma patient's admission INR value given its prognostic utility for a variety of clinical outcomes.

48. A retrospective analysis of quetiapine use in the intensive care unit.
Cara M. Olsen, Pharm.D., Lee E. Morrow, M.D., FCCP, Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: Although quetiapine is indicated for treatment of schizophrenia and bipolar disease, it is often prescribed off-label in the intensive care unit (ICU) setting. The purpose of this study was to describe quetiapine use in the ICU population of an academic medical center.
Methods: This was a retrospective cohort study consisting of all adults admitted to Creighton University Medical Center's ICUs during 2007 and 2008. To be included patients had to receive at least two doses of quetiapine on at least two consecutive days while in the ICU. Patients prescribed quetiapine as a continuation of their home medication were excluded. Abstracted information included indication for use, prescribing team, mean dosage, discharge disposition and continuation of quetiapine therapy at discharge.
Results: In all, 71 patients met the inclusion/exclusion criteria. Quetiapine-treated patients averaged 57 years of age, had a male to female ratio of 2:1 and a mean length of stay of 26 days. None of the patients received quetiapine for an FDA-approved indication; the most common indication was agitation (65%). The majority of quetiapine prescriptions were written by the psychiatry (50%) or ICU team (33%). Overall, 44% were ultimately discharged from the hospital on quetiapine. A documented response to quetiapine therapy was significantly correlated with fewer days in the ICU (p=0.01) as well as discharge on quetiapine (p<0.001).
Conclusion: Despite the common off-label use of quetiapine in the ICU, this agent was continued through discharge in 44% of patients. The significant correlation between discharge on quetiapine and documentation of a clinical response suggests that much of this off-label use was appropriate.

49. Economic evaluation of a point-of-care blood glucose value.
Mark A. Malesker, Pharm.D., FCCP, BCPS, Daniel E. Hilleman, Pharm.D., FCCP, Lee E. Morrow, M.D., FCCP; Creighton University Medical Center, Omaha, NE

Purpose: Frequent monitoring of blood glucose is an essential component of care for many patients in the critical care setting. Although analyses of the cost-effectiveness of various glycemic management strategies have been completed, the direct and indirect costs attributable to point-of-care (POC) blood glucose measurements are unknown and often ignored. The purpose of this study was to estimate the overall costs to perform a POC glucose determination at an academic medical center.
Methods: Estimates of the cost to determine a POC blood glucose value included the acquisition costs of the meter and attendant supplies in addition to the cost of time spent by the nurses obtaining the equipment and performing the blood glucose test. The costs of supplies and hardware used were based upon current wholesale acquisition pricing. The nursing costs were based upon salary information from three metropolitan Omaha hospitals.
Results: The average time spent in obtaining a POC glucose value was 5.19 ± 0.66 minutes, equivalent to an average of 2.53 ± 0.49 dollars for nursing salary cost. The total cost of disposable supplies was 57 cents per measurement: 19 cents for the cotton ball, bandage, alcohol swab,, and lancet plus 38 cents per blood glucose test strip. The cost of the meter to run one POC blood glucose value was estimated at 17 cents based on the manufacturer's projected performance data for the device. The total cost of a single POC blood glucose value was estimated at 3.27 ± 0.49, the sum of the costs for nursing salary, the disposable supplies, and the glucometer.
Conclusion: Multiple variables must be considered when estimating the cost for a POC blood glucose determination. A disproportionate amount of our cost was attributable to the nursing salary component.

50. Noncompliance with ATS-IDSA guidelines' empiric antibiotic therapy for pneumonia.
Kyle W. Bierman, Pharm.D., Lee E. Morrow, M.D., Josh D. Holweger, M.D., John Ratelle, M.D., Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: The ATS and IDSA have jointly authored treatment guidelines for community-acquired pneumonia (CAP), healthcare-associated pneumonia (HCAP), hospital-acquired pneumonia (HAP), and ventilator-associated pneumonia (VAP). Little data exist regarding guideline compliance and the consequences of non-compliant regimens.
Methods: We retrospectively reviewed the charts of patients with a discharge ICD-9 code for pneumonia in 2008. We abstracted data regarding pneumonia subtypes, guideline compliance of prescribed therapy, and the reason(s) for guideline noncompliance. Microbiology data were reviewed to assess antibiotic adequacy regardless of guideline compliance.
Results: The study cohort included 280 HCAP patients, 161 CAP patients, 42 HAP patients and 40 VAP patients. Microbiology data confirmed infection in 36.1%. Combination therapy rates varied between CAP (44.8%), HCAP (68.5%), HAP (50.0%), and VAP (62.5%, p<0.001). Guideline compliance rates were also varied for CAP (54.7%), HCAP (15.1%), HAP (16.7%), and VAP (10.0%, p<0.001). Reasons for guideline noncompliance varied significantly by pneumonia subset (p<0.001). Patients with HCAP, HAP, and VAP were more likely to receive therapy which was too narrow (61.4%, 69.0%, and 62.5% respectively) when compared to CAP patients (14.3%). Similarly, patients with HCAP, HAP, and VAP were more likely to receive inappropriate doses of antibiotics (34.6%, 47.6%, and 34.0% respectively) when compared to CAP patients (8.7%). Inappropriately broad therapy was more likely in CAP patients (27.3%) compared to HCAP, HAP, and VAP patients (7.5%, 2.4%, and 5.0% respectively). Despite high rates of guideline noncompliance, therapy was adequate for the isolated pathogens in 96.3% of CAP patients, 93.9% of HCAP patients, 92.9% of HAP patients, and 90.0% of VAP patients.
Conclusion: HCAP was the most commonly encountered pneumonia subtype at this institution. Although rates of guideline-noncompliance was surprisingly high, rates of adequate therapy were at least 90% in all pneumonia subsets. Current guideline recommendations may need to be revised in order to avoid over-prescription of antibiotics.

51. Is healthcare-associated pneumonia more similar to community-acquired pneumonia than we think?
Kyle W. Bierman, Pharm.D., Lee E. Morrow, M.D., FCCP, Josh D. Holweger, M.D., John Ratelle, M.D., Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: Several investigators have suggested that healthcare-associated pneumonia (HCAP) patients are more similar to hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP) patients than community-acquired pneumonia (CAP) patients. However, existing studies are limited by inconsistent application of the ATS-IDSA criteria for HCAP.
Methods: We retrospectively reviewed the charts of 523 patients with a discharge ICD-9 code for pneumonia in 2008. Patients were rigorously stratified as CAP, HCAP, HAP or VAP using all existing ATS-IDSA defining criteria. We then compared groups regarding microbiology and clinical outcomes.
Results: The study included 523 patients: 280 (53.5%) had HCAP, 161 (30.9%) had CAP, 42 (8.1%) had HAP and 40 (7.7%) had VAP. Microbiologic-confirmation of infection was established in 36.1%. Mean APACHE II scores were similar for HCAP and CAP patients. HAP/VAP patients had scores (17.7 ± 8.0) which were higher than HCAP (p=0.001) and CAP (p<0.001) patients. The rate of infection with a resistant pathogen was similar for HCAP and HAP/VAP patients (21.1% vs. 26.8%, p=0.44) while CAP patients had rates (6.8%) which were significantly lower than HCAP and HAP/VAP (p<0.001 for each comparison). Hospital length of stay was not different for HCAP and CAP patients, but both were significantly

different from HAP/VAP patients (p<0.001 for each comparison). Mortality rate was not different for HCAP and CAP patients (10.7% vs. 6.2%, p=0.30); both had significantly lower mortality rates than HAP/VAP patients (20.7%, p=0.002 for CAP and p=0.03 for HCAP). **Conclusion:** Our rigorous application of HCAP-defining criteria resulted in a higher incidence of HCAP than has been generally reported. Although HCAP patients had rates of infection by resistant pathogens that were more similar to HAP/VAP than CAP, severity of illness, length of stay, and mortality were more similar to CAP than HAP/VAP. These data suggest that HCAP may be more similar to CAP and less similar to HAP/VAP than currently believed.

52. Is healthcare-associated pneumonia a good predictor of infection with antibiotic-resistant pathogens?
Kyle W. Bierman, Pharm.D., Lee E. Morrow, M.D., FCCP, Josh D. Holweger, M.D., John Ratelle, M.D., Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: The concept of healthcare-associated pneumonia (HCAP) was devised to identify patients with increased risk for infection with resistant pathogens despite residing in the community. It is unknown how well the current ATS-IDSA HCAP-defining criteria actually identify such at-risk patients when all criteria are rigorously applied to a general hospitalized population.
Methods: In this single-center study, we retrospectively reviewed the charts of all hospitalizations in 2008 with an ICD-9 code for pneumonia and identified patients with HCAP. We recorded the presence/absence of each individual HCAP-defining criterion and recorded microbiology data regarding infection with resistant pathogens.
Results: The study cohort included 523 patients of whom 280 (54%) met at least one HCAP-defining factor. Microbiology data identified at least one pathogen in 36% of subjects. The presence of at least one ATS-IDSA HCAP-defining criterion had a sensitivity of 64% and a specificity of 49% in indentifying patients infected by a resistant organism. Although univariate analysis found that some HCAP-defining criteria were associated with infection caused by a resistant organism (immunosuppression, nursing home resident, prior hospitalization), others were not (hemodialysis, prior antibiotics, chemotherapy, outpatient infusion, wound care, hospital based clinic). Multivariate logistic regression modeling identified variables independently associated with pneumonia caused by a resistant pathogen. These included: the clinical pulmonary infection score (AOR 1.53, p<0.001); the APACHE II score (AOR 1.03, p=0.04); and the current ATS-IDSA definition of HCAP (AOR 2.54, p<0.001).
Conclusion: Although HCAP is a commonly encountered subtype of pneumonia, its optimal definition merits more rigorous study. In this study population, current HCAP-defining criteria and increased severity of illness identified patients at-risk for infection caused by resistant pathogens. Creation of a more parsimonious HCAP definition could minimize excessive antibiotic prescription.

53E. Effect of a silver-coated endotracheal tube on ventilator-associated pneumonia and medical resource utilization in clinical practice.
Lee E. Morrow, M.D., FCCP, Edward Mintz, M.D., Mark A. Malesker, Pharm.D., FCCP, BCPS; Creighton University Medical Center, Omaha, NE

Purpose: Ventilator associated pneumonia (VAP) is associated with excess medical resource utilization (MRU). A silver-coated endotracheal tube (SC-ETT) reduced the rate of microbiologically-confirmed VAP compared with a conventional ETT in a large randomized trial. The objective of this study was to evaluate VAP rates by clinical criteria and MRU before and after systemic implemenation of SC-ETT use in clinical practice.
Methods: In this retrospective study, we determinted VAP rates and MRU for the 12-month periods before and after systematically replacing conventional ETTs with SC-ETTs in high-risk patients in April 2008 in a large university hospital. We identified adults requiring ≥ 2 days of mechanical ventilation and performed detailed chart review to determine the combined rate of VAP by either National Healthcare Safety Network criteria or clinically significant VAP as

defined by abnormal chest x-rays, CPIS≥7, and 3 days of appropriate antiotics. Intervention consisted of intubation with SC-ETTs in high-risk patients, defined as requiring mechanical ventilation in the emergency department or intensive care unit, or on wards. SC-ETT was also encouraged in patients likely to require postoperative mechanical ventilation.
Results: We reviewed 314 ventilator episodes lasting ≥ 2 days before systematic SC-ETT use and 274 during it. VAP rates per 1000 days of mechanical ventilation decreased from 32.7 (95% CI 29.3–36.6) before intervention to 17.9 (95% CI 15.1–21.2; p=0.0002) during it. The corresponding mean duration of antibiotic use decreased from 8.9 to 6.1 days (p=0.003). Between-cohort differences in durations of stay in the ICU and hospital were not statistically signficant in 546 patients with unique records (pre-intervention, 290; intervention, 256).
Conclusion: Systematic use of SC-ETT was associated with lower VAP rates and shorter duration of antibiotic use in clinical practice. More studies are needed to confirm our findings.
Published in 1. Morrow, L., Mintz, E, and Malesker, M.: Effect of a Silver-Coated Endotracheal Tube on Ventilator-Associated Pneumonia and Medical Resource Utilization in Clinical Practice. Crit Care Med 2009;37(12 Suppl):A185. Presented at SCCM 2010

54. Adequacy of international normalized ratio (INR) reversal after receiving 3-factor prothrombin complex concentrate.
Jennifer H. Baggs, Pharm.D., Asad E. Patanwala, Pharm.D., Evan Williams, Pharm.D. Candidate, Brian L. Erstad, Pharm.D.; University of Arizona, Tucson, AZ

Purpose: The objective of this study was to determine if patients with higher initial INR levels are less likely to achieve adequate INR reversal after receiving 3-factor prothrombin complex concentrate (PCC).
Methods: In this retrospective cohort study, medical records of 89 consecutive patients who received 3-factor PCC between June 1, 2007 and September 30, 2009 were evaluated. Patients with an initial pre-dose INR <2 were excluded. Included patients were grouped *a priori* into two categories defined as adequate (INR ≤ 1.5) or inadequate (INR > 1.5) reversal after receiving 3-factor PCC. Information collected included demographic and laboratory data, indication, PCC doses, vitamin K and blood product use. Initial pre-dose INR was compared between the two groups using the Wilcoxon rank-sum test. A multivariate logistic regression analysis was used to adjust for confounders and determine predictors of adequate INR reversal.
Results: Fifty patients met criteria for inclusion in the final analyses, 29 (58%) with adequate and 21 (42%) with inadequate reversal. There were no significant differences in patient demographics, indications, vitamin K or blood product use between the two groups. Median PCC dose was also similar between the two groups, 25.2 units/kg with adequate vs. 24.5 units/kg with inadequate reversal, p=0.2. The group that did not achieve adequate INR reversal had a significantly higher initial INR (3.5 vs. 2.5, p=0.012) prior to receiving PCC. In the multivariate logistic regression analysis initial INR was a significant predictor of adequate INR reversal after adjusting for PCC dose, vitamin K and fresh frozen plasma use (OR = 0.446; 95% CI = 0.215 to 0.926, p=0.03).
Conclusion: Patients with a higher initial INR are less likely to achieve adequate INR reversal after receiving 3-factor PCC.

55. The Impact of a Registered Nurse-Driven Electrolyte Replacement Protocol in the Intensive Care Unit.
Linda A. Sitkiewicz, Pharm.D., *Meera Patel, Pharm.D.*, Daniel Feinstein, M.D.; Moses H. Cone Memorial Hospital, Greensboro, NC

Purpose: Hypokalemia is extremely common in the intensive care unit setting. Repletion is often inadequate and may lead to increased morbidity and mortality in this patient population. This study was designed to determine the effect of a registered nurse-driven electrolyte replacement protocol on adequacy and timeliness of replacement of potassium in the intensive care unit.
Methods: This prospective study compared patients in the intensive care unit receiving potassium using a newly developed nurse-driven potassium replacement protocol with a historical group who received traditionally dosed potassium supplementation. Primary outcomes

were the time from low potassium level reported by the lab to administration of the replacement dose and the adequacy of potassium repletion, measured by difference in absolute serum concentration between the pre- and post-repletion levels. The secondary outcome assessed the incidence of adverse events.

Results: The two groups had similar baseline characteristics. The time to first dose increased from an average of 361 minutes in the non-protocol group to 409 minutes in the protocol group (p=0.26). The adequacy of repletion to a normal serum concentration increased from 48% of non-protocol patients to 90% of protocol patients (p=0.02).

Conclusion: Implementation of a registered nurse-driven potassium replacement protocol did not statistically significantly change the time to first dose of potassium but did significantly improve the adequacy of overall repletion.

56. Hydrocortisone Plus Fludrocortisone Versus Hydrocortisone Alone for Vasopressor-Dependent Septic Shock.
Jessica L. Brown, Pharm.D., Nita Johnston, Pharm.D., Meera Patel, Pharm.D., Daniel Feinstein, M.D.; Moses Cone Health System, Greensboro, NC

Purpose: Low dose steroids are frequently utilized in septic shock patients requiring vasopressor therapy. According to current guidelines, the use of hydrocortisone less than 300mg, or its equivalent, is recommended in septic shock and the addition of fludrocortisone is optional. There is controversy over whether adding fludrocortisone is effective. This study sought to determine whether adding fludrocortisone to hydrocortisone is more effective than hydrocortisone alone in decreasing vasopressor requirements for septic shock.

Methods: Eligible participants were adults admitted to the ICU in septic shock requiring vasopressor and steroid therapy. Exclusions were contraindications to corticosteroids; steroid dependence prior to shock onset; hydrocortisone >300 mg or its equivalent; etomidate administration within 6 hours of steroid therapy; pregnant or breast-feeding; cardiac arrest this hospital stay; or requiring renal replacement therapy. A retrospective review was conducted on eligible patients as a control group. Prospective data was collected in which fludrocortisone 50 μg daily was added to medication regimens of septic shock patients.

Results: Primary outcomes included time to discontinuation of vasopressor therapy and the dose of vasopressor therapy on/off steroid therapy. The secondary outcomes were time on mechanical ventilation, length of stay in the ICU and hospital, adverse events, sequential organ failure assessment score, and in-hospital mortality. The combination group resulted in less time on vasopressors at 20.9 hrs vs. 28.7 hrs for the hydrocortisone alone group and less dopamine (7.9 μg/kg/min vs. 13 μg/kg/min) and norepinephrine (0.11 μg/kg/min; n=6 vs. 0.12 μg/kg/min; n=5) requirements. However, no outcomes attained statistical significance.

Conclusion: No significant differences resulted between hydrocortisone plus fludrocortisone and hydrocortisone alone for the primary or secondary endpoints. However, a trend towards less vasopressor requirements and decreased time on vasopressors resulted with the use of the combination group. Based on this clinical significance, we sought IRB extension and our institution is continuing to enroll patients in this study.

57E. Effect of Organ Dysfunction on Sedative and Analgesic Prescribing and Dosing in Mechanically Ventilated ICU Patients.
Stacy A. Voils, Pharm.D.[1], Gregory Chenault, Pharm.D.[2], Kimberly Varney, Pharm.D.[3], *Gretchen M. Brophy, Pharm.D.*[4]; (1)Virginia Commonwealth University Health System, Richmond, VA; (2)Virginia Commonwealth University Medical Center, Richmond, VA; (3)VCU Medical Center, Richmond, VA; (4)VCU Medical College of Virginia, Richmond, VA

Purpose: Sedative and analgesic medications are widely prescribed to ICU patients. The impact of organ dysfunction on prescribing and dosing of these medications is unknown despite existing guidelines. Presence of organ dysfunction in ICU patients may impact selection and dosing of sedative and/or analgesic medications.

Methods: Eighty-five ICUs from 42 US study sites participated in this prospective, observational study. Critical care pharmacists from the Clinical Pharmacy and Pharmacology section of SCCM were recruited to participate. Data were collected during a 24-hour period for all mechanically ventilated adult ICU patients. Patients were stratified by presence or absence of liver, renal, and cardiovascular dysfunction. Drugs selected for analysis were those with the potential to have altered pharmacokinetic/pharmacodynamic properties in patients with organ dysfunction.

Results: A total of 496 patients were included in this study. Overall, 20% of patients were hemodynamically unstable, 27% had renal dysfunction and 22% had liver dysfunction. Comparing patients with organ dysfunction versus those without, there was no difference in the use of dexmedetomidine (2% vs. 3%, p=0.58) or propofol (23% vs. 23%, p=0.99) in patients with hemodynamic instability, or in the use of morphine (0.8% vs. 2.8%, p=0.18), midazolam (12.7% vs. 16%, p=0.36), or lorazepam (10.5% vs. 7.2%, p=0.24) in patients with renal dysfunction. Presence of liver dysfunction had no effect on utilization of midazolam (16.8% vs. 14.7%, p=0.58), fentanyl (39.2% vs. 34.7%, p=0.38), or lorazepam (8.4% vs. 8%, p=0.88). Dosing of analgesic or sedative medications did not differ significantly among any group considered to have organ dysfunction when compared to patients without organ dysfunction.

Conclusion: Despite existing guidelines, presence of organ dysfunction did not affect selection or dosing of sedative and analgesic medications in mechanically ventilated ICU patients.
Published in Crit Care Med 2009; 37(12 Suppl): A982.

58. Effect of real-time unit-level visualization of prophylaxis status on the incidence of venous thromboembolism in a surgical intensive care unit.
Melissa M. Chesson, Pharm.D., Alley Killian, Pharm.D., Candace Stearns, Pharm.D., Jason Stein, M.D.; Emory Healthcare, Atlanta, GA

Purpose: Hospital-acquired venous thromboembolism (HA-VTE) is a predictable complication which increases morbidity and mortality. A large proportion of critically ill patients are considered at high risk for VTE. Despite the overwhelming evidence supporting the effectiveness of VTE prophylaxis, safe, effective, and cost-efficient methods to prevent VTE remain underutilized. This study aimed to determine whether the implementation of a real-time visualization of surgical intensive care unit (SICU) patients without VTE prophylaxis would be associated with decreased rates of HA-VTE.

Methods: Electronic medical records for 154 patients with a SICU stay and a VTE event in a 550-bed tertiary care teaching hospital between January 1, 2008 and December 31, 2009 were reviewed. The primary outcome was the rate of HA-VTE per 1000 patient days. Secondary outcomes were the rates of lower-extremity deep venous thrombosis (DVT), upper extremity DVT, pulmonary embolism, and potentially preventable HA-VTE per 1000 patient days. Outcomes were compared for the year before and after implementing real-time visualization of VTE prophylaxis status in the SICU.

Results: A total of 35 patients in 2008 were identified as having a HA-VTE compared to 18 in 2009. Rates of HA-VTE decreased significantly in the post-implementation period compared to the pre-implementation period (3.10% vs 5.84%, P<0.036). Potentially preventable HA-VTE also significantly decreased (0.52% vs 2.00%; P<0.04). Other secondary endpoints did not differ significantly.

Conclusion: Real-time visualization of VTE prophylaxis status was associated with decreased rates of HA-VTE in a SICU. Unit-level visualizations of performance may be useful for other ICU quality-of-care measures.

Drug Information

59E. Investigation of blood-brain barrier (BBB) permeability and immune-cell population of brain tissue in belatacept-treated monkeys.
Wj Freebern, M.D.; Drug Safety Evaluation, Research and Development, Bristol-Myers Squibb. Syracuse, NY, Syracuse,, NY

Purpose: A 1-month investigative monkey study was conducted to assess the ability of belatacept, a selective co-stimulation blocker in development for kidney transplantation, to cross the BBB, and to

evaluate its effects on the presence of immune cells (antigen-presenting cells, B-cells and T-cells) and expression of CD80 or CD86 in the brain.

Methods: Belatacept was administered intravenously to male cynomolgus monkeys (4/group) for 5 weekly doses of 0 (saline control), 10, or 50 mg/kg (AUC [0–168h] 15,200 and 72,400 µg•h/mL, ~1X and 6X efficacious clinical exposures, respectively). Scheduled necropsies, including whole-body saline perfusions, were conducted 24 hours after last dose.

Results: Minute levels of belatacept (<0.07% systemic exposures) were detected in CSF and brain at 10 and 50 mg/kg. The concentrations of belatacept in CSF were consistent with low-level blood contamination as demonstrated by hematology analysis of CSF samples. Minuscule concentrations of belatacept in brain were consistent with belatacept localized in residual blood within brain microvasculature, as shown via standard histologic findings of blood components in some microvasculature spaces. Immunofluorescent staining confirmed that belatacept was present in the microvasculature and not in non-vasculature portions of brain. The range of brain to serum ratios of belatacept (0.03–0.14%) were similar to those calculated for IgG and albumin (0.03–0.16% and 0.02–0.03%, respectively), proteins that do not pass the BBB in healthy animals. There were no effects on brain tissue morphology or on the presence of MHC class II cells, including macrophages, dendritic cells, granulocytes, B-cells or T-cells. Moreover, CD80 and CD86 receptor expression in the brain was very low and not altered with treatment. CD86 was not detected on the vascular endothelium.

Conclusion: The data collectively demonstrated that belatacept does not pass the BBB and has no effect on the presence of immune cells in the brain following 1 month of treatment in monkeys.

60. Midwest residents' understanding of basic concepts of evidence-based medicine and perception of drug information preparation before and after residency training.
Amy F. Wilson, Pharm.D., Philip J. Gregory, Pharm.D., Zara Risoldi Cochrane, Pharm.D.; Center for Drug Information and Evidence Based Practice (CDIEBP), Creighton University School of Pharmacy and Health Professions, Omaha, NE

Purpose: A survey of Midwest pharmacy residents was conducted to assess their understanding of basic concepts of evidence-based practice and their perception of their preparation for providing drug information services at the beginning and end of their residency year.

Methods: An anonymous survey was emailed to 198 PGY1 and PGY2 pharmacy residents from the Midwest region in June 2009. Information on residency focus, residency training facility, institution where pharmacy degree was conferred, and formal drug information training provided during the degree program was obtained. Questions regarding preparation and confidence at performing drug information activities were asked. In addition, basic knowledge questions related to evidence-based medicine were included.

Results: Of 198 surveys emailed, 115 were completed (58%). The majority of respondents (85.1%) were completing a PGY1 residency program. The program focus of respondents was as follows: pharmacy practice (61.1%), ambulatory care (9.5%); community practice (8.4%), critical care (6.3%), drug information (1.1%). The remaining 13.6% were completing programs with another focus. Nearly all (97.9%) respondents indicated that their didactic Pharm.D. program included one or more "drug information" or "literature evaluation" courses. About half (54.3%) had a drug information rotation during their Pharm.D. training. Higher numbers of respondents felt less confident in critically evaluating the literature or developing evidence-based responses. Less than 50% of respondents correctly identified definitions for evidence-based medicine and absolute risk. Approximately 70% of respondents correctly identified definitions related to relative risk and number needed to treat. The majority of respondents (55.3%) indicated the amount of drug information training in the didactic and experiential curriculum of Pharm.D. programs should be increased.

Conclusions: Based on residents' perception of drug information skills prior to starting their residency training and their belief that more drug information training is needed, additional and/or more rigorous drug information training in Pharm.D. programs should be considered.

Education/Training

61. A new analogy for teaching the well-stirred model (WSM) to pharmacy students.
Arden R. Barry, B.Sc., B.Sc.(Pharm.), ACPR, Pharm.D.[1], *Mary H.H. Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS*[2]; (1)Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC, Canada; (2)Faculty of Pharmaceutical Sciences, University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

Purpose: Educating pharmacy students about the well-stirred model (WSM) of hepatic drug clearance can be challenging. While students typically grasp the mathematical aspects, they have difficulty with the intuitive and graphical aspects. This study evaluated the effectiveness of using a novel analogy (cartoon consisting of four panels relating the WSM to patrons in a pub), in addition to a didactic lecture, to improve students' understanding of this model.

Methods: The WSM was the subject of a 2-hour session in an elective pharmacokinetics class consisting of 55 third- and fourth-year students. A 5-point Likert scale questionnaire consisting of seven questions to ascertain students' understanding of the WSM and their confidence in explaining it or applying it in practice was administered twice: pre-test 1 at the beginning of class and pre-test 2 after a 60-minute didactic lecture regarding the WSM's mathematics but before a 20-minute PowerPoint presentation of the analogy. At the end of class, students completed a post-test questionnaire containing the same seven questions, plus two additional questions regarding whether the analogy helped their understanding above explanation alone, and if it should be included in next year's class.

Results: Students' understanding of the WSM improved significantly, according to responses to all seven questions between pre-test 1 vs. pre-test 2 vs. post-test ($p<0.05$;ANOVA with posthoc LSD), with one exception. Specifically, the analogy led to significant improvement in intuitive and graphical understanding but no additional improvement in mathematical understanding beyond the didactic lecture. Furthermore, 98% of students agreed or strongly agreed that the analogy helped their understanding above explanation alone and should be included next year.

Conclusion: A novel analogy relating the WSM to a social setting of patrons in a pub led to improved student understanding of the model intuitively and graphically and will be incorporated into the course in subsequent years.

62. Student performance on and attitudes toward peer evaluations on rotation assignments.
Rochelle F. Rubin, Pharm.D., BCPS, Traci L. Turner, Pharm.D. Candidate; Midwestern University, Chicago College of Pharmacy, Downers Grove, IL

Purpose: To compare student (peer) and preceptor assessment of required rotation assignments and assess students' attitudes toward this process.

Methods: All fourth year Chicago College of Pharmacy students completing their Ambulatory Care rotation at Dreyer Medical Clinic from March 2009–February 2010 were required to complete peer evaluations on three assignments (Case Presentation, Journal Club and Drug Information Paper). The principal investigator trained all students on proper use of peer evaluations. Each student completed one peer evaluation for each required assignment on a peer's rough draft before the final assignment was due. Peer evaluation forms used the college approved grading rubric for these assignments plus additional formative feedback questions. After receiving feedback, students had the opportunity to revise before turning in final assignments. Preceptors graded final versions using the same college approved grading rubric, out of 15 possible points. At the end of the rotation students were asked to give feedback on the process.

Results: 22 students completed the peer evaluations on rotation. Descriptive statistics were used to obtain the mean score for each assignment. Mean total scores for peers evaluations were similar to preceptor evaluations for Case Presentation (13.2 vs. 12.6, p=0.599), Journal Club (12.6 vs 13.1, p=0.318), and Drug Information Paper (12.4 vs. 13.1, p=0.242). Feedback at the end of the rotation indicated

that students liked receiving their peers' feedback, plus evaluating someone else's assignment helped the students see how to improve their own assignments.

Conclusion: Peer evaluations of rough draft rotation assignments produced similar scores as preceptor evaluations of final submissions. Students often grade peers more liberally, thus a difference in peer and preceptor evaluations was expected. However, students believed the opportunity for revisions after peer feedback improved final assignments. Thus, though preceptors' evaluations are usually more strict, they were actually similar to peer evaluation.

63. Impact of implementing physical assessment in a problem-based pharmacy school course.
Justin J. Sherman, M.C.S., Pharm.D., Daniel M. Riche, Pharm.D., BCPS, CDE, Kayla R. Stover, Pharm.D., BCPS; The University of Mississippi School of Pharmacy, Jackson, MS

Purpose: This study evaluated the impact of implementing a physical assessment learning experience (PALE) into the problem-based learning (PBL) format of the third professional year of pharmacy school.
Methods: Students enrolled in a PBL group course completed a pre- and post-questionnaire for a PALE. The pre-PALE questionnaire consisted of 12 knowledge-based questions and 6 confidence-based questions, the latter in a Likert-scale format. The post-PALE questionnaire contained the initial 12 questions and added 12 similar knowledge-based questions, and the confidence-based questions were repeated. A simulation stethoscope was used to teach students abnormal pulmonary and cardiovascular sounds in 1-hour PALE sessions for each of 12 PBL groups. The pre-PALE knowledge questions were compared with both sets of post-PALE questions via a Wilcoxon signed-rank test.
Results: All 92 students completed the knowledge-based pre- and post-PALE questions. On the pre-test, an average of 4.9 ± 1.4 ($40.4\%\pm11.4\%$) responses were correct. An average of 7.5 ± 1.7 ($62.5\%\pm13.73\%$) and 7.6 ± 1.4 ($63.1\%\pm11.6\%$) on each set of post-test knowledge questions were correct. Performance on both sets of post-test knowledge questions improved significantly versus pre-test questions ($p<0.0001$). Also, the percentage of students who responded with "agree" or "strongly agree" to confidence questions regarding physical assessment tools for pulmonary and cardiovascular assessment increased an average of 13.4% after a PALE.
Conclusion: Use of a simulation stethoscope to implement a PALE increased knowledge and confidence of PBL students in performing pulmonary and cardiovascular assessment. Thorough implementation of other physical assessment techniques during this PBL course could provide further educational benefit.

64. Multi-campus colleges and schools of pharmacy in the U.S.: an update.
Heather B. Congdon, Pharm.D., BCPS, CACP, CDE[1], Lauren C. Harrison, Pharm.D. Candidate[2], Joseph T. DiPiro, Pharm.D.[3]; (1)University of Maryland School of Pharmacy, Rockville, MD; (2)South Carolina College of Pharmacy, Charleston, SC; (3)South Carolina College of Pharmacy, Medical University of South Carolina, Charleston, SC

Purpose: Assess the status of multi-campus colleges and schools of pharmacy within the United States.
Methods: Colleges and schools of pharmacy in the US were reviewed to determine whether they held classes on more than one campus. Data was collected via websites, email and phone interviews from each multi-campus program regarding their technology and communication methods, and their opinions regarding benefits and challenges of multi-campus programs.
Results: Twenty schools and colleges of pharmacy (18 public, 2 private) had multi-campus programs; 16 ran parallel campuses (students attend one of multiple campuses during the first 3 years) and 4 ran sequential campuses (students move from one campus to another during first 3 years). 12 of 16 parallel campus schools used synchronous class delivery. Students communicated with one another mostly through videoconferencing or web-cam technology. Almost half of those programs used live on-line chat rooms and forums,

online discussion boards, or electronic office hours. All sequential campus schools taught classes at one site only for a specific class year. The most frequently reported reasons for establishing multi-campus programs were to have access to a hospital and/or medical campus and clinical resources located away from the main campus and to increase class size. Effectiveness of distance education technology was most often cited as a challenge.
Conclusion: About 20% of colleges and schools of pharmacy have multi-campus programs most often to facilitate access to clinical resources and to increase class size. These programs expand learning opportunities and face challenges related to technology, resources, and communication.

65. Email communication: Faculty and students' expectations and perceptions of accessibility and response time.
Pamela A. Foral, Pharm.D., BCPS[1], Jennifer J. Merkel, Pharm.D. Student[1], Paul D. Turner, Ph.D.[2], Thomas L. Lenz, Pharm.D.[1], Michael S. Monaghan, Pharm.D.[1], Ryan W. Walters, M.S.[2]; (1)Creighton University School of Pharmacy and Health Professions, Omaha, NE; (2)Creighton University Medical Center, Omaha, NE

Purpose: The convenience and continuous accessibility of email communication place new demands on faculty. Our objective was to investigate expectations/perceptions on faculty accessibility and response time to email communication within a pharmacy program.
Methods: Data were collected via survey employing three parallel questionnaires with phrasing tailored specifically for the campus student, distance student, or faculty member. A table of specifications guided statistical analyses. Omnibus effects were tested by Kruskal-Wallis tests and post-hoc analyses utilized Mann-Whitney U tests. Bonferroni adjustments were employed to reduce the probability of Type I errors.
Results: Overall, 80.2% of those surveyed responded (N=566; n=194, 324, 48 for distance, campus, and faculty respectively). Significant differences were indicated in the expectation faculty should be available outside normal business hours the night before an exam with campus/distance students agreeing significantly more than faculty, $Z=47.39$, $p<0.001$, and campus students agreeing significantly more than distance students, $Z=5.11$, $p<0.001$. Additionally, faculty perceive they are accessible to answer email questions agreeing significantly more than campus/distance students, $Z=34.03$, $p<0.001$. Significant differences were found in the perception that email questions are the same type of question a student would ask in the classroom, with distance students agreeing significantly more than campus students and faculty, $Z=54.98$, $p<0.001$. Faculty are less likely to agree with the campus/distant students that they consistently formulate the answer to their question prior to asking, $Z=81.81$, $p<0.001$. Interestingly, campus students expect a shorter email response time from faculty compared to the distance students, $Z=5.38$, $p<0.001$, and a shorter email response time from faculty the day prior to an exam compared to faculty and distance students, $Z=23.53$, $p<0.001$.
Conclusion: We identified expectation differences on accessibility and email response times, which benefit all pharmacy programs utilizing email communication. Clear expectations should be developed and incorporated into course syllabi to address these issues.

66. Admission type as a predictor of performance in a problem-based learning course series.
Daniel M. Riche, Pharm.D., BCPS, CDE, Kayla R. Stover, Pharm.D., BCPS, Gary D. Theilman, Pharm.D., Joel R. Pittman, Pharm.D.; University of Mississippi School of Pharmacy, Jackson, MS

Purpose: At the University of Mississippi School of Pharmacy, the problem-based learning (PBL) course series during professional year-3 (PY-3) is generally considered the most difficult component of the curriculum. This project is intended to ascertain if any difference in performance during this course series is predictable based on admission type.
Methods: This retrospective review analyzed admission-type and student academic performance in the PBL course series from 2002-2009. Student scores were compiled based on admission type into 3 groups: early entry (high school admission), previous degree (bachelor's degree or higher), and no degree (some college). Each

student's scores for the year were averaged, providing individual performance measures. A *t*-test was used for continuous data, and a χ^2 was used for dichotomous data.

Results: Six-hundred students have received at least one score in the PY3 PBL course series. Fifty-six percent of these students (n=333) were admitted with "no degree", while the remainder of students were split between "early entry" (n=125) and "previous degree" (n=142). "Early entry" students had significantly higher scores than either the "no degree" or "previous degree" students (p<0.0001 for both). "Early entry" also had significantly fewer students fail a course versus "no degree" (3 fold higher) and "previous degree" (6-fold higher) groups (p<0.0001 for both). Additionally, the "no degree" students had significantly higher averages and fewer failing grades compared to the "previous degree" students (p<0.01 for both).

Conclusion: Students admitted into our early entry program perform better than any other admission type in the PBL course series. Additionally, students admitted with a previous degree are most likely to be unsuccessful in the PBL course series.

67. Pharmacy students' pain management confidence versus competence.

Mark A. Douglass, Pharm.D., Margarita V. DiVall, Pharm.D., BCPS, Jason Lancaster, Pharm.D., BCPS, Michael J. Gonyeau, B.S., Pharm.D., BCPS, Adam Woolley, PharmD, BCPS; Northeastern University School of Pharmacy, Boston, MA

Purpose: To compare pharmacy students' confidence versus competence in selected pain management skills.

Methods: Pharm.D. students within their third (P3) and fourth (P4) professional years were asked to complete a questionnaire that assessed their self-reported comfort level (confidence) with a knowledge assessment (competence) of four pain management skills (managing chronic-continuous pain, equianalgesic dose conversion, breakthrough pain, and opioid side effects) using standardized case vignettes. The survey was administered to 100 P3's at the conclusion of a pain management Therapeutics lecture, and to 112 P4's following the end of their Advanced Pharmacy Practice Experiences (APPEs). A Fisher's exact test was used to compare confidence and competence measures.

Results: The overall questionnaire response rate was 78% (166/212). P3's were more confident than P4's in all four pain management skills and significantly more confident in three of four skills: chronic-continuous pain, p=0.02; equianalgesic dose conversion, p=0.003; breakthrough pain, p<0.0001. The P3's exhibited significantly more competence in managing chronic continuous pain (p=0.03) and were nonsignificantly more competent than P4's in equianalgesic dose conversion, and opioid side effects.

Conclusions: Despite an additional year of advanced clinical practice experiences, P4 Pharm.D. students lack confidence and competence in pain management skills, compared to less experienced P3 students. A more thorough assessment of classroom versus APPE pain management content and skills is needed to address this disparity between P3 and P4 confidence and competence.

68E. Implementation of a pharmacy political advocacy elective.

Elizabeth W. Blake, Pharm.D., Richard Schulz, Ph.D.; South Carolina College of Pharmacy, University of South Carolina Campus, Columbia, SC

Purpose: Per defined educational outcomes, students are expected to have some awareness and involvement in public health issues upon graduation from an accredited school of pharmacy. To help achieve this objective, the elective Pharmacy Political Advocacy was created to enable pharmacy students to become aware of and actively involved in legislative issues affecting pharmacy and/or healthcare by providing them with various ways to become advocates and influence legislative decisions.

Methods: The class convened during the spring semester 2008 through 2010 to coincide with the legislative session of the South Carolina State House. Various speakers with legislative influence were invited to speak to the class of second-year pharmacy students. Additionally, students completed various assignments throughout each semester, including identifying the advocacy agendas for pharmacy associations and relating them to their own beliefs, participating in classroom debates, and developing presentations describing healthcare legislative issues. At the end of the semester, students completed a 45-item questionnaire to assess the impact of this course on their knowledge of political activity and potential for future advocacy.

Results: Of the 40 respondents (80% response rate), 37 agreed or strongly agreed that the class increased their knowledge of current issues. Almost all (38 respondents) agreed or strongly agreed that the class increased their awareness of legislation that would affect the pharmacy profession. Thirty-nine respondents learned how to obtain information regarding legislation that would affect the pharmacy profession after participating in this class. Sixty-eight percent of the respondents plan to become involved with a pharmacy organization in a leadership capacity in the future.

Conclusion: Participation in an elective devoted to pharmacy political advocacy increased awareness of legislation and the desire to become involved in pharmacy organizations to promote the pharmacy profession.

Presented at Presented at the South Carolina Pharmacy Association, Myrtle Beach, SC, June 26, 2009. Presented at the South Carolina Society of Health-System Pharmacists, Hilton Head, SC, March 14, 2010.

69. Enhancing student success through creating a community of learners.

Lynette R. Moser, Pharm.D., Micah J. McCuistion, Pharm.D. Candidate, Francine D. Salinitri, Pharm.D., Helen D. Berlie, B.Sc., Pharm.D., Richard Slaughter, B.S., M.S.; Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI

Purpose: To evaluate the impact of a learning community (LC) on academic success among second year (P2) pharmacy students.

Methods: The P2 class attended an orientation workshop and participated in 4 mandatory LC sessions per semester. These sessions were designed to identify and address deficiencies in student knowledge and study skills. P2s were divided into 6 groups with each assigned a third year peer mentor (PM). PMs worked with course coordinators to develop LC sessions. Academic success was determined by comparing progression in the program and grade distribution in individual courses. Surveys after each LC session assessed whether the sessions influenced their studying, if they learned new study techniques, and if the PM enhanced the experience. PM surveys evaluated their benefit from the experience.

Results: Ninety P2s and 6 PMs participated in the program. Successful progression was improved in the current class (98% with 2 failures) compared to the previous class (87% and 15 failures). Six of the 7 courses required in the P2 year had a significant increase in the number of A's compared to the previous year (30% ± 18 vs. 19% ± 14, p=0.03). The number of B's and C's did not differ between the 2 years. Combining the survey results from the 8 sessions, 71% ± 6% reported that their group worked well together, 50% ± 15% agreed that the sessions affected their study habits, 92% ± 4 believed the PM enhanced the session. Five out of 6PM's responded and rated their overall experience as great or exceptional. The biggest challenges identified by PMs were student receptiveness and balancing time commitments.

Conclusion: Implementation of a learning community in the second year pharmacy curriculum resulted in improved academic outcomes.

70. Design and implementation of a pharmacy residency teaching certificate program.

A. Shaun Rowe, Pharm.D., BCPS[1], Shaunta' M. Ray, Pharm.D., BCPS[2]; (1)The University of Tennessee Medical Center, Knoxville, TN; (2)The University of Tennessee College of Pharmacy, Knoxville, TN

Purpose: We describe the development and administration of a teaching certificate program for pharmacy residents. The goals of this study were to illustrate the methods of developing such a program and measure the ability of this program to increase the knowledge of pedagogy in PGY1 and PGY2 residents.

Methods: A comprehensive program, including didactic and

experiental learning experiences, was designed and administered to PGY1 and PGY2 residents from July 2007 through June 2010. All residents completed a pre- and post-experience assessment. The survey consisted of 30 questions on a five-point likert scale. The questions were designed to assess the residents' confidence in their ability to: teach in different environments, effectively manage classroom dynamics, develop organizational materials such as learning objectives and syllabus, administer presentations effectively, assess classroom learning, develop career support materials such as a teaching portfolio and effective curriculum vitae, and provide appropriate feedback. Scores were aggregated and analyzed for statistical significance using a Wilcoxon Matched-Pairs Signed Rank Test.

Results: A total of 6 residents have completed the program. Results are presented as median [IQR]. Overall, numeric and statistical improvement was seen in most areas of assessment (3[0.5] vs. 4[0.375], p<0.05). statistical improvement was not seen in four of the questions asked, which dealt with preparing a presentation for a specific audience, using PowerPoint™, and dealing with unprofessional behavior. All of these questions had a pre-experience score of 3 or greater (3[1]). High pre-experience score in these areas may account for the observed non-statistical change. Areas with the largest improvement included writing instructional objectives (Δ2) and designing teaching methods to achieve those objectives (Δ1.75), preparing a teaching portfolio (Δ2), assessing classroom learning (Δ1.75) and giving feedback (Δ1.75).

Conclusion: The program successfully improved the residents' self-perceived ability to perform the essential functions necessary for providing high quality education.

71E. Impact of pharmacy students on advanced pharmacy practice experiences at a community non-teaching hospital.

Angela O. Shogbon, Pharm.D., BCPS, Lisa M. Lundquist, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

Purpose: To assess the impact of pharmacy students on advanced pharmacy practice experiences (APPE) at a community non-teaching hospital by evaluation of clinical interventions for cost savings, intervention class, and acceptance rate.

Methods: Clinical interventions of 18 fourth-year pharmacy students on Medication Safety (n=5), Advanced Institutional (n=5) and Internal Medicine (n=8) APPE were collected from June 2009 to December 2009. Students documented their daily clinical interventions on a data collection form. The clinical intervention types were therapeutic (antibiotic recommendations, medication initiation/discontinuation), safety (dose evaluation, drug interactions), quality assurance (medication history, duplicate avoidance), lab evaluation, IV to PO, and information/education. The data were entered into a pharmacy intervention database for analysis of total cost savings, intervention class, and acceptance rates.

Results: A total of 318 clinical interventions were attempted (76 medication safety, 54 advanced institutional, 188 internal medicine). The total cost savings was $33,955. The types of interventions included: therapeutic (n=37, 11.6%), safety (n=16, 5%), quality assurance (n=27, 8.5%), lab evaluation (n=15, 4.7%), IV to PO (n=93, 29.2%), and information/education (n=130, 40.9%). Internal medicine APPE students contributed to most of the therapeutic (91.9%), safety (93.8%), quality assurance (92.6%) and lab evaluation (93.3%) interventions. Acceptance rate for all interventions was 96%.

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

Presented at Presented at the American Association of Colleges of Pharmacy Annual Meeting and Seminars, Seattle, WA, July 12, 2010

72. Pharmacy student expectations of an online diabetes elective offered in an accelerated Doctorate of Pharmacy program.

Courtney I. Jarvis, Pharm.D.[1], Helen Pervanas, Pharm.D.[2], Heather Upchurch, Pharm.D.[3]; (1)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Worcester, MA; (2)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Manchester, NH; (3)Holyoke Health Center, Holyoke, MA

Purpose: This study evaluated the experiences and expectations of pharmacy students enrolled in the first-time offering of an exclusively online elective course; including: 1) previous online course experience, 2) anticipated difficulty compared to traditional face-to-face courses, 3) primary reason for selecting the online course, and 4) anticipated challenges of online courses.

Methods: On the first day of class, a total of 36 first-year accelerated PharmD students enrolled in the online diabetes elective course were asked to complete an anonymous survey.

Results: Surveys were completed by all 36 students. The majority of students (69.4%) reported their age as less than 25 years and 63.9% were male. Previous experience with college-level online coursework prior to entering the pharmacy program was reported by 53% of students; 92% in exclusively online courses and 21% with some face-to-face interaction. Most agreed that the online format would offer greater flexibility with their schedules (97%) and have an equal difficulty level compared to a traditional face-to-face course (91%). The most commonly reported reasons for selecting the online elective were diabetes related content (72%) and exclusively-online format (25%). Participation in online discussion boards (41.7%), time management (30.6%), and online lectures (27.8%) were the biggest anticipated challenges in an online course.

Conclusion: Many pharmacy students have previous experience with online courses prior to entering pharmacy programs, however many pharmacy schools do not offer online coursework. Our survey indicates that first year pharmacy students expect that an online elective course will be equally as difficult as a traditional face-to-face course and will provide greater flexibility with their schedule. Despite the greater flexibility, course content was rated as more important than online availability of the course.

73. Critical literature evaluation: student preparedness before and after advanced pharmacy practice experiences.

Kathryn M. Momary, Pharm.D., BCPS, *Lisa M. Lundquist, PharmD, BCPS*; Mercer University, Atlanta, GA

Purpose: Compare students' performance and perceptions of preparedness to critically evaluate literature before and after advanced pharmacy practice experiences (APPE).

Methods: A perception of preparedness questionnaire and a knowledge assessment were distributed to the students in January 2009 (before APPE) and in May 2010 (after APPE). The knowledge assessment and preparedness instrument consisted of questions related to core knowledge and application of critical literature evaluation. Students were asked to rate the adequacy of their preparedness on a 4-point Likert scale with 1 = extremely unprepared, 2 = unprepared, 3 = prepared, and 4 = extremely prepared. Knowledge assessment was done via a 9-question multiple choice quiz. Data collection for this study was approved by the Institutional Review Board and students signed informed consent prior to participation in 2009 and 2010. Students' perceptions of preparedness and performance before and after APPE were compared with descriptive statistics and Pearson's correlation; pre- and post-APPE data were compared with paired t-test.

Results: One hundred three students (71.5%) consented for participation and completed all pre- and post-APPE perception of preparedness questionnaires and knowledge assessments. The perception of preparedness mean (SD) increased significantly from 2.23 (0.48) pre-APPE to 2.95 (0.42) post-APPE [p<0.001]. Knowledge assessment also increased significantly from 56.2% (17.6%) pre-APPE to 60.5% (15.8%) post-APPE [p=0.035]. There was a statistically significant correlation between the pre- and post-APPE knowledge assessment and perception of preparedness (p<0.001 and p<0.001, respectively).

Conclusion: Through clinical experiences during APPE, students' perceptions of preparedness and knowledge of critical literature evaluation statistically significantly improved. However, student knowledge is still poor. APPE provide an invaluable opportunity to reinforce and expand knowledge of literature evaluation and its

importance as a practicing pharmacist. Increased review of critical literature evaluation during APPE will likely further improve student performance.

74. A novel approach to anticoagulation course instruction: Incorporation of a patient modeling component.

Candice L. Garwood, Pharm.D., Maureen A. Smythe, Pharm.D.; Wayne State University, Detroit, MI

Purpose: The AACP 2007 Graduating Student Survey conducted at Wayne State University identified didactic elective availability as an area of concern. As a result, a new two credit hour anticoagulation elective course was developed for third year Pharm.D. students. The overall goals of the course were to expand the anticoagulant knowledge and patient management skills already gained and to ensure students developed an understanding of the patient's perspective of anticoagulation therapy.
Methods: The course was taught entirely though the use active learning strategies including case based discussions, an experiential site visit and a team project. The most innovative strategy was the living with anticoagulation assignment. This unique patient and health care provider role modeling exercise was designed to develop anticoagulation management skills and patient empathy skills. In the assignment students played the role of a patient and managed themselves as a caregiver simultaneously. Students wrote a SOAP note and a reflection of their experience. An anticoagulation competency test was administered on the first and last day of class. Case based midpoint and final exams were part of the course assessment plan. Students completed an 8 question survey to assess the living with anticoagulation assignment.
Results: Student performance on the anticoagulation competency exam increased from 58.6% to 83.1%. All students (n=10) scored > 90% on a case based final exam. Reflective narratives of the living with anticoagulation assignment provided support of student development of patient empathy. On the survey, 100% of students either agreed or strongly agreed that the living with anticoagulation assignment: "improved ability to manage anticoagulation therapy with confidence", "improved anticoagulation management skills", and "increased empathy for patients on anticoagulation therapy."
Conclusion: The construct of this course enabled the use of active teaching strategies which took learning beyond the classroom setting, in attaining the planned learning objectives.

75. Synchronous distance learning technology in an application-based PharmD course: an inter-campus comparison of student learning and perception.

Courtney I. Jarvis, Pharm.D.[1], Maryann R. Cooper, Pharm.D., BCPS, BCOP[2], Kimberly A. Pesaturo, Pharm.D., BCPS[1]; (1)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Worcester, MA; (2)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Manchester, NH

Purpose: Synchronous distance learning technology is becoming more prevalent in Doctor of Pharmacy degree programs in the United States. However, little data is available regarding consistency of student grades and perceptions between multiple campuses in application-based courses that utilize this technology. The goal of this study is to compare inter-campus student learning and perception in a core course (drug literature evaluation) for first year Pharm.D. students delivered via synchronous distance technology from an on-site to a remote classroom.
Methods: This is a retrospective evaluation designed to compare student grades and course perceptions between on-site and remote-site campuses in a core application-based course. The primary endpoint is the comparison of rubric-based grades between campuses for three application-based assignments (conducting literature searches, analyzing journal articles, and answering drug information questions). Secondary endpoints include inter-campus comparisons of: multiple-choice based examination grades, final course grades, and numerical Likert scale data on student course perception. A pre-defined significance level was set at 0.05.
Results: A total of 247 students participated in the course (194 on-site; 53 remote site). There was no difference in rubric-based

assignment grades for three assignments between the on-site and remote site campuses (88.11% versus 89.03%, p=0.60; 85.80% versus 84.81%, p=0.51; 88.55% versus 88.08%, p=0.71, respectively). There was no difference between multiple-choice based examination grades or final course grades. There was no difference in median Likert data between campuses, despite limited student response (54/247 = 22% response rate).
Conclusion: Synchronous learning technology does not alter inter-campus rubric or multiple-choice based examination grades in an application based course for Pharm.D. students. This implies that these may be valid methods of assessment of student learning in a distance-education environment. Student course perception is not affected by distance education.

76. Communication of clinical recommendations during cardiovascular therapeutics oral examinations.

Lisa M. Lundquist, Pharm.D., BCPS, Kathryn M. Momary, Pharm.D., BCPS, Angela O. Shogbon, Pharm.D., BCPS, Sharon L. Leslie, M.S.L.S., AHIP; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

Purpose: To compare students' self-assessment and faculty evaluation of communication of clinical recommendations during therapeutics oral examinations.
Methods: Two patient case-based oral examinations were given to all second-year pharmacy students enrolled in the Cardiovascular / Renal III therapeutics course (one individual and one in groups of 4 students). Students were provided with patient cases prior to each oral examination. In addition to evaluation of pharmacotherapy knowledge, faculty evaluated students' communication skills using a scoring rubric divided into two areas: rapport (confidence, non-verbal, tone of voice, eye contact) and presentation of therapeutic recommendations (concise, correct pronunciation, well-prepared, patient-focused). Immediately following each oral examination, students self-assessed their communication skills using the same rubric. This study was approved by the IRB and students signed informed consent prior to participation. Students' self-assessments were compared to faculty evaluation of their communication skills using descriptive statistics and paired *t*-tests.
Results: A total of 136 (97.8%) students completed communication self-assessments following each oral examination. For the individual oral examination, mean (SD) student self-assessment of communication was 3.27 (0.49); faculty evaluation was 3.50 (0.41). For the group oral examination, mean student self-assessment of communication was 3.41 (0.49); faculty evaluation was 3.60 (0.31). Faculty evaluations in both the individual and group oral examinations were statistically significantly higher than the student self-assessments (p<0.001 for both). In addition, students' self-assessment of communication increased from the individual examination to the group examination (p<0.001).
Conclusion: Students' self-assessment of communication skills were consistently lower than the evaluation scores provided by faculty. A potential cause of students' lower self-assessment may be a lack of practice in the verbal communication of clinical recommendations, which is supported by the increase in student self-assessment with the second oral examination. Greater utilization of formal case-based oral examinations may help to improve student's confidence and self-assessment of their communication skills.

77. Patient case-based oral examinations: four years of experience comparing students' performance and perceptions of preparedness.

Lisa M. Lundquist, Pharm.D., BCPS[1], Angela O. Shogbon, Pharm.D., BCPS[1], Kathryn M. Momary, Pharm.D., BCPS[1], Justine S. Gortney, Pharm.D., BCPS[2]; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2)Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI

Purpose: To compare students' performance and perceptions of preparedness for patient case-based oral examinations over a four year period.
Methods: A case-based individual oral examination was given to all second professional year pharmacy students enrolled in the

Cardiovascular / Renal III therapeutics course for four consecutive years. The patient case was provided prior to the oral examination. Voluntary survey completion was requested prior to the oral examination to assess the students' perceptions of preparedness on a 4-point Likert scale with 1=extremely unprepared, 2=unprepared, 3=prepared, and 4=extremely prepared. Data collection for this study was approved by the Institutional Review Board and students signed informed consent prior to participation. Students' perceptions of preparedness were compared to performance on the oral examination using descriptive statistics and Pearson's correlation.

Results: A total of 141 (96%) surveys were received year one, 101 (72%) year two, 71 (48%) year three, and 137 (99%) year four. The mean (SD) overall student performance and perception of preparedness for the oral examination were 93.2% (7.45%) and 3.41 (0.34) in year one; 87.5% (6.29%) and 3.18 (0.37) in year two; 72.3% (15.2%) and 2.64 (0.48) in year three; 90.7% (8.99%) and 3.47 (0.35) in year four, respectively. Interestingly, there was little correlation between students' performance and perception of preparedness in any of the four years (r=0.20, r=0.13, r=0.27, r=0.08, years one through four, respectively.)

Conclusion: During four consecutive years of oral examinations in a therapeutics course, little correlation was seen between students' perceptions of preparedness for the oral examination and their actual examination scores. Increased utility of case-based oral therapeutic examinations may improve the correlation between students' perception of preparedness and their performance in making clinical recommendations. This is important because the ability to provide verbal clinical recommendations is key to the practice of pharmacy.

78. The benefits of utilizing a learning plan for professional development in fourth year pharmacy students on clinical rotations.
Christy M. Weiland, Pharm.D., BCPS, Mary Onysko, Pharm.D., BCPS, Kem Krueger, Pharm.D., Ph.D; University of Wyoming, Laramie, WY

Purpose: The purpose of the students' personalized learning plan is to identify self perceived areas of improvement during a clinical rotation. Secondary outcomes are to identify if the learning plan improves the students' perceived ability to identify and achieve learning needs.

Methods: Students selected 5 out of 13 competencies to work on during the rotation (e.g. patient communication, journal club presentations, etc.). Each competency was categorized into: communication, evidence based medicine, or patient care. For each competency, the student identified 3 responsibilities to focus on and rated themselves on a scale (1= "I require significant guidance" to 3= "I require minimal guidance"). A summed score was calculated for each competency (potential score range: 3–9). Students were given one week to complete a pre and post personalized learning plan for the academic year 2009–2010 during an Internal Medicine and an Ambulatory Care rotation. The pre-learning plan was reviewed with each student to assist the student in reaching his or her goals. The post learning plan was reviewed to discuss if the professional goals were achieved. Wilcoxon Signed Rank Test was used to analyze changes in pre-post scores. Logistic regression was used to analyze differences in responses by rotation type or competency category

Results: Fourteen pharmacy students completed a pre and post rotation personalized learning plan, identifying a total of 66 competencies. The competencies most frequently cited for improvement were: Presentations (20%), Journal Club (18%), and Communication with providers (15%). The summed score improved an average of 2.2 points (p<0.001). No significant difference was detected between rotation type or competency category.

Conclusion: This tool is useful to help students identify areas of improvement. It also personalized the rotation activities. The results provide informal feedback to the curriculum committee to identify areas where students may need additional practice.

79. An evaluation of employers' perceptions on the value of a pharmacy resident teaching certificate program.
Douglas L. Jennings, Pharm.D., BCPS, (AQ, Cardiology)[1], Ayesha Kheiri, Pharm.D.[2], James S. Kalus, Pharm.D.[1]; (1)Henry Ford Hospital, Detroit, MI; (2)Butler University, Indianapolis, IN

Purpose: Many pharmacy residency programs have developed teaching certificate programs to provide residents with the skills required to be successful educators. Although there are studies evaluating the resident's perceptions of teaching certificates, little is known about the perception of potential employers. The purpose of the study is to describe the perceived value of teaching certificate programs by college of pharmacy department chairs (DC) and experiential coordinators (EC) and define which aspects of these programs they consider to be most important.

Methods: A survey of all college of pharmacy DC and EC was conducted from February 27, 2008 to March 26, 2008 via electronic mail. Contact information was obtained from college of pharmacy websites. The survey consisted of a demographic section and two sections designed to evaluate the subjects' perceptions. The first section assessed the value of informal versus formal teaching training, while the other section was designed to identify desirable skills and experiences of potential pharmacy faculty or preceptors.

Results: The response rate was 46 of 99 for DC and 24 of 99 for EC. DC and EC agree that a residency teaching certificate program is suitable training for pharmacists who will have either didactic (72.8%) or clinical (71.4%) teaching responsibilities. Also, attending seminars focused on the development of teaching skills was perceived as being valuable for pharmacists who will be either full-time faculty (100%) or adjunct faculty/preceptors (97.2%). For full-time faculty candidates, DC most valued presenting didactic lectures (84%), completing research (88%), and manuscript preparation (78%). For adjunct faculty/preceptors, EC most valued informal topic discussions (77%) and precepting students (85%).

Conclusion: Both DC and EC feel that a teaching certificate program during residency provides valuable training to candidates for jobs as full-time faculty or adjunct faculty/preceptors.

80. Evaluation of a virtual poster presentation defense in Second Life to prepare pharmacy students for live presentation.
Peter G. Koval, Pharm, D; Moses Cone Family Practice Center, Greensboro, NC

Purpose: This study utilized a virtual poster session to assist pharmacy students acclimate to the professional task of sharing and defending research. The goals were to improve student communication skills and effectiveness in presenting clinical research while more efficiently utilizing pharmacy school faculty in student development through the use of a virtual experience.

Methods: Final year students completing clinical research projects were randomly selected to participate in a virtual poster presentation using Second Life (SL). Both students and faculty participants received a brief (<60 minute) orientation to SL. Three poster presentation times were scheduled and pharmacy faculty members from across the state were assigned to evaluate the presentations. Student participants defended their uploaded posters using the interactive voice feature in SL. Formative feedback was provided via a standardized poster evaluation rubric. All presenters received written feedback from at least two faculty evaluators.

Results: All students (n=33) and 80% (n=10) of faculty had never used SL prior to this project. The majority of students (87.5%) and faculty (71%) agreed that the time to learn and become comfortable in 2L was worth the utility of using 2L. The intervention students consistently agreed that the SL training improved their ability to present and defend their research. Following the live presentation none of the intervention group versus 14% of the control students reported feeling "unprepared to present". Following the virtual poster presentation all faculty participants agreed with the statement "in cases where I cannot travel, SL is a reasonable way to evaluate poster presentation delivery".

Conclusion: The use of a virtual poster presentation defense in Second Life is an effective way to prepare pharmacy students for live presentation.

81. Impact of training student pharmacists on an electronic platform to document MTM encounters.
Anne C. Pace, Pharm.D., *Schwanda K. Flowers, Pharm.D.*; University of Arkansas College of Pharmacy, Little Rock, AR

Purpose: Arkansas Pharmacists are having difficulty integrating Medication Therapy Management (MTM) into their community practice. Third year pharmacy students receive training on MTM electronic documentation using a commercially available an electronic platform. Therefore, the two required Community Pharmacy Practice Advanced Pharmacy Practice Experiences (APPE) represent an opportunity to educate pharmacists on completing MTM cases, and provide manpower to this important endeavor. The purpose of this study is to determine if training students on MTM electronic documentation had improved the ability of pharmacists to perform MTMs.

Methods: A nine question survey was distributed to 105 senior student pharmacists after completion of their APPEs. All members of the senior class were eligible to participate; students were provided a request for voluntary participation, rationale for the study and the risks and benefits of their participation prior to participating. No personal identifying information was collected. Data was analyzed using descriptive statistics.

Results: 95 students completed the survey. Of those, 41 performed an MTM during their APPEs, with 25 students completing 1–2 cases and 16 completing 3 or more. 12 students enrolled their pharmacy in an MTM program (12.6%). 59% reported that training on the electronic platform made them more comfortable performing MTM's and 49.5% responded they were comfortable or very comfortable in performing MTM's.

Conclusion: Training third year students on MTM electronic documentation using a commercially available electronic platform increases their ability to document MTM prior to entering their APPEs. This training helps students gain confidence in performing MTM and provides trained manpower to assist Arkansas community pharmacies in initiating and providing MTM services to their patients.

82. Assessing pharmacogenomics education in pharmacists.

Christine M. Formea, Pharm.D., Wayne T. Nicholson, M.D., Pharm.D., Kristen B. McCullough, Pharm.D., Kevin D. Berg, B.S.Pharm., Melody L. Berg, Pharm.D., Julianna A. Burzynski, Pharm.D., Julie L. Cunningham, Pharm.D., Narith N. Ou, Pharm.D., Joanna L. Stollings, Pharm.D.; Mayo Clinic, Rochester, MN

Purpose: This study measured the impact of a pharmacogenomics education program presented to Mayo Clinic inpatient and outpatient pharmacists.

Methods: An 11-question, electronic educational survey was provided to 272 pharmacists. The multiple-choice survey probed pharmacists' knowledge relative to targeted administration of a pharmacogenomics education program. Survey domains included pharmacogenomics fundamentals, metabolism, and Food and Drug Administration pharmacogenomics labeling. The survey was administered in a matched fashion at baseline and two months after delivery of education by the Mayo Clinic Survey Research Center in order to maintain respondents' anonymity.

Results: Of the initial survey administration to 272 inpatient and outpatient pharmacists, 84 completed both surveys (31% response rate). On average, pharmacists significantly improved their test scores by 0.65 questions (pre-test average 46%; post-test average 53%, p=0.0006). There was a trend towards improvement in test scores based upon attendance of additional pharmacogenomics expertise lectures (p=0.056). Although pharmacists self-reported an increased delivery of pharmacogenomics information to health care providers, the increase was not significantly different (pre-test 19%; post-test 25%, p=0.13).

Conclusion: Pharmacogenomics is a rapidly expanding field that is marching from the bench top towards bedside application. As the era of personalized medicine changes the face of pharmacotherapeutics, pharmacists are being challenged to increasingly incorporate pharmacogenomics knowledge into their daily practices. In this study, pharmacists who participated in a pharmacogenomics education program demonstrated marginal, although significant, improvements on pharmacogenomics test scores. The results of this educational experience suggest that pharmacogenomics is a complex topic that requires a large resource investment to effectively improve pharmacists' pharmacogenomics knowledge and clinical confidence at the bedside.

83. A qualitative analysis of students' motivations for pursuing pharmacy as a potential vocation.

Michael W. Firmin, Ph.D.[1], Valerie Bouchard,[1], Jordan Flexman,[1], *Douglas C. Anderson Jr., B.S.Pharm., Pharm.D.*[2]; (1)Cedarville University, Cedarville, OH; (2)Cedarville University School of Pharmacy, Cedarville, OH

Purpose: We present the findings from a phenomenological, qualitative research study that explored the personal constructs of an inaugural class, entering a newly-established direct-entry, preferred admission, pre-pharmacy program at a private, selective, Midwestern university with an enrollment of 3000. The focus of the study was to appraise students' perceptions regarding their rationale for pursuing a future career in pharmacy and the psychological dynamics involved with the decision-making.

Methods: Data was collected via in-depth interviews of each student who had enrolled in first year of the program. Open coding procedures were utilized in analyzing the data, generating themes that represented the consensus of the participants' stated perceptions. Internal validity for the study was enhanced via generating a data trail, the use of an independent qualitative investigator, member checking, and saturation that occurred through constant-comparison of new transcripts with previously collected interview data. The survey was approved by the IRB and all students gave informed consent.

Results: The sample consisted of 36 students (26 females, 10 males). Results showed participants in our study were influenced by a variety of cognitions, experiences, and people as they decided to pursue pharmacy. Overall, students demonstrated their belief that they would be a good fit for the pharmacy field and looked forward to enjoying their future profession. Participants also evidenced a penchant for science and healthcare, and having previously interacted with pharmacists and the pharmacy field prior to entering college. Benefits such as salary, job security, and prestige were of secondary importance to students, but they played a role nonetheless, and encouragement from parents and other respected individuals also was significant. Overall, these factors contributed to students' perceptions that they would fit in the field of pharmacy.

Conclusion: We relate the results broadly, including applications for those interested in recruitment and retention of pharmacy students.

84. Interprofessional Education Utilizing Human Patient Simulation Scenarios.

Megan Willson, Pharm.D.[1], Brenda S. Bray, B.Pharm., M.P.H.[1], Don Coerver, Ph.D., PA-C[2], Suzan Kardong-Edgren, Ph.D., R.N.[3], Mark W. Garrison, Pharm.D.[1]; (1)Washington State University College of Pharmacy, Spokane, WA; (2)University of Washington, Medex PA Program, Spokane, WA; (3)Washington State University College of Nursing, Spokane, WA

Purpose: To describe the use of human patient simulation (HPS) scenarios in interprofessional education involving students from different healthcare disciplines representing three regional colleges.

Methods: Since May 2009, faculty from the Washington State University (WSU) Colleges of Pharmacy and Nursing and University of Washington (UW) physician assistant (PA) program have collaborated to conduct interprofessional HPS scenarios in the following content areas: Adult Shortness of Breath, Advanced Cardiac Life Support (ACLS) and Pediatric Respiratory Distress. Doctor of Pharmacy (WSU), Nursing (WSU and Spokane Community College) and PA (UW) students were included in all three scenarios with the addition of first year medical students (UW) during the ACLS scenario. Each scenario lasted approximately 20 minutes and was immediately followed with a 30-minute debriefing session facilitated by faculty from all disciplines. The four global learning objectives for each simulation included the following: * Demonstrate appropriate discipline specific skills. * Diagnose and implement appropriate initial treatment plan. * Demonstrate professional communication skills in a healthcare team. * Communicate effectively when giving a patient case report for nursing change of shift and/or a clinical case presentation to a consultant or preceptor.

Results: Throughout the three scenarios, a total of 23 students from the various programs participated. During the debriefing session, students were able to reflect on their individual roles as well as the

interactions of the team. For each scenario a common theme has emerged centering on lack of familiarity with each other's roles.
Conclusions: These simulation scenarios are unique because multiple healthcare disciplines and different academic institutions all worked together. Challenges included the coordination of academic and class schedules across programs and matching appropriate skill levels amongst the students. Continued efforts are underway to expand interprofessional opportunities to allow wider student participation and to develop scenarios in other areas of practice.

Emergency Medicine

85. Do elderly patients require less propofol for procedural sedation in the emergency department?
Anna C. Christich, Pharm.D., Karalea D. Jasiak, Pharm.D., Christopher J. Edwards, Pharm.D., Hanna Phan, Pharm.D., Asad E. Patanwala, Pharm.D.; University of Arizona, Tucson, AZ

Purpose: The objective of this study is to determine the effect of patient age on total propofol dose required for procedural sedation in the emergency department (ED).
Methods: Medical records of 244 adult patients who received propofol for procedural sedation in the ED between September 9, 2007 and October 20, 2009 were retrospectively reviewed. Patients were grouped a priori by age into 3 categories: 1) 18–40 years; 2) 41–64 years; and 3) ≥65 years. Specific information collected included patient demographics, procedure type, sedation times, propofol doses and analgesic use. Patients who received other concurrent sedatives or had missing demographic data were excluded. Age groups were compared with respect to total propofol dose requirements using the Kruskall-Wallis test. Multivariate linear regression analysis was used to adjust for confounders and determine predictors of propofol dose requirements.
Results: A total of 170 patients were included in the final analyses: 18–40 years (n = 67), 41-64 years (n = 58) and ≥65 years (n = 45). Total median propofol dose required was 1.9 mg/kg (interquartile range 1.3–2.7 mg/kg), 1.8 mg/kg (interquartile range 1–2.5 mg/kg) and 1.2 mg/kg (interquartile range 0.8–1.6 mg/kg) in the 18–40, 41–64 and ≥65 year old groups, respectively (p<0.001). In the multivariate linear regression analysis the following variables were significantly predictive of total propofol dose requirements: procedure sedation time (p<0.001), age ≥65 years (less required) (p=0.007) and opioid requirement prior to procedure (expressed as morphine IV equivalents) (p=0.011). Variables not significantly predictive of propofol requirements were sex, race, procedure type, pain score prior to the procedure and opioid used during the procedure.
Conclusion: Elderly patients require lower doses of propofol for procedural sedation in the ED compared to younger adults.

86E. The effect of a medical resident educational program on emergency department pharmacy interventions and medication errors.
Megan E. Foster, Pharm.D.[1], Randy Bradley, Ph.D.[2], Donald E. Lighter, M.D., M.B.A.[3], Brandon Edgerson, Pharm.D.[1], Sandip A. Godambe, M.D., Ph.D., M.B.A.[4]; (1)Le Bonheur Children's Medical Center, Department of Pharmacy, Memphis, TN; (2)Business Administration, University of Tennessee-Knoxville, Knoxville, TN; (3)Business Administration, University of Tennessee-Knoxville, and Institute of Health Care Quality, Knoxville, TN; (4)Pediatric Emergency Medicine, University of Tennessee Health Science Center, Memphis, TN

Background: Because of its chaotic atmosphere, the pediatric emergency department (ED) is very susceptible to medication errors. Medical residents are especially at risk for making these errors. The presence of a pharmacist in the ED has been shown to decrease the number of medication errors.
Purpose: To implement a medical resident educational program utilizing attending physicians and an ED pharmacist and determine the effects on ED pharmacist interventions and medication errors.
Methods: The ED pharmacist recorded all pharmacy interventions on weekdays from 3pm-11pm using a pre-existing database during the 3-month observation and intervention phases. Data from a random 3-

month period prior to the study initiation were also evaluated. The data were divided into categories based on the type of intervention and level of training. Weekly data were analyzed using statistical process control (SPC) u chart analyses. χ^2 analyses of independence were also performed. Resident educational interventions consisted of monthly lectures and daily discussions in the ED. Resident feedback was elicited through blinded internet surveys.
Results: A total of 3507 interventions occurred during the 9-month period. There was a statistically significant decrease in the overall number of adverse drug events (ADE) and dose adjustments (DA) during the intervention phase (p<0.03). The number of medication order clarifications decreased during the intervention phase as well. Discharge prescription clarifications increased, partially because of the increase in ED patient volume related to H1N1 influenza. The total number of drug information questions asked by the ED staff increased. Survey analysis revealed a positive response to the pharmacist and the educational intervention.
Conclusions: The implementation of a medical resident educational program increased staff awareness of the potential for medication errors, increased pharmacist utilization, and decreased the overall number of medication errors in the ED.
Presented at Pediatric Academic Societies Annual Meeting, Vancouver, B.C., Canada, May 1–4, 2010

87. Validation of a risk quantification instrument for acute acetaminophen overdose patients treated with *N*-acetylcysteine at a university teaching hospital.
Kyle A. Weant, Pharm.D., BCPS, A. Kendall Gross, Pharm.D., Stephanie N. Baker, Pharm.D.; University of Kentucky HealthCare, Department of Pharmacy Services, Lexington, KY

Purpose: A more accurate risk stratification tool than the Rumack and Matthew nomogram might help clinicians individualize pharmacotherapy and better predict those in need of more or less intensive *N*-Acetylcysteine (NAC) therapy following acetaminophen (APAP) overdose. The primary objectives of this study are to evaluate the validity of a risk quantification instrument for APAP overdose (Psi-a composite measure incorporating timed-APAP concentration and time to NAC treatment) as well as additional factors that should be evaluated in a clinical analysis.
Methods: A retrospective analysis of acute APAP overdoses at a university teaching hospital over a three year period that received NAC therapy was conducted. Cases were evaluated utilizing a previously validated measure of exposure following acute APAP overdose in those patients who received NAC. Additional cofactors such as age, sex, ethanol use (acute vs chronic), and coingestion of hepatically metabolized drugs (acute vs chronic) were also evaluated.
Results: Overall, 43 patients were evaluated and included in the analysis. Linear regression analysis determined a significant association between Psi and AST/ALT values (p=0.033). However, Psi was found to not significantly predict the likelihood of at least one serum aspartate aminotransferase (AST) or alanine aminotransfease (ALT) >1000 IU/L (p=0.056). Backward stepwise regression analysis of different variables demonstrated that Psi was the only independent variable that resulted in the best model associated with AST/ALT elevations (p=0.033).
Conclusions: Although patient numbers are limited, available data is consistent with published data evaluating this novel risk quantification instrument. This novel instrument has potential to provide direction as to the intensity of NAC treatment and patient risk of hepatotoxicity despite therapy. In addition, it also has the potential to provide clinicians with an efficient way to quantify additional adjustments that should be made to the risk analysis equation based on patient-specific factors.

88. Results of a multidisciplinary survey evaluating a pediatric emergency department's satisfaction with implementation of ED-based pharmacy services: a two year review.
Megan E. Foster, Pharm.D.[1], Brandon Edgerson, Pharm.D.[1], Sandip A. Godambe, M.D., Ph.D., M.B.A.[2]; (1)Le Bonheur Children's Medical Center, Department of Pharmacy, Memphis, TN; (2)Pediatric Emergency Medicine, University of Tennessee Health Science Center, Memphis, TN

Background: The pediatric emergency department (ED) is an environment prone to chaos which can increase the potential for medication errors. The presence of an ED pharmacist has been shown to decrease the number of medication errors and decrease the delay in drug delivery to a time-dependent patient population.

Purpose: To evaluate the ED staff perspective on medication safety and error rates two years post-pharmacist implementation using a blinded internet-based survey.

Methods: ED pharmacy services were established two years prior, with weekday coverage from 3–11pm. A blinded internet-based survey was created utilizing a pre-existing internet survey tool. The survey asked the participant to assess the following using a five-level Likert-based scale: their job role, their position on medication safety, the ED pharmacist's effect on medication errors, their use of the ED pharmacist for drug information, and their view on the expansion of ED pharmacy services. A final question allowed for open-ended comments. The survey was available for a one month period.

Results: A total of 103 staff members completed the survey. ED nurses accounted for 51.5% of the response total, while attending and resident physicians comprised 28.1% of participants. The remaining responses came from other allied health professionals. Survey analysis revealed that 92.2% strongly agreed that medication safety had improved and error rates were decreased over the two year period. Furthermore, 86.3% strongly agreed with utilizing the ED pharmacist as a valuable drug information resource. Overall, 93.2% strongly agreed that coverage should be expanded to 24 hours per day, including weekends. Open-ended comments were provided by 49% of respondents, all of which were favorable with regards to the ED pharmacist.

Conclusion: The survey results confirm that the ED pharmacist has been well received and utilized in the pediatric ED. There is clearly unanimous support for expanding ED pharmacy coverage.

89. Retrospective review of the treatment of hypertensive emergency in an academic medical center emergency department.

Lindsey M. Clark, Pharm.D., Nicole Harger, Pharm.D., BCPS, Michelle Wiest, Pharm.D., BCPS; University Hospital, Cincinnati, OH

Purpose: Adult patients with hypertension have a 1–2% chance of experiencing a hypertensive crisis in their lifetime. Hypertensive emergency is associated with acute end-organ damage that may encompass the central nervous system, the heart, the kidneys, or eclampsia in pregnancy. Appropriate medical management in hypertensive emergencies is essential to prevent reduced perfusion, infarction or ischemic events, or further end organ damage. The purpose of this study is to describe the treatment approaches for patients presenting with hypertensive emergency in an academic medical center emergency department.

Methods: A single-center, retrospective study conducted through chart review of patients presenting to The University Hospital in Cincinnati, Ohio between July 2004 through June 2009 with a primary or secondary diagnosis of malignant hypertension. The primary outcome identified the mean arterial blood pressure reduction in the first hour of treatment and the overall blood pressure reduction six hours after initiation of treatment. Secondary outcomes evaluated agent selection based on patients' end organ damage at presentation, and adverse outcomes (death, myocardial infarction, stroke, and acute renal failure) and adverse effects (arrhythmia, hypotension, bradycardia, and tachycardia) associated with treatment.

Results: After screening 989 patients, 61 patients were included in the final analysis. Results from the primary outcome showed 23 patients (38%) were treated appropriately, 27 patients (44%) were overaggressively treated, and 11 patients (18%) were treatment failures. The secondary outcomes revealed 53% of the agents chosen for patients were preferred based on predefined criteria for the type of end organ damage. Lastly, there was a trend toward increased risk for myocardial infarction in patients who were overaggressively treated (p=0.059).

Conclusion: There is significant room for improvement in the management of hypertensive emergencies at University Hospital. An orderset including monitoring parameters, goals of treatment, and preferred agents would be beneficial in the treatment of these patients.

Endocrinology

90E. Initial treatment with metformin + colesevelam provides greater glycemic control than metformin alone in Hispanic patients with type 2 diabetes mellitus.

Eric Hernandez-Triana, M.D.[1], W. Timothy Garvey, M.D.[2], Ronald B. Goldberg, M.D.[3], Yehuda Handelsman, M.D.[4], Vivian A. Fonseca, M.D.[5], Michael R. Jones, Ph.D.[6], Stacey L. Abby, Pharm.D.[6], Magdalena Markiewicz, B.A.[6], Xiaoping Jin, Ph.D.[7], Soamnauth Misir, Pharm.D.[6], Sukumar Nagendran, M.D.[6], Julio Rosenstock, M.D.[8]; (1)Endocare Research Institute, Universidad del Rosario, Bogota, Colombia; (2)UAB Diabetes Research and Training Center, University of Alabama at Birmingham, Birmingham, AL; (3)University of Miami Miller School of Medicine, Miami, FL; (4)Metabolic Institute of America, Tarzana, CA; (5)Tulane University Health Sciences Center, New Orleans, LA; (6)Daiichi Sankyo, Inc., Parsippany, NJ; (7)Daiichi Sankyo Pharma Development, Edison, NJ; (8)Dallas Diabetes and Endocrine Center at Medical City, Dallas, TX

Purpose: Colesevelam is indicated for glycemic control and LDL-C lowering in patients with type 2 diabetes mellitus (T2DM) and hypercholesterolemia, respectively. A 16-week, randomized, double-blind, placebo-controlled, multinational study evaluated the effect of initial therapy with metformin+colesevelam in patients with T2DM and hypercholesterolemia.

Methods: This *post-hoc* analysis evaluated the efficacy and safety of metformin+colesevelam in a subpopulation of Hispanic patients (self-identified; enrolled in Colombia, Mexico, and US) included in the 16-week study. Drug-naïve adults with T2DM (HbA$_{1c}$ 6.5–10.0%), LDL-C $\geq$100 mg/dL, and triglycerides <500 mg/dL were randomized to metformin+colesevelam 3.75 g/d or metformin+placebo. Metformin was initiated at 850 mg/d and was uptitrated at Week 2 to 1700 mg/d. Efficacy parameters included change in HbA$_{1c}$ and lipids from baseline to Week 16 with last observation carried forward.

Results: In total, 173 Hispanic patients were treated with metformin+colesevelam (n=85) or metformin+placebo (n=88). Mean baseline HbA$_{1c}$ was similar in the two groups (7.7% and 7.6%, respectively). At Week 16, the mean change from baseline in HbA$_{1c}$ was significantly greater with metformin+colesevelam vs metformin+placebo (-1.2% vs -0.8%; treatment difference [TD]: -0.4%; P=0.001), resulting in significantly more patients achieving HbA$_{1c}$<7.0% (75% vs 56%; P=0.02). Metformin+colesevelam resulted in significantly greater reductions in LDL-C vs metformin+placebo (-22.8% vs -3.4%; TD: -19.4%; P<0.0001), resulting in significantly more patients achieving LDL-C<100mg/dL (49% vs 14%; P<0.0001). There were significant decreases in non–HDL-C (-13.6% vs -3.3%; TD: -10.3%; P<0.0001), total cholesterol (-9.1% vs -1.2%; TD: -7.9%; P<0.0001), and apoB (-11.4% vs -1.7%; TD: -9.8%; P<0.0001), and increases in triglycerides (9.5% vs -11.1%; TD: 21.2%; P<0.0001) and apoA-I (9.7% vs 5.4%; TD: 4.2%; P=0.01) with metformin+colesevelam vs metformin+placebo. In total, 66% (metformin+colesevelam) and 71% of patients (metformin+placebo) reported an adverse event; most were mild-to-moderate in severity.

Conclusion: Metformin+colesevelam may be an appropriate initial treatment option to improve glycemic and lipid control in Hispanic patients with T2DM.

Presented at Presented at the Annual Meeting of the European Association for the Study of Diabetes, Stockholm, Sweden, September 20–24, 2010

91E. Colesevelam for Hispanic patients with hypercholesterolemia and prediabetes.

Yehuda Handelsman, M.D.[1], Ronald B. Goldberg, M.D.[2], Julio Rosenstock, M.D.[3], W. Timothy Garvey, M.D.[4], Vivian A. Fonseca, M.D.[5], Eric Hernandez-Triana, M.D.[6], Michael R. Jones, Ph.D.[7], Yu-Ling Lai, RNC, MSN[7], Xiaoping Jin, Ph.D.[8], Soamnauth Misir, Pharm.D.[7], Sukumar Nagendran, M.D.[7], Stacey L. Abby, Pharm.D.[7]; (1)Metabolic Institute of America, Tarzana, CA; (2)University of Miami Miller School of Medicine, Miami, FL; (3)Dallas Diabetes and Endocrine Center at Medical City, Dallas, TX; (4)UAB Diabetes Research and Training Center, University of Alabama at Birmingham, Birmingham, AL; (5)Tulane University Health Sciences Center, New

Orleans, LA; (6)Endocare Research Institute, Universidad del Rosario, Bogota, Colombia; (7)Daiichi Sankyo, Inc., Parsippany, NJ; (8)Daiichi Sankyo Pharma Development, Edison, NJ

Purpose: Both hypercholesterolemia and prediabetes increase cardiovascular disease risk. Colesevelam has been shown to reduce LDL-C and fasting plasma glucose (FPG) in patients with hypercholesterolemia and prediabetes. A 16-week, randomized, double-blind, placebo-controlled, multinational study evaluated the effect of colesevelam in patients with hypercholesterolemia and prediabetes.

Methods: This *post-hoc* analysis evaluated the efficacy and safety of colesevelam in a subpopulation of Hispanic patients (self identified; enrolled in Colombia, Mexico, and US) included in the 16-week study. Adults with untreated prediabetes (2-hour post-oral glucose tolerance test glucose: 140–199 mg/dL and/or FPG: 110–125 mg/dL), LDL-C ≥100mg/dL, and triglycerides (TG) <500 mg/dL were randomized to colesevelam 3.75 g/d or placebo. Primary endpoint was percent change in LDL-C from baseline to Week 16. All efficacy analyses were performed using last observation carried forward at Week 16.

Results: In total, 153 Hispanic patients received colesevelam (n=77) or placebo (n=76). There was a significant mean percent change with colesevelam versus placebo from baseline to Week 16 in: LDL-C (treatment difference: -19.4%; $P<0.0001$), non-HDL-C (-12.0%; $P<0.0001$), total cholesterol (-9.7%; $P<0.0001$), apoB (-10.2%; $P=0.0002$), and TG (median: 15.4%; $P=0.003$). ApoA-I increased with both colesevelam (5.0%) and placebo (4.4%) at Week 16. Significantly more patients achieved LDL-C <100 mg/dL with colesevelam versus placebo at Week 16 (27% vs 11%; $P=0.002$). Colesevelam versus placebo also produced significantly greater reductions in FPG (median: -2.0 mg/dL; $P=0.024$) and HbA$_{1c}$ (mean: -0.12%; $P=0.009$) at Week 16. The proportion of patients achieving normalization of glucose (FPG <100 mg/dL) was significantly greater with colesevelam versus placebo (44% vs 23%; $P=0.0497$). Overall, colesevelam was well tolerated in Hispanic patients with hypercholesterolemia and prediabetes.

Conclusion: In Hispanic patients with hypercholesterolemia and prediabetes, colesevelam may be a suitable option for lowering LDL-C and improving the metabolic profile. Further investigation regarding the effect of colesevelam on progression to type 2 diabetes is warranted.

Presented at The Annual Meeting of the European Association for the Study of Diabetes, Stockholm, Sweden, September 20–24, 2010

92. Effect of statin lipophilicity and dose on adiponectin concentrations: a systematic review and meta-analysis.
Daniel M. Riche, Pharm.D., BCPS, CDE[1], S. Travis King, Pharm.D.[2], *Krista D. Riche, Pharm.D., BCPS*[3]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi School of Pharmacy, Jackson, MS; (3)Mississippi Baptist Medical Center, Jackson, MS

Purpose: Statins have obvious benefit for cardiovascular disease. However, several trials have linked statins to increases in new-onset diabetes. Most recently, a large, prospective study (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin [JUPITER]) found an increase in diabetes among statin-treated patients. One hypothesis for this increase is statin-induced changes in adiponectin, an anti-atherogenic cytokine involved in glucose homeostasis. Thus, the aim of this meta-analysis is to evaluate the effect of statin lipophilicity and dosing on adiponectin concentrations.

Methods: A systematic literature search of PubMed and MEDLINE through February 2010 was conducted to identify randomized, statin versus statin trials reporting change in adiponectin concentrations. Statin treatment arms were categorized based on relative dose intensity and relative lipophilicity. Data is reported as weighted mean differences (WMD) with 95% confidence interval (CI) using a fixed-effects model.

Results: Seven statin comparator trials (n=536) reported serum adiponectin concentrations. Upon meta-analysis, there was a statistically significant increase in adiponectin favoring the higher-dosed statins (WMD 0.72 [95% CI, 1.11 to 0.33]) versus lower-dosed

statins. Less lipophilic statins also significantly increased adiponectin (0.82 [0.41 to 1.22]) versus the more lipophilic statins. There was no significant statistical heterogeneity (Q-statistic) or publication bias in any group.

Conclusions: When analyzed based on relative dose and lipophilicity, higher-dosed and less lipophilic statins significantly increased adiponectin concentrations over lower-dosed and more lipophilic statins. While the precise relationship amongst adiponectin, statins, and diabetes remains unclear, these results imply that a non-adiponectin pathway may play a larger role in statin-related diabetes.

93. Impact of mulberry leaf extract on type 2 diabetes (Mul-DM).
Daniel M. Riche, Pharm.D., BCPS, CDE[1], Krista D. Riche, Pharm.D., BCPS[2], Li-Tao Zhong, M.D., Ph.D.[3], Honey E. East, M.D.[4]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)Mississippi Baptist Medical Center, Jackson, MS; (3)NatureGen, Inc., San Diego, CA; (4)University of Mississippi School of Pharmacy, Jackson, MS

Purpose: Mulberry leaves have been used anecdotally in Asia to treat many disease states, including glucose abnormalities. Animal and human studies illustrate potential benefit of mulberry leaf extract (MLE) in type 2 diabetes mellitus (DM2). The purpose of this study is to evaluate the glycemic and safety effects of MLE in patients with DM2.

Methods: This randomized, double-blind, placebo-controlled pilot study evaluated MLE (1000 mg standardized) versus matching placebo given three times daily with meals. Patients (n=24) were included if they had DM2 on single or combination oral therapy with a stable hemoglobin A1C (A1C). A 2-week placebo run-in (baseline) was followed by initiation of randomized medication for 3 months. The primary endpoints were change in A1C and self-monitoring blood glucoses (SMBG). Safety was evaluated at each study visit. A *t*-test was used for continuous data, and χ^2 was used for dichotomous data.

Results: Of 24 patients enrolled, 17 patients completed the study. Post-prandial SMBG significantly decreased in the MLE group versus baseline (16.1%) and placebo (18.2%) (p<0.05 for both). A1C decreased from 7.30% at baseline to 6.94% in the MLE group but did not reach statistical significance (p=0.079). There was no difference in A1C between MLE and placebo. A significant 15% increase occurred in serum creatinine when the MLE group was compared to baseline or placebo (p<0.05 for both). There was no significant effect on body weight, fasting SMBG, blood pressure, hypoglycemia, or other safety evaluation markers.

Conclusion: These results suggest that mulberry leaf extract may be a useful complementary mealtime glucose regulator for patients with DM2. Using this pilot data, A1C and renal dosing should be evaluated in a large, dose-ranging, randomized controlled trial. *ClinicalTrials.gov Identifier* NCT00795704.

Geriatrics

94. Cross-sectional study of gabapentin for sleep.
Lisa C. Hutchison, Pharm.D., M.P.H., Catherine E. O'Brien, Pharm.D.; University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR

Purpose: Over 50% of elderly have a sleep complaint. Gabapentin is used off-label to treat insomnia in this population although little data supports this practice. This was a cross-sectional pilot study to evaluate sleep, balance, and daytime alertness in elderly patients using gabapentin for insomnia.

Methods: A convenience sample of individuals over age 65 with insomnia who were on gabapentin at bedtime were eligible for participation. All subjects completed the MOS Sleep measure, Sleep/Wake Activity Inventory (SWAI), Trail Making Tests (TMT), SF36 Health Survey, Geriatric Depression Scale (GDS), and Short Physical Performance Battery (SPPB). A sleep questionnaire with questions about sleep habits, physical activity, and perception of drug efficacy was administered.

Results: Ten gabapentin-treated subjects with a mean age of 76.1 ± 5.7 years (80% female) were evaluated. Most subjects had good sleep hygiene but a long sleep latency period and arose at least twice each

night without gabapentin. The mean for the 12 items in the SWAI ranged from 5.3 to 8.9 indicating difficulties in all areas. The TMT mean times were 41.8 seconds for Part A and 145.8 seconds for Part B. The MOS showed moderate to severe problems with sleep disturbance, snoring, and sleep adequacy with an average of 6.85 hours sleep/night. The SF36 placed 6/10 patients at the <25th percentile for bodily pain and 9/10 at the < 50th percentile for mental health. The GDS mean was 2.8 ± 2.6 and the SPPB mean was 8.8 ± 3.0.

Conclusion: These elderly subjects had poor sleep quality despite practicing good sleep hygiene and treatment with gabapentin. Mental health and pain issues predominated, although few had significant depression. The SPPB indicated moderate functional limitations which are associated with increased risk for disability. Gabapentin requires further evaluation to determine its risk and benefit to treat insomnia in the elderly.

95. Gastrointestinal tolerability of NSAIDs in elderly arthritis patients.
Margaret Noyes Essex, Pharm.D., Sharon R. Mallen, M.D., Richard Y. Zhang, Ph.D.; Pfizer Medical, New York, NY

Purpose: Gastrointestinal intolerability may be a common reason elderly arthritis patients discontinue NSAID therapy. We compared the GI tolerability of celecoxib and nonselective NSAIDs in patients aged ≥ 65 years with osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis.
Methods: Randomized, parallel-group trials with a duration ≥ 2 weeks, and at least one celecoxib 200 or 400 mg total daily dose and one nsNSAID (naproxen, ibuprofen, or diclofenac) arm were selected from the Pfizer Clinical Trials Registry. Patient-level data from the trial safety populations were pooled. Pre-specified endpoints included the combined incidence of GI tolerability AEs (defined as ≥ 1 of the 6 most common GI AEs: dyspepsia, abdominal pain, diarrhea, nausea, constipation, flatulence), and incidence and time to discontinuation due to these GI tolerability AEs.
Results: 21 trials were selected involving 9461 elderly patients (mean age 71.9 years); 5872 received celecoxib, 1104 naproxen, 151 ibuprofen, 2334 diclofenac. Combined incidence of GI tolerability AEs were reported by significantly fewer celecoxib patients (16.7%) than naproxen (29.4%; $P < 0.0001$), ibuprofen (26.5%; $P<0.01$), or diclofenac (21.0%; $P<0.0001$). Discontinuation rate due to GI tolerability AEs was significantly lower for celecoxib (4.0%) vs naproxen (8.1%; $P<0.0001$) and ibuprofen (7.3%; $P<0.05$), but not diclofenac (4.2%; $P=0.75$). Significantly fewer celecoxib patients withdrew due to GI tolerability AEs starting at week 1 vs naproxen (1.6% vs 3.9%; p<0.0001) and starting at week 2 vs ibuprofen (2.5% vs 6.0%; p<0.01).
Conclusion: The combined incidence of GI tolerability AEs was lower in elderly patients treated with celecoxib vs naproxen, ibuprofen, or diclofenac. In addition to longer time to study withdrawal, fewer elderly patients treated with celecoxib discontinued due to GI tolerability AEs than patients treated with naproxen or ibuprofen. GI tolerability is an important treatment consideration for providers when choosing an NSAID for elderly arthritis patients.

96. Results of an Independent Pharmacist Managed Oral Anticoagulation Service in a Long-Term Care Facility.
Haley M. Phillippe, Pharm.D.; Harrison School of Pharmacy, Owens Cross Roads, AL

Purpose: Anticoagulants are the most common drug class associated with preventable adverse drug events in long-term care facilities (LTCF). Eighty percent of these potential adverse events are due to errors in anticoagulation management; therefore, regular monitoring is crucial. The amount of time that the INR is within therapeutic range (TTR) is strongly associated with these adverse events, specifically bleeding or thromboembolic events. The impact of oral anticoagulation monitoring by pharmacists in a LTCF has not been studied. The objective was to compare warfarin therapy managed by physicians to a pharmacist-managed anticoagulation service in a LTCF.
Methods: Patients receiving warfarin at a LTCF were identified. INRs

were monitored and warfarin dosages were adjusted at the discretion of the pharmacist. After three years, a retrospective chart review was conducted. Patients were included if they were anticoagulated for a minimum of 1 month and had at least 2 INR values. Information on demographics, indication for and length of warfarin therapy, INR values, time in therapeutic range, drug interactions, and thromboembolic and bleeding events were recorded.
Results: A total of 142 patients met our inclusion criteria. The post-pharmacist TTR was 59% compared to 29% before intervention. The extended TTR (goal INR ± 0.2) was 96% post-pharmacist intervention and 43% prior to the intervention. Before pharmacist intervention 30% of INRs were less than 2 and 2% were greater than 4, compared to 51% of INRs less than 2 and 9% greater than 4 following intervention. No adverse events were reported.
Conclusion: Although there were limitations to this retrospective analysis, the results of this study demonstrate that a clinical pharmacist does improve the management of anticoagulation therapy by increasing the TTR and decreasing supra and subtherapeutic INRs. The clinical pharmacist provides a consistent approach to anticoagulation management, and is an asset that should be utilized in caring for patients in LTCF.

97. Evaluation of the role of clinical pharmacists in nitrofurantoin stewardship at a long-term care facility.
Amber N. McLendon, Pharm.D., C. Brock Woodis, Pharm.D.; Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC

Purpose: Nitrofurantoin is frequently used in long-term care facilities (LTCF) to treat urinary tract infections (UTIs) due to low rates of bacterial resistance. However, nitrofurantoin is contraindicated for use in patients with a creatinine clearance less than 60 ml/min due to concerns of subtherapeutic concentrations in the urine, as well as possible gastrointestinal , allergic, pulmonary, hepatic, neurological and hematological reactions. Addition of a clinical pharmacist to an interdisciplinary quality assurance (QA) team may improve the appropriate use of nitrofurantoin for UTIs in a LTCF. The objective of this study was to evaluate use of nitrofurantoin for UTIs in a LTCF before and after clinical pharmacist intervention based on documented creatinine clearance.
Methods: A retrospective review of infection QA data from skilled nursing and assisted living residents was conducted to determine nitrofurantoin prescribing patterns for UTIs from September 2007 to December 2008. A clinical pharmacist joined the QA team and provided recommendations regarding appropriate nitrofurantoin use in April 2008 using calculated creatinine clearance values based on Cockroft-Gault. Data from September 2007 to April 2008 were compared to data from May to December 2008 to determine if a change in prescribing patterns resulted from clinical pharmacist involvement in QA.
Results: A total of 99 UTIs occurred from September 2007 to December 2008 (52 before and 47 after clinical pharmacist intervention) in patients with a documented creatinine clearance less than 60 ml/min. Nitrofurantoin was used in 52% of UTIs prior to clinical pharmacist intervention. After clinical pharmacist education on nitrofurantoin contraindications and adverse effects, nitrofurantoin use dropped to 36% (p<0.01).
Conclusion: The contribution of a clinical pharmacist to QA can greatly reduce the inappropriate use of nitrofurantoin in long-term care facilities.

98E. Anticholinergic burden of older adults in the community.
Teri L. West, Pharm.D., Maria C. Pruchnicki, Pharm.D., Ruth E. Emptage, Pharm.D.; The Ohio State University, Columbus, OH

Purpose: Studies suggest that the burden of multiple medications with anticholinergic activity are additive and increase the risk of side effects. Seniors may be particularly susceptible to adverse cognitive effects. Scales have been derived to assess the potential cumulative danger of medications with anticholinergic properties, though their appropriate use in clinical practice is not well-defined. Our purpose is to describe the anticholinergic burden of an older adult population receiving medication therapy management (MTM) services.

Methods: A retrospective study of comprehensive medication reviews completed by a geriatric pharmacist was conducted. Inclusion criteria included all patients age 65 years and older who received a comprehensive medication review in the specified time period. Data collected include demographics, medications, chronic conditions and prescribers, and number of pharmacies used. Using the Anticholinergic Cognitive Burden (ACB) scale, cumulative scores were calculated for each patient. ACB scores > 3 are considered clinically significant.
Results: A total of 341 records were included in the study, with a prevalence of ACB > 3 of 47.8% (N=163). ACB ≥3 was associated with increasing number of prescription medications [OR=1.23, CI 1.14-1.32, p≤0.001] and over the counter medications [OR=1.17, CI 1.02-1.33, p=0.02]. Hypertension and depression also increased the likelihood of a significant score [OR=3.01, CI 1.73-5.21, p≤0.001; and OR=2.6, CI 1.14-5.9, p=0.02, respectively]. In patients with ACB ≥ 3, the most frequently appearing medication classes contributing to anticholinergic burden were cardiovascular [65.6%, (n=107)] and diuretics [56.4%, (n=92)].
Conclusion: These results suggest that ACB is a significant and potentially modifiable drug-related problem. Pharmacists providing medication therapy management services could identify ACB in community-dwelling seniors in a variety of practice settings, and mitigate risk due to adverse effects and negative cognitive outcomes.
Presented at Presented at the Annual Meeting of the American Association of Colleges of Pharmacy, Seattle, WA, July 10–14, 2010.

Health Services Research

99. A multicenter, retrospective chart review study comparing therapy change rates in open-angle glaucoma or ocular hypertension patients newly treated with latanoprost (LAT) or travoprost-Z (TRAV-Z) monotherapy.
J. Fain, Ph.D., RPh[1], S. Kotak, BSPharm, M.S.[1], J. Mardekian, Ph.D.[1], J. Bacharach, M.D.[2], D. Edward, M.D.[3], S. Rauchman, M.D.[4], T. Brevetti, M.D.[1], *J. Fox, Pharm.D.*[1], C. Lovelace, Pharm.D., JD[1]; (1)Pfizer Ophthalmics, New York, NY; (2)North Bay Eye Associates, Petaluma, CA; (3)Summa Health System, Akron, OH; (4)North Valley Eye, Mission Hills, CA

Purpose: Uninterrupted, long-term use of topical ocular hypotensive therapy is prerequisite to controlling intraocular pressure (IOP). The negative impact of medication-related adverse events on such use has been documented. Our purpose was to compare initial change rates and reasons for changes in patients newly treated with LAT or TRAV-Z monotherapy.
Methods: At 14 clinical practice sites, medical records were abstracted for patients with a diagnosis of open-angle glaucoma or ocular hypertension and who were ≥40 years of age, had a baseline and least 1 follow-up visit, and had no prior history of ocular prostaglandin use. Data regarding demographics, ocular/systemic medical histories, clinical variables, therapy initiations and reasons for changes, adverse events, and resource utilization were recorded. Primary outcomes were rates of and reasons for changing from the initial therapy within 6 months and within the full study period (1000 days).
Results: Data from 900 medical charts (LAT, 632; TRAV-Z, 268) were included. For both cohorts, average follow-up was >1 year. Cohorts were similar with regard to age (median ~67years), gender distribution (>50% female), and diagnosis (~80% with open-angle glaucoma). Within 6 months, rates of first change from index therapy for LAT versus TRAV-Z were 21.8 % (138/632) and 29.1% (78/268), respectively (p=0.0195); across the full study period, rates were 35.1% (222/632) and 46.6% (125/268), respectively (p=0.0012). Among those who changed therapy, insufficient IOP control was the most commonly reported reason followed by adverse events; hyperemia was the most commonly reported adverse event at initial therapy change.
Conclusions: Although medication changes were common in this population prescribed initial monotherapy with LAT or TRAV-Z, the rate of change from initial therapy was significantly lower with LAT. In addition to the need for additional IOP control, adverse events remain an important cause of medication changes.

100. The impact of a pharmacist on a short-term medical mission trip.
Jennifer N. Clements, Pharm.D., Michelle Horn, Pharm.D., Emily Vescovi, Pharm.D.; Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA

Purpose: Pharmacists are key members for the clinical services of a medical mission trip by providing assistance with drug knowledge and therapeutics. This study determined the impact of a pharmacist as a member of a medical mission team through (1) pharmacy interventions on two medical and one women's health team and (2) team satisfaction of the pharmacist.
Methods: The medical teams saw a total of 1143 patients over the course of four days. Pharmacy interventions were documented by two medical and one women's health team and included, but were not limited to dosing recommendations, drug selection and therapeutic substitution. These interventions occurred from Monday, May 10 through Thursday, May 13, 2010. Team satisfaction was determined from a ten-question survey was administered on the last clinical day, Thursday, May 13, 2010 to all team members.
Results: The medical teams provided free medical care to the people of Leon, Nicaragua and surrounding areas. The age of patients ranged from 16 days to 94 years. The pharmacy service dispensed 2110 prescriptions, with an average number of prescriptions of 1.85 per patient. A total of 2340 interventions were provided by the pharmacy service, averaging 2.05 interventions per patient and 1.1 interventions per prescription. For the secondary objective, the survey indicated that a pharmacist serves an integral role for the multidisciplinary medical team.
Conclusion: Pharmacists have an important role in a short-term medical mission trip by assisting with organization, preparation, and execution of the trip. They serve as sources for drug knowledge and ensure appropriate medication therapy management as part of the interdisciplinary team.

101. The effects of dosing complexity on adherence with prescription medications commonly used for cardiovascular patients.
Jay P. Bae, Ph.D.[1], *Paul P. Dobesh, Pharm.D.*[2], Johnna D. Anderson, M.S.[1], Anthony Zagar, M.S.[1], Donald G. Klepser, Ph.D., M.B.A.[2], Patrick L. McCollam, Pharm.D.[1], Molly E. Tomlin, M.S.[1]; (1)Eli Lilly & Company, Indianapolis, IN; (2)University of Nebraska Medical Center, Omaha, NE

Purpose: To compare patient adherence with chronic-use prescription medications between once- (QD) and twice-daily (BID) dosing.
Methods: Using a large claims database (MarketScan), prescription medications were defined as QD if ≥80% of claims showed a quantity/day=1 and were defined as BID if ≥80% of claims had a quantity/day=2. Data for patients ≥18 years with the first claim in 2007 were selected for analysis and were further limited to 4 classes of medications frequently used by cardiovascular patients. Adherence was measured by medication possession ratio (MPR) defined as number of days of medication supplied (between the first prescription fill date and 365 days following)/365 days. A linear model (generalized estimating equation) accounting for within patient correlations in patients using multiple medications was used to model the MPR. The model was stratified on medication class and adjusted for baseline confounding variables (gender, age, Charlson Comorbidity Index).
Results: 1,077,936 patients were included and the number of patient-medication combinations was 1,440,917 (QD: 1,384,565 and BID: 56,352). The overall mean MPR ± SD value for QD agents was 5% greater than BID agents: 0.63 ± 0.36 vs. 0.60 ± 0.36;P<0.01, respectively. Except for the general cardiac class of medications, the mean MPR value for QD agents was greater than the mean MPR for BID agents. The antiplatelet class of medications showed the largest difference between the dosing regimens.

Therapeutic Class	Mean MPR ± SD QD	BID	BID Difference % from QD
Antidiabetic agents (86,737)	0.70 ± 0.34	0.65 ± 0.33	-7.1%*
Antihyperlipidemic agents (543,820)	0.62 ± 0.35	0.50 ± 0.34	-19.4%*
Antiplatelet agents (47,798)	0.71 ± 0.35	0.51 ± 0.38	-28.2%*
Cardiac agents (762,562)	0.62 ± 0.36	0.64 ± 0.36	3.2%*

* $P < 0.01$

Conclusion: This unique claims analysis, which investigated multiple therapeutic classes of medications in a large database, generally found lower adherence in BID dosing in medications frequently used by cardiovascular patients; however, a wide range in the MPR differences between QD and BID dosing was observed between the therapeutic classes.

102. An evaluation of once- versus twice-daily dosing on persistence with prescription medications in cardiovascular patients.
Jay P. Bae, Ph.D.[1], *Paul P. Dobesh, Pharm.D.*[2], Anthony Zagar, M.S.[1], Johnna D. Anderson, M.S.[1], Molly E. Tomlin, M.S.[1], Patrick L. McCollam, Pharm.D.[1], Donald G. Klepser, Ph.D., M.B.A.[2]; (1)Eli Lilly & Company, Indianapolis, IN; (2)University of Nebraska Medical Center, Omaha, NE

Purpose: To compare patient persistence with chronic-use prescription medications between once- (QD) and twice-(BID) daily dosing.
Methods: Using a large claims database (MarketScan), prescription medications were defined as QD if ≥80% of claims showed a quantity/day=1 and as BID if ≥80% of claims had a quantity/day=2. Data for patients ≥18 years with a first claim in 2007 were selected for analysis and were further limited to 4 classes of medications frequently used by cardiovascular patients. Persistence was measured by time-to-discontinuation (TTD), defined as the number of days from the first prescription filled to the first gap of >30 days between exhausting the supplied medication and filling the next prescription. The mean TTD with censoring at 365-days was estimated and tested. A proportional hazards model accounting for within-patient correlations in patients using multiple medications was used to model the TTD. The model was stratified on medication class and adjusted for baseline variables (gender, age, Charlson Comorbidity Index).
Results: 1,077,936 patients were included, and the number of patient-medication combinations was 1,440,917 (QD: 1,384,565 and BID: 56,352). The overall estimated mean TTD ± standard error for QD agents was 8% greater than BID agents: 198 ± 0.1 and 184 ± 0.6 days; $P < 0.01$. Except for the general cardiac class of medications, the mean TTD value for QD agents was greater than the mean TTD for BID agents.

Therapeutic Class	Mean MPR ± SE QD	BID	BID Difference % from QD
Antidiabetic agents (86,737)	221 ± 0.5	200 ± 1.1	-9.5%**
Antihyperlipidemic agents (543,820)	193 ± 0.2	151 ± 1.2	-21.8%**
Antiplatelet agents (47,798)	235 ± 0.7	159 ± 1.5	-32.3%**
Cardiac agents (762,562)	197 ± 0.2	199 ± 0.9	1.0%*

*$P < 0.05$, **$P < 0.01$

Conclusion: In this unique claims analysis, investigating multiple therapeutic classes of medications in a large database, persistence with antidiabetic, antihyperlipidemic, and antiplatelet agents was greater with QD compared with BID dosing; however, a wide range in the differences in persistence between QD and BID dosing was noted between therapeutic classes.

Hematology/Anticoagulation

103. Comparison of unfractionated heparin versus enoxaparin for venous thromboembolism prophylaxis in the very elderly.
Luigi Brunetti, Pharm.D., CGP[1], Paul Auriemma, Pharm.D. Candidate[1], Fatema Dhanaliwala, R.Ph.[2]; (1)Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey, Piscataway, NJ; (2)Somerset Medical Center, Somerville, NJ

Purpose: Current American College of Chest Physician guidelines recommend low molecular weight heparin (LMWH) or unfractionated (UFH) subcutaneously for prophylaxis in patients at risk for a venous thromboembolism (VTE). The risk of VTE increases with age; however, advanced age is also a risk factor for bleeding. The most appropriate agent for VTE prophylaxis in advanced age has not been adequately defined.
Methods: This retrospective cohort study utilized the Somerset Medical Center pharmacy database to identify all inpatients at risk for VTE prophylaxed with UFH or enoxaparin, aged 85 years or older and receiving prophylaxis for at least 3 days. All patient characteristics were captured through chart review. The primary outcome included readmission due to deep vein thrombosis (DVT) or pulmonary embolus (PE) within 60 days of discharge identified using International Classification of Diseases, 9th Revision (ICD-9) codes and verified by chart review. Secondary endpoints included the occurrence of minor or major bleeding. All data was analyzed using descriptive statistics. Fisher's exact test and χ^2 were used to compare nominal data. Continuous data were analyzed using an independent t-test
Results: A total of 572 patients met inclusion criteria. There were no significant differences in readmission due to DVT between the UFH (n=233) and the enoxaparin (n=339) group (3% versus 0.9%, respectively; p=0.0996) or PE (0.4% versus 0.9%, p=0.649). A significantly greater percentage of minor bleeding events were observed in the UFH group in comparison with the enoxaparin group (2.1% versus 0.3%, p=0.044), but no difference in major bleeding (0.4% versus 0.3%, p>0.05) was observed.
Conclusion: UFH did not differ from enoxaparin in terms of hospital readmission for DVT or PE within 60 days of discharge or major bleeding events in this cohort. Minor bleeding complications were significantly higher in the UFH group.

104. Benchmarking the use of iron dextran infusions in non-CKD and non-cancer patients in an academic teaching hospital.
David M. Baribeault, B.S., BCOP; Boston Medical Center, Boston, MA
Purpose: The purpose of this retrospective chart analysis was to evaluate the use of iron dextran infusions in anemic patients without chronic kidney disease or malignancy. Specifically, the goal of the evaluation was to identify services using iron dextran infusions, evaluate the appropriateness of use, its efficacy, and the incidence of adverse drug events or transfusions.
Methods: A restrospective chart review was conducted by auditing the pharmacy system as well as the CPOE system for all iron dextran infusions administered to hospitalized patients over the period of January 2003 through December 2006. Data collected included baseline demographic information, hemogram, iron studies, levels of vitamin B12 and folate, admitting diagnosis, and admitting medical service. Information on the average dose administered, the administration of a test dose, and rate of infusion was also collected. Additionally, charts were reviewed for the incidence of transfusion, adverse events and the existence of efficacy parameters surrounding hemoglobin, serum iron and transferrin saturation.
Results: Three hundred sixty-eight patients were identified over the examination period. The majority of patients were female with an average age of 54 years. Most patients were admitted with diagnoses of anemia, shortness of breath, or bleeding event and were admitted to the Medicine Service. The vast majority of patients had WHO Grade 2 anemia with transferrin saturation rates indicating absolute iron deficiency. In patients for whom follow-up labs were available, an average hemoglobin increase of 2.29 g/dl was observed without transfusion. Most patients received total-dose infusions over a 6 hour period. Seventy-five percent of patients received test doses and only 8 experienced adverse events.
Conclusion: Iron dextran infusions can effectively treat iron-deficiency anemia in hospitalized patients without CKD or malignancy.

105. Evaluation of a direct thrombin inhibitor titration protocol in patients with heparin induced thrombocytopenia (HIT).
Allison M. Mann, Pharm.D.[1], Toby C. Trujillo, Pharm.D., BCPS[2], Kathryn L. Hassell, M.D.[3], Tyree H. Kiser, Pharm.D., BCPS[2];

(1)University of Colorado Hospital, Aurora, CO; (2)University of Colorado School of Pharmacy, Aurora, CO; (3)University of Colorado School of Medicine, Aurora, CO

Purpose: The aim of this study was to evaluate the use of a direct thrombin inhibitor (DTI) titration protocol in patients with suspected or diagnosed HIT.
Methods: This observational study compared adult patients treated with argatroban or bivalirudin according to the University of Colorado Hospital DTI titration protocol versus a historical control of patients treated prior to protocol implementation. Patients in the protocol group had DTI initial doses based on organ function and fixed dosage adjustments of 10%, 25%, or 50% according to aPTT results. Initial doses and titrations in the control group were made per physician discretion. The primary outcome was time to achieve first therapeutic aPTT. Secondary outcomes included time to dose stabilization, number of titrations made before reaching therapeutic aPTT, and percentage of aPTT values in goal range.
Results: A total of 130 patients were enrolled: 47 in the protocol group and 83 in the control group (median age 54 years, 63% male, 83% critically ill, and 54% received argatroban). Goal aPTT was achieved with initial DTI dose in 64% of protocol patients and 46% of control patients (p=0.07). Median (IQR) time to goal aPTT was reduced in the protocol group compared to the control group [5 hours (2–10 hours) vs. 13 hours (6–29 hours); p<0.0001]. Median time to dose stabilization was 10 hours (6–27hours) and 22 hours (13–40 hours) in the protocol and control groups, respectively; p<0.0001. Median number of titrations to goal was 0 (0–1) versus 1 (0–4), respectively; p=0.02. Median percentage of aPTT values in goal was 67% (41–100%) versus 53% (33–76%), respectively; p=0.027.
Conclusions: The DTI titration protocol shortened time to achieve goal aPTT, reduced time to dose stabilization, decreased the number of titrations required to achieve aPTT goal, and improved the percentage of aPTT values in goal range.

106E. Monitoring and treatment among patients with trans-fusional iron overload: preliminary findings from an electronic medical records review study at H. Lee Moffitt Cancer Center and Research Institute.
Leslie A. Ray, Pharm.D.[1], Gene A Wetzstein, Pharm.D., BCOP[1], Caroline Korves, Sc.D.[2], Si-Tien Wang, M.S.[2], Bentley Clinton, B.A.[2], Robert Wei, B.A.[2], Mitra Corral, M.S., M.P.H.[3], Mei Sheng Duh, M.P.H., Sc.D.[2]; (1)H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; (2)Analysis Group, Inc., Boston, MA; (3)Novartis Pharmaceuticals Corporation, East Hanover, NJ

Purpose: Patients with red blood cell (RBC) transfusion-dependent conditions, such as myelodysplastic syndrome or severe anemia, risk developing transfusional iron overload (TIO) which can cause organ damage. Iron chelation therapy (ICT) prevents and limits organ damage in patients with TIO; however, TIO monitoring and ICT utilization in clinical practices are not well described.
Methods: The medical records of patients aged ≥18 years that had received ≥10 RBC units and were followed for ≥6 months after receiving the tenth RBC unit at the H. Lee Moffitt Cancer Center were reviewed. Patients were observed from tenth RBC unit transfusion to earliest of death, clinic departure, or data extraction. TIO monitoring was defined as receipt of ≥1 serum ferritin test. ICT-eligibility was defined as ≥2 serum ferritin tests ≥1,000 mcg/L or ≥20 RBC units transfused. Study endpoints were the proportion of patients monitored for TIO after ten, twenty and thirty RBC units and the proportion of ICT-eligible patients who were treated.
Results: Medical records data for 70 patients were extracted. TIO monitoring was generally low: 18.6% after the tenth RBC unit, 29.7% after the twentieth RBC unit, and 27.8% after the thirtieth RBC unit. Overall, 28.6% were monitored anytime after the tenth RBC unit. Among the 39 (55.7%) patients eligible for ICT, only 5 (12.8%) received ICT.
Conclusion: A minority of patients are monitored for TIO following transfusion of ten, twenty, and thirty RBC units. Only 12.8% of ICT-eligible patients received ICT, suggesting that TIO may not be sufficiently managed in clinical practice.
Presented at Presented at the 2010 annual meeting of the

Hematology/Oncology Pharmacy Association, New Orleans, Louisiana, March 24–27, 2010.

107. Initial evaluation for gastrointestinal prophylaxis in patients receiving concomitant warfarin and antiplatelet therapy at Jesse Brown VA Medical Center.
Claresta Bergman, Pharm.D., BCPS, Blair J Schwartz, Pharm.D.; Jesse Brown VA Medical Center, Chicago, IL

Purpose: A common risk with anticoagulants and antiplatelets is gastrointestinal (GI) complications such as ulcers and associated bleeding. Therefore, the American College of Cardiology Foundation (ACCF) Task Force recommends concomitant proton pump inhibitor (PPI) in patients receiving combination therapy. The purpose of this study is to evaluate current assessment, based on ACCF task force recommendations, in patients who need to start warfarin therapy when already taking antiplatelet therapy to identify methods for improve-ment.
Methods: Patients were identified by prescription fills in 2009 for warfarin if also filled an antiplatelet (either aspirin, clopidogrel, or aspirin/dipyridamole) and confirmed with chart review of warfarin initiation date. Data was retrospectively collected on 6 quality indicators.
Results: Of the 93 included, 7% had antiplatelet therapy discontinued with the decision to continue only warfarin, 41% were not assessed, 41% were incompletely assessed, and 11% were completely assessed for GI prophylaxis. Fifty-five percent were on some form of GI prophylaxis, while 45% had no GI prophylaxis. Of the 12 on triple therapy, 33% were not assessed, 42% were incompletely assessed, and 25% were completely assessed. The INR goal was lowered in 17% on triple therapy. While on combination therapy, 4% had a GI bleed and 2% developed peptic ulcer disease.
Conclusion: GI bleed risk is not adequately assessed, either by discontinuation of antiplatelet, initiation of GI prophylaxis, or adjustment of INR goal. Almost half of patients on combination therapy (33% on triple therapy) received no GI prophylaxis. Of the patients experiencing GI-related adverse events, the majority were not receiving prophylaxis. Improvement could be made in assessing patients receiving concomitant warfarin/antiplatelet therapy. Proposed changes include adding a reminder regarding concomitant antiplatelet therapy, recommendation for GI prophylaxis, and an order set for formulary PPI to the current annual warfarin risk/benefit assessment.

108E. Iron deficiency (ID) and anemia after Roux-en-Y gastric bypass (RYGP).
Margaret Malone, Ph.D., FCCP[1], Sharon Alger-Mayer, M.D.[2], Jennifer Lindstrom, M.D.[2], George R. Bailie, Pharm.D.[1]; (1)Albany College of Pharmacy and Health Sciences, Albany, NY; (2)Albany Medical College, Albany, NY

Purpose: We evaluated the prevalence of ID and anemia in our RYGP population, and noted the therapy prescribed for their treatment.
Methods: We reviewed charts of patients with RYGP and documented ID or anemia seen in clinic between 01-01-08 and 12-31-09. Patients were identified through the institutional billing department: RYGP patients with a diagnosis of fatigue, malnutrition, ID, or anemia. Demographics, iron indices, hemoglobin (Hgb) and prescribed treatments for ID and anemia were recorded since time of surgery.
Results: 122 patients were included, mean age and BMI at surgery: 44.7 years and 47.3. Baseline diagnoses included malnutrition (50.8%), fatigue (35.2%), ID (74.6%), anemia (26.2%); 89.3% and 87.7% were female and white; mean Hgb, transferrin saturation (Tsat) and serum ferritin were 12.4 g/dl, 16.9% and 44.2 ng/ml. Patients data were followed up to 60 mo. 69 patients received multiple transfusions (T), 53 did not receive transfusions (NT) and were prescribed oral iron (n=52) or intravenous iron (n=1). T patients had significantly lower mean Hgb than NT at >3 to 5 years (11.2 and 13.8 g/dl, p=0.0153) and >5 years (11.9 and 13.4 g/dl, p=0.0083) post surgery. # (%) values below target* : Males, T/NT Hgb 61/71 (85.9), 37/52 (71.2); Tsat 27/31 (87.1), 22/40 (55.0), Ferritin 13/38 (34.2), 16/50 (32.0); Females T/NT Hgb 33/71 , 12/52 (23.1) (46.5),; Tsat, 20/31 (64.5), 13/40 (32.5), Ferritin 8/38 (21.1), 14/50 (28.0) *Target Hgb <13.8 [male], <12.1 g/dl [female]. Ferritin <15 ng/ml or Tsat <20% [male]; Ferritin <12 ng/ml or Tsat <16% [female].

Conclusion: Both anemia and ID were common in RYGP patients. Most were treated with multiple transfusions and/or oral iron. T patients had worse parameters than NT patients. Multiple ID and Hgb values were below target for sustained periods. An opportunity exists for development of evidence-based iron management after gastric bypass surgery.
To be presented at the Society for the Advancement of Blood Management (SABM) Fall 2010, Puerto Rico.

109. Hospital characteristics and guidelines regarding the management of heparin-induced thrombocytopenia (HIT) in US hospitals (the HIT-ME study).
Alan S. Multz, M.D.; Nassau University Medical Center, East Meadow, NY

Purpose: To describe how heparin-induced thrombocytopenia (HIT) is managed in "HIT-aware" US hospitals and to gain an understanding of policies on the use of direct thrombin inhibitors (DTIs).
Methods: A third-party data source identified US institutions utilizing high volumes of argatroban and lepirudin. Data on formulary status, prevalence of guidelines for the management of patients with HIT and frequency of heparin antibody testing procedures were collected. All data were blinded for analysis.
Results: Participants were pharmacy directors or clinical pharmacists from 26 US hospitals. Hospital affiliation was divided between academic hospitals (n = 8; 30.8%), community teaching hospitals (n = 13; 50.0%), and community nonteaching hospitals (n = 5; 19.2%). Larger hospitals (≥500 beds) were 57.7% (n = 15) of the sample; hospitals with ≤499 beds accounted for 42.3% (n = 11). Two thirds of participating hospitals (n=17, 65.4%) had "test and treat" guidelines in place (DTI initiated prior to antibody test results) and 7 (26.9%) had "test and wait" guidelines (DTI initiated after positive antibody test results). Wait times for HIT antibody results were 1 day or less in 8 (30.8%) hospitals, 1 to 2 days in 10 (38.5%) hospitals, and at least 3 days in 8 (30.8%) hospitals. Of the 7 hospitals with "test and wait" guidelines, 3 (42.9%) had wait times of 1 day or more. In the face of a positive heparin antibody test, 5 (19.2%) of hospitals had guidelines recommending delaying treatment with an alternative to heparin until confirmatory diagnosis by hematology. Argatroban was the most commonly recommended treatment, listed in 22 of 26 (84.6%) guidelines of participating hospitals.
Conclusion: In patients with suspected HIT, treatment was delayed in a large proportion of participating hospitals due to directives included in local hospital guidelines for the management of HIT.

110E. PREVENT-HIT: A randomized, comparative trial of desirudin vs. argatroban in suspected HIT.
Steven W. Boyce, M.D.[1], Dennis F. Bandyk, M.D.[2], Lawrence Rice, M.D.[3]; (1)Washington Hospital Center, Washington, DC; (2)University of South Florida, Tampa, FL; (3)Methodist Academic Medicine Associates - Weill Cornell Medical College, Houston, TX

Purpose: Desirudin is the first subcutaneous (SC) direct-thrombin inhibitor (DTI) approved for deep vein thrombosis (DVT) prophylaxis, but has not previously been studied in patients with heparin-induced thrombocytopenia (HIT).
Methods: PREVENT-HIT was a randomized, open-label, exploratory study comparing fixed-dose, SC desirudin vs. aPTT-adjusted, IV argatroban in patients with clinically suspected HIT. Patients were randomized to desirudin 15 or 30 mg SC Q12H or IV argatroban. The primary endpoint was a composite of new or worsening thrombosis, amputation, or death from any cause. Secondary endpoints included major and minor bleeding.
Results: Of 16 patients randomized, heparin antibody tests were positive in 11 (70%) with similar frequency between groups. Mean baseline platelet count was 121,000/mm³ vs. 88,000/mm³ in the argatroban and desirudin groups, respectively. The mean initial dose of argatroban was 1.6 mcg/kg/min; 7/8 desirudin-treated patients received 15 mg SC Q12H. No patients died or required amputation in either group. One argatroban patient developed new thrombosis, but continued on argatroban therapy. No patients in the desirudin group developed thrombosis. Major bleeding occurred in 2/8 argatroban patients vs. 0/8 desirudin patients. Each group had one minor bleed.

Argatroban required dose-adjustment an average of 3.8 times per patient, while desirudin was adjusted one time during the entire study (from 15 to 30 mg SC Q12H).
Conclusion: This is the 1st head-to-head comparison of DTI therapy in patients with HIT. The low rate of thrombotic events in a population with a high prevalence of antibody positive HIT confirms the usefulness DTI's for this clinical condition. The costs and ease of administration of subcutaneous desirudin at a dose of 15 or 30 mg Q12H may be an attractive alternative to IV argatroban in patients with suspected HIT and warrants further study.
Presented at Presented at the 2010 Hemophilia and Thrombosis Research Society Scientific Symposium, Chicago, IL, April 15-17, 2010

111. Efficacy of intravenous heparin monitoring using a heparin antifactor Xa assay.
Adrian P. Sykes, Pharm.D., Sarah M. Gaffney, Pharm.D., BCPS, Amy R. Knauss, Pharm.D., BCPS; Northeast Georgia Health System, Gainesville, GA

Purpose: To confirm the institution's decision to expand heparin antifactor Xa monitoring to unfractionated heparin infusion by comparing the efficacy of the heparin antifactor Xa assay and activated partial thromboplastin time (aPTT).
Methods: The study was a retrospective chart review of adult patients receiving intravenous heparin infusions. The first 110 patients in the first quarter of 2009 were monitored with aPTT while the first 110 patients during the first quarter of 2010 were monitored with a heparin antifactor Xa assay. Patients were excluded if they 1) received the infusion for less than twelve hours, 2) were pregnant or lactating, or 3) prescribed heparin infusion deviating from the hospital's nomogram.
Results: The median time to first therapeutic level was 19.5 hours (IQR 12–27.25 hours) in patients monitored with aPTT and 14 hours (IQR 6–21.5 hours) in patients monitored with the heparin antifactor Xa assay. Patients on the acute coronary syndrome nomogram had a median of 13.5 and 16.5 hours, respectively. Patients on the deep vein thrombus/pulmonary embolism/atrial fibrillation nomogram had a median of 24 hours for those monitored with the aPTT and 13.5 hours for the heparin antifactor Xa assay group. The percentage of patients within therapeutic range at the first six hour laboratory draw was higher in patients monitored with heparin antifactor Xa than aPTT (25.9% versus 17.5%, respectively). The percentage of patients above therapeutic range at this laboratory draw was also in favor of the heparin antifactor Xa assay (75% versus 34.6%, respectively).
Conclusion: The study demonstrated that utilizing a more specific measurement of heparin activity, the heparin antifactor Xa assay, results in patients obtaining therapeutic range more quickly and more often when compared to activated partial thromboplastin time. This study validates monitoring unfractionated heparin infusions with a heparin antifactor Xa assay.

112E. Superior oral anticoagulation management with self testing and automated management; An interim analysis.
Henry I. Bussey Jr., B.S., Pharm.D.[1], Christopher Frei, Pharm.D.[2], Marie Walker, BBA[3], Kristin Bussey-Smith, M.D.[4]; (1)The University of Texas at Austin, University of Texas Health Science Center at San Antonio, and Genesis Clinical Research, San Antonio, TX; (2)The University of Texas at Austin and University of Texas Health Science Center at San Antonio, San Antonio, TX; (3)ClotCare and Genesis Advanced Technologies, Inc., San Antonio, TX; (4)Allergy, Asthma, Immunology & Rheumatology Institute, San Antonio, TX

Purpose: To evaluate the impact of frequent INR self testing, daily low dose vitamin K, and online automated management on the international normalized ratio (INR) control and efficiency of management.
Methods: INR control was evaluated for 6 months before and 12 months after implementing the management approach described in "Purpose". Time required for each "virtual visit" was recorded for visits that requiring intervention and 1 minute was assigned for each automated visit.
Results: Fifty-five patients recruited from 12 anticoagulation services demonstrated improvement in all measures of INR control. Clinician

management time averaged 8.94 minutes (range 4 to 13 minutes) per 4 virtual visits.

Conclusion: This management method achieved unsurpassed improvement in INR control to a degree that has been associated with a 50% reduction in stroke, MI, major bleeding, and death in 2 large studies. An estimated 15 patients would need to be treated for one year (NNT = 15) to prevent one such event; or 70 events should be prevented per 1,000 patients for a cost avoidance of approximately $4.4 million per year. Reduced clinic visit time is estimated to save an additional $168,000 per 1,000 patients per year.

Table. INR control with clinic management and ClotFree management

End Point	Clinic n=55, 26.83 pat-yrs	Study n=55, 54.14 pat-yrs
% TTR	56.83	79.65
% TTR ± 0.3 INR units	82.55	93.57
% Time INR < 1.5	2.41	0.40
% Time INR > 5	0.09	0.07
No. (%) Patients with TTR > 75%	11 (20)	39 (70.01)
No. (%) Patients with TTR ± 0.3 INR units > 75% time	17 (30.1)	55 (100)
No. (%) Patients with TTR < 60 %	30 (54.5)	4 (7.3)
No. (%) Patients with TTR ± 0.3 INR units < 60% time	7 (12.7)	0 (0.0)

TTR = time in therapeutic range

Presented at The American Heart Association meeting on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2010, Washington, DC, May 20–21, 2010

113E. INR self-testing in warfarin anticoagulation improves patient satisfaction and clinic efficiency while reducing patient costs.

Henry I. Bussey Jr., B.S., Pharm.D.[1], Nicolas A. Forcade, PharmD[2], Marie Walker, BBA[3], Christopher Frei, Pharm.D.[4], Kristin Bussey-Smith, M.D.[5], Kelly R. Daniels, Pharm.D. Candidate[6]; (1)University of Texas HSC and Genesis Clinical Research, San Antonio, TX; (2)The University of Texas at Austin and The University of Texas Health Science Center San Antonio, San Antonio, TX; (3)ClotCare and Genesis Advanced Technologies, Inc., San Antionio, TX; (4)The University of Texas at Austin College of Pharmacy and The University of Texas Health Science Center at San Antonio, San Antonio, TX; (5)Allergy, Asthma, Immunology & Rheumatology Institute, San Antonio, TX; (6)The University of Texas at Austin and University of Texas Health Science Center at San Antonio, San Antonio, TX

Purpose: To estimate the time and travel costs of anticoagulation clinic visits and examine how self-testing and online management may alter the efficiency of clinic visits, patient quality of life, and patient satisfaction.

Methods: Fifty-five patients who transitioned from clinic management to self-testing with online management were asked to complete a survey to assessment demographics as well as time and travel associated with clinic visits. They also were asked to complete the Duke Anticoagulation Satisfaction Survey (DASS). These surveys were administered at the start of the self-testing study to assess the prior clinic management period and an appropriately modified survey together with the DASS were repeated at 3 to 6 months into the study to assess the study management method. Survey results were compared for the two periods (clinic management and self-testing with online management).

Results: 90% (38 of 42) preferred or strongly preferred self-testing, and significantly more patients in the in-study survey indicated home testing was less inconvenient (p=0.02), less complicated (p=0.03), and more satisfying (p=0.01). During the study, patients were significantly more likely to recommend this therapy to someone with the same condition (p=0.0001). Travel per INR test decreased from 20 to 0 miles and time from 108 to 10 min. Patients with an annual income of more than $50,000 were willing to pay $25 or more to eliminate one clinic visit (p=0.02)

Conclusion: INR self-testing with online management is preferred by patients who also are willing to pay for the service. This approach saves the patient time and money (and allows them to travel without interrupting or complicating their management).

Presented at The American Heart Association meeting on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2010, Washington, DC, May 20–21, 2010

---

114. Bleeding with enoxaparin bridging therapy in Veterans with atrial fibrillation.

Maria Pham, Pharm.D.[1], Johanna L. Norman, Pharm.D. Candidate[2], Kelly C. Rogers, Pharm.D.[3], Shannon W. Finks, Pharm.D.[3], Robert Parker, Pharm.D.[3]; (1)Veterans Affairs Medical Center Memphis, Memphis, TN; (2)University of Tennessee Health Science Center, Memphis, TN; (3)University of Tennessee College of Pharmacy, Memphis, TN

Purpose: The use of bridging anticoagulant treatment with enoxaparin is a common clinical practice in patients with atrial fibrillation who require temporary interruption of warfarin therapy. Balancing the risk of bleeding with bridge therapy versus the risk of thromboembolic events remains a challenge. The purpose of this study is to evaluate outcomes in patients with atrial fibrillation receiving enoxaparin bridging therapy.

Methods: Patients with atrial fibrillation receiving prescriptions for concomitant warfarin and enoxaparin treatment during the period from July 1, 2007 to June 30, 2009 were included in this retrospective analysis. Demographic data, $CHADS_2$ score, duration of concomitant therapy, enoxaparin dose, baseline and follow-up laboratory data, need for transfusion, and emergency department or hospital admission within 30 days of the initiation of bridging therapy were evaluated. Bleeding events were classified according to both GUSTO and TIMI criteria.

Results: A total of 67 patients meeting the inclusion criteria were reviewed. Enoxaparin 1 mg/kg twice daily was used in 63 (94%) patients with 64 patients (95%) receiving appropriate doses according to weight and renal function. A total of 14 patients (20.9%) experienced a bleeding episode that met either or both TIMI or GUSTO criteria. Nine patients (13%) met TIMI (2 major, 4 minor, and 3 minimal) and 12 patients (18%) met GUSTO criteria for bleeding (0 severe, 2 moderate, and 10 mild). Six patients (9%) required hospital admission for bleeding, with two patients (3%) requiring transfusions. Thirteen of the 14 bleeding incidents (93%) occurred in patients with $CHADS_2$ scores < 4. No thromboembolic events occurred in this population.

Conclusions: Enoxaparin bridging in patients with atrial fibrillation is associated with frequent episodes of bleeding. Clinicians should carefully assess the potential benefits and risks of bridging in this patient population.

HIV/AIDS

115. The awareness of HIV post exposure prophylaxis protocols and the availability of antiretroviral agents in small rural US hospital pharmacies.

Lucas Gasco, Pharm.D.[1], Jonathan W. Ho, Pharm.D.[2], Vincent W. Li, Pharm.D.[3], Jeffery R. Proctor, Pharm.D.[4], Betty J. Dong, Pharm.D.[5]; (1)Wilford Hall Medical Center, Lackland AFB, TX; (2)CVS Pharmacy, Visalia, CA; (3)VA Hospital, PaloAlto, CA; (4)Safeway Pharmacy, San Francisco, CA; (5)University of California, San Francisco, San Francisco, CA

Purpose: The purpose is 1) to evaluate pharmacist familiarity with the Centers for Disease Control and Prevention (CDC) Post-exposure Prophylaxis (PEP) protocols 2) determine the availability of antiretroviral agents (ARVs) for immediate HIV prophylaxis in small rural hospital pharmacies across the United States (US).

Methods: Sixteen hundred twenty two hospitals that participated in the 2007 Small Rural Hospital Improvement Program (SHIP) were identified. Of these, 540 hospitals were randomly selected using systematic sampling of every third applicant listed. All sampled hospital pharmacy directors or pharmacist-in-charge were sent a 10-question questionnaire to evaluate their familiarity with the CDC PEP protocols, situational PEP indications, and ARVs availability.

Results: Of the 540 hospital pharmacies surveyed, 85 or 16% responded. Seventy-four pharmacies (87.1%) were familiar with the PEP guidelines. Sixty- three (74.1%) had existing protocols, while 20

(23.5%) had no protocols. Twelve (14.1%) of the pharmacies had no ARVs for immediate dispensing. Seventy-two pharmacies (84.7%) stocked ARVs that could be combined to provide a basic (two drug) PEP regimen. Fifty hospitals (58.8%) stocked ARVs that could comprise an expanded (three drug) regimen; of these; 16 (32%) could provide a preferred expanded regimen. Only 10 hospitals stocked TDF/3TC and LPV/r was available in only 16 hospital pharmacies.

Conclusions: Although the majority of rural hospitals had basic PEP regimens for low-risk exposures and about half of them had expanded PEP regimens for higher risk exposures, considerable improvement in both pharmacist knowledge about PEP and the immediate availability of essential antiretroviral agents are critical for the successful management of these urgent situations. Timely post-exposure prophylaxis for risky occupational and non-occupational exposures to HIV contaminated blood and body fluids is an important strategy to prevent HIV transmission.

116E. SHIELD: 48-Week Results of Abacavir/Lamivudine (ABC/3TC) and Raltegravir (RAL) in Antiretroviral Naive HIV-1 Infected Subjects.
Benjamin Young, M.D., Ph.D.[1], Thanes Vanig, M.D.[2], Edwin DeJesus, M.D.[3], Trevor Hawkins, M.D.[4], Marty St. Clair, B.S.[5], Linda H. Yau, Ph.D.[5], Belinda Ha, Ph.D.[5]; (1)Rocky Mountain CARES/DIDC, Denver, CO; (2)Spectrum Medical Group, Phoenix, AZ; (3)Orlando Immunology Center, Orlando, FL; (4)Southwest Care Clinic, Santa Fe, NM; (5)GlaxoSmithKline, Research Triangle Park, NC

Purpose: RAL is a HIV-1 integrase strand-transfer inhibitor with potent in vitro activity that has not been evaluated with ABC/3TC in antiretroviral naïve HIV-1 infected individuals. The objective of this study was to evaluate the efficacy and safety of ABC/3TC+RAL as initial therapy.
Methods: This is an ongoing 96-week, open-label, pilot, prospective, multicenter study evaluating ABC/3TC (600 mg/300 mg once-daily)+RAL (400 mg twice daily) in subjects with entry viral load (VL) >1,000 c/mL. Subjects were excluded if they were HLA-B*5701 positive or had RAL, ABC, or 3TC resistance mutations. Virologic failure (VF) was defined as failure to achieve VL<400 c/mL by Wk 24 or confirmed rebound ≥400 c/mL or confirmed 1 $\log_{10}$ c/mL increase above nadir. The planned Week 48 interim analysis is reported.
Results: SHIELD enrolled 35 subjects. Baseline (BL) characteristics were: median HIV-RNA 4.8 $\log_{10}$ c/mL (34% ³100,000 c/mL), median CD4+ 301 cells/mm³ (20% <200 cells/mm³). Two subjects (6%) prematurely discontinued study by Week 48: adverse event (1) and lost-to-followup (1). At Week 48, the proportion of subjects with HIV-1 RNA <400 and <50 c/mL were both 91% (32/35) by ITT M=F. Median CD4+ change from BL was 247 cells/mm³. One subject met VF criteria. Five subjects (14%) had drug-related grade 2–4 adverse events and 8 (23%) had grade 3-4 lab abnormalities. No drug-related SAEs were reported. Week 48 fasting lipid changes [median (95% confidence intervals)] were not different from BL for total/HDL cholesterol [0.01 (-0.23, 0.46)], triglycerides [-1 (-11.5, 58.5)] mg/dL, and increased for LDL cholesterol [9 (3.5, 17)] mg/dL, HDL cholesterol [5.5 (2–8)] mg/dL, and total cholesterol [16.5 (11–29.5)] mg/dL.
Conclusion: ABC/3TC + RAL produced rapid virologic suppression and robust CD4 cell increases over 48 weeks of treatment, with limited impact on fasting lipids.
Presented at XVIII International AIDS Conference, Vienna, July 18-23, 2010

117E. Fosamprenavir/Ritonavir (FPV/r) vs. Efavirenz (EFV) with Abacavir/Lamivudine (ABC/3TC) in Underrepresented, Antiretroviral (ARV) Naïve, HIV-Infected Subjects (SUPPORT): 24 Week Efficacy, Safety, and Tolerability.
Princy N. Kumar, M.D.[1], Edwin DeJesus, M.D.[2], Gregory Huhn, M.D.[3], Louis Sloan, M.D.[4], Fernando Garcia, M.D.[5], Catherine Small, M.D.[6], Howard Edelstein, M.D.[7], Franco Felizarta, M.D.[8], Ritchie Hao, M.D.[9], Katrina Oie, Ph.D.[10], Lisa L. Ross, M.S.[10], Britt S. Stancil, B.S.[10], *Belinda Ha, Ph.D.*[10], Keith Pappa, Pharm.D.[10]; (1)Georgetown University, Washington, DC; (2)Orlando Immunology Center, Orlando, FL; (3)Ruth M. Rothstein CORE Center, Chicago, IL; (4)Baylor University Medical Center, Dallas, TX; (5)Valley AIDS

Council, Harlingen, TX; (6)New York Medical College, Valhalla, NY; (7)Alameda County Medical Center, Oakland, CA; (8)Franco Felizarta, MD, Bakersfield, CA; (9)Chase Brexton Health Services, Inc., Baltimore, MD; (10)GlaxoSmithKline, Research Triangle Park, NC

Purpose: People of color have been largely underrepresented in clinical trials of ARVs in HIV. In this 96-week, open-label, prospective, randomized, multicenter study, we compared once-daily ABC/3TC 600 mg/300 mg taken with FPV 1400 mg/r 100 mg or EFV 600 mg in underrepresented ART-naïve subjects with entry viral load (VL) >5,000 c/mL.
Methods: Randomization was stratified by screening VL (< vs ≥10⁵ c/mL). Subjects were excluded if they were HLA-B*5701 positive or had EFV or FPV resistance mutations. The primary endpoint was time to switch of third drug or time to development of any treatment-related Grade 3 or 4 adverse events (AEs). The planned week 24 (W24) interim analysis results are reported.
Results: SUPPORT enrolled 32% (32/101) women and 79% (80/101) people of color. Baseline and demographic characteristics were generally similar between groups. A total of 93 subjects (92%) completed study through W24. Three subjects in each arm met the primary endpoint. At W24, by missing-equals-failure analysis, 78% (40/51) and 84% (42/50) of subjects achieved VL <50 c/mL for FPV/r vs. EFV, respectively. Median change from baseline to W24 in CD4 cell count was 134 vs. 145 cells/mm³ for FPV/r vs. EFV, respectively. Rate of treatment-related grade 2–4 AEs was lower for FPV/r (9/51, 18%) vs. EFV (14/50, 28%) primarily due to EFV-related rash and dizziness (8% each). Rates of treatment-related grade 3-4 AEs (4% each), serious AEs (4% each), and grade 3–4 lab abnormalities (16% vs. 14%) were similar between FPV/r vs. EFV. At W24, median fasting lipid levels increased in both arms. Four virologic failures occurred through W24: 1 subject on FPV/r had no treatment-emergent mutations at failure and 3 subjects on EFV failed with treatment-emergent PRO and RT mutations.
Conclusions: In this predominantly minority population, tolerability/safety and virologic/immunologic responses were not demonstrably different between treatments through 24 weeks.
Presented at XVII World AIDS Conference, July 18–23, 2010

118. Evaluation of the incidence and severity of vitamin D deficiency in a southeastern US HIV-infected population.
Kelly Hester, Pharm.D., BCPS[1], Brandon Hicks, Pharm.D.[2]; (1)Auburn University Harrison School of Pharmacy, Auburn, AL; (2)Harrison School of Pharmacy, Auburn University, Auburn, AL

Purpose: To evaluate the incidence and severity of vitamin D deficiency in HIV-infected patients.
Methods: Single-center, retrospective chart review was conducted on 100 randomly selected HIV-infected patients in Montgomery, Alabama evaluating 25-dihyroxyvitamin D levels. Additional information collected included demographics, duration of HIV infection, antiretroviral treatment history, HIV viral load, CD4 count, hepatitis B and C serology, liver function tests, and serum creatinine.
Results: Vitamin D deficiency (< 30 ng/mL) was observed in 75% of the patients. Of those, 21% had severe deficiency (< 10 ng/mL). The mean age was 48, 47% male and 73% were African American. Of those with vitamin D deficiency, 70% were male and 79% were female with 8% and 23% with levels < 10 ng/mL, respectively. Patients had been diagnosed with HIV infection for an average of 9 years, treated with protease inhibitor therapy an average of 3 years, with an average BMI of 26.6.
Conclusion: Overall, there was a high incidence of vitamin D deficiency and significant proportion with severe deficiency. In a population at higher risk for cardiovascular disease and metabolic abnormalities related to HIV infection and antiretroviral therapy, routine screening and treatment of vitamin D deficiency is imperative.

Infectious Diseases

119. Impact of a pharmacy practice resident on an antimicrobial stewardship program during an elective learning experience in infectious diseases.

Ashley B. Townsend, Pharm.D., Elias B. Chahine, Pharm.D., BCPS; Palm Beach Atlantic University, Lloyd L. Gregory School of Pharmacy, West Palm Beach, FL

Purpose: The Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America recommend establishing institutional programs led by infectious diseases physicians and clinical pharmacists trained in infectious diseases to enhance antimicrobial stewardship. This project was designed to identify the impact of a pharmacy practice resident on an established antimicrobial stewardship program.
Methods: The pharmacy resident was asked to interpret microbiology culture and sensitivity reports, review patients' profiles, and make the necessary recommendations to optimize antimicrobial therapy for all hospitalized patients with at least one positive microbiology culture during a 4-week learning experience in infectious diseases. All recommendations were communicated to decentralized clinical pharmacists for initial review and then to prescribing physicians for final approval. The pharmacists and the resident were surveyed at the conclusion of the rotation to assess their satisfaction with the service provided.
Results: A total of 179 interventions were made during the 18 days the resident served on the antimicrobial stewardship team. Antimicrobial selection, initiation, and discontinuation accounted for the majority of interventions (48%), followed by dose optimization (22%), drug information (22%), and IV to PO conversion (8%). Seventy-three percent of the recommendations were approved by physicians and implemented. Surveyed pharmacists were satisfied with the service provided by the resident and agreed that the program helped optimize antimicrobial therapy in hospitalized patients. The resident indicated a significant improvement in her knowledge, skills, and attitude in infectious diseases pharmacotherapy.
Conclusion: Adding pharmacy residents to antimicrobial stewardship teams may be helpful to enhance antimicrobial stewardship, increase the job satisfaction of pharmacists involved in stewardship, and provide residents with the opportunity to improve their abilities as providers of infectious diseases pharmacotherapy services.

120E. High-Dose Vancomycin for Methicillin-Resistant *Staphylococcus aureus* Ventilator-Associated Pneumonia.
Leslie A. Hamilton, Pharm.D.[1], G. Christopher Wood, Pharm.D.[2], Louis J. Magnotti, M.D.[2], Martin A. Croce, M.D.[2], Joseph M. Swanson, Pharm.D.[2], Bradley A. Boucher, Pharm.D.[2], Timothy C. Fabian, M.D.[2]; (1)Auburn University, Birmingham, AL; (2)University of Tennessee Health Science Center, Memphis, TN

Purpose: The purpose of this retrospective study was to determine the clinical cure rate of high-dose vancomycin for the treatment of methicillin-resistant *Staphylococcus aureus* (MRSA) ventilator-associated pneumonia (VAP) in critically ill trauma patients. Recent trials and guidelines suggest that a traditional dose of 1 g q12h results in unacceptable cure rates. More aggressive vancomycin dosing has the potential to improve efficacy.
Methods: All patients admitted to the trauma ICU from 1997-2008 diagnosed with MRSA VAP were reviewed. Diagnosis of VAP required bacterial growth ≥ 100,000 colony forming units/mL from a bronchoscopic bronchoalveolar lavage (BAL), new or changing infiltrate in chest x-ray, plus at least two of the following: fever, leukocytosis or leukopenia, or purulent sputum. The goal initial vancomycin dose was 20 mg/kg q12h. Clinical and microbiological success were evaluated using standard definitions.
Results: Overall, 129 patients with 148 episodes of MRSA VAP were identified. Mean age was 45 (± 20) years, mean injury severity score was 32 (± 13), patients were 73% male, and the mean length of ICU stay was 36 (± 35) days. Seventy-two patients (56%) had polymicrobial VAP. The mean initial vancomycin dose was 19.8 mg/kg/dose with a mean duration of therapy of 11 days. Clinical success was achieved in 88% (130/148) of episodes, and microbiological success in 89% (76/85) of episodes with a follow-up BAL. Overall mortality was 21% (27/129), with death due to VAP in 13/27 deaths. Clinical success was not related to *S. aureus* MIC. Mean vancomycin trough concentrations were 11.8 mg/L in the clinical success group and 12.2 mg/L in the clinical failure group (p=NS). No

patient required hemodialysis attributable to vancomycin therapy.
Conclusion: High-dose vancomycin provided an acceptable cure rate for MRSA VAP in trauma ICU patients.
Published in Presented and published in: Crit Care Med 2009; 37(12): A222.

121. Moxidectin does not induce CYP3A4 activity when evaluated by oral midazolam pharmacokinetics in healthy subjects.
Joan Korth-Bradley, Pharm.D., Ph.D.[1], Virginia Parks, B.Sc., (Hons)[2], Stephan Chalon, M.D., Ph.D.[2], Ian Gourley, M.D.[1], Kyle Matschke, MAS[1], Sophie Gossart, M.Sc.[2], Lawrence L. Fleckenstein, Pharm.D.[3], Frank Wagner, Dr., med.[4]; (1)Pfizer Inc., Collegeville, PA; (2)Wyeth Research, Paris, France; (3)University of Iowa, Iowa City, IA; (4)Charite Research Organisation GmbH, Berlin, Germany

Purpose: To evaluate potential CYP3A4 induction activity of single oral dose of moxidectin through changes in the PK of midazolam (MDZ) administered 1 week and 3 months after moxidectin compared with baseline MDZ PK.
Methods: Thirty-eight subjects received 7.5-mg MDZ doses after overnight fast on study days 1, 10 and 92. Safety was evaluated from adverse events (AEs), laboratory data, physical examinations, pulse oximetry monitoring, vital signs, and ECGs. Serial plasma samples were collected for 24 hours after administration and assayed for MDZ, 1-OH-MDZ and 4-OH-MDZ. On day 3, moxidectin was administered immediately after the subjects finished eating a standard, medium fat breakfast. ANOVA of log-transformed MDZ parameters with treatment day as a fixed effect performed.
Results: Thirty-nine subjects (2 women, mean age 38 yr, mean BMI 25 kg/m[2]) were enrolled in the study. One subject dropped out after the 1st MDZ dose and was replaced and another subject dropped out on day 59 but was not replaced, so complete PK results are available for 37 subjects. AEs reported were generally mild and there were no relevant changes in safety assessments. Mean ± sd moxidectin PK parameters were: Cmax 77.2 ± 17.8 ng/mL, tmax: 3.90 ± 1.40, Vz/F 2372 ± 661 L, CL/F 1.87 ± 0.60 L/hr, t½ 981 ± 438 h. Baseline mean ± sd MDZ PK parameters were: Cmax 32.7 ± 13.6 ng/mL, tmax: 0.929 ± 0.464 h, Vz/F 638 ± 225 L, CL/F 95.6 ± 46.8 L/h, t½ 5.14 ± 1.62 h, ratio MDZ-1-OH/MDZAUC 0.312 ± 0.135 and ratio 4-OH/MDZ AUC 0.0692 ± 0.0173. ANOVA showed no change in any parameter.
Conclusions: No change in MDZ PK and thus no induction of CYP3A4. Other sensitive CYP3A4 substrates are unlikely to be affected by moxidectin.

122. Outcomes of daptomycin (DAP) treatment in Intensive Care Unit (ICU) patients (pts) with Gram-positive bloodstream infections (GPBSI).
Marina B. Rabinovich, Pharm.D., BCPS[1], Prasad Abraham, Pharm.D., BCPS[1], Katherine P. Holloway, Pharm.D., BCPS[2], Hina N. Patel, Pharm.D., BCPS[2]; (1)Grady Health System, Atlanta, GA; (2)Cubist Pharmaceuticals, Lexington, MA

Purpose: Little data exist on DAP outcomes in critically-ill pts. The purpose of this study was to investigate outcomes of DAP treatment for GPBSI, specific to ICU setting.
Methods: Pts with GPBSI who received DAP in an ICU were identified in CORE 2005–2009, a retrospective, multicenter, observational registry. Investigators assessed outcome (cured, improved, failed, NE-nonevaluable) at end of DAP therapy. Efficacy population was the resulting cured, improved and failed pts. Pt characteristics were based on efficacy population. All pts were included in safety analysis. Outcomes were compared to non-ICU DAP pts with GPBSI.
Results: 1533 pts with GPBSI were identified; 1172 pts were evaluable. 361 (31%) received DAP in an ICU. Overall pt characteristics included: 53% male, 31% > 65 yrs, 26% CrCl < 30 mL/min and 20% dialysis. CrCl < 30 mL/min and dialysis was significantly higher in ICU group. AEs possibly related to DAP were not significantly different between ICU and non-ICU groups (9 and 8%, respectively). Mortality in ICU and non-ICU groups was 26 and 4%, respectively (p<0.0001).

	DAP ICU (n=361)	DAP non-ICU (n=811)	p-value
S. aureus, n (%) MRSA	143 (40)	114 (32)	0.8193
	327 (40)	220 (27)	0.1191
Enterococcus, n (%) VR *E. faecium*	147 (41)	268 (33)	0.0112
	90 (25)	151 (19)	0.0136
Endocarditis, n (%)	73 (20)	71 (9)	<0.0001
Median dose, mg/kg (min, max)	6 (3,10)	6 (3,12)	0.4268
Median duration, days (min, max)	13 (1, 370)	14 (1, 119)	0.1433
Success rate, n (%) Cured	279 (78)	753 (93)	<0.0001
Improved	147 (41)	420 (52)	
	132 (37)	333 (41)	

Conclusion: As observed in other studies, ICU pts with GPBSI treated with DAP had less-favorable outcomes vs. non-ICU pts. Greater severity of illness, higher endocarditis rates, renal dysfunction and VR *E. faecium* likely contributed to worse outcomes. Further analysis is warranted.

123. Retrospective assessment of vancomycin dosing requirements in pediatric burn patients.
Stephanie Wead, Pharm.D.[1], *Daniel P. Healy, Pharm.D.*[1], Roy Saylors, B.S.Pharm.[2], Mary T. Rieman, R.N., B.S.N.[2], Paula Durkee, B.S.[2], Alice N. Neely, Ph.D.[2], Richard J. Kagan, M.D.[2]; (1)James Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH; (2)Shriners Hospitals for Children®-Cincinnati, Cincinnati, OH

Purpose: With recent changes in vancomycin dosing guidelines for adult patients and the lack of published information on vancomycin in pediatric burn patients, the purpose of this study was to describe the current dosing practices in this population.
Methods: This was a single-center, retrospective chart review conducted at Shriners Hospital for Children®- Cincinnati. All pediatric burn patients who received vancomycin from January 2007 to December 2009 were included for analysis.
Results: Ninety-six patients were identified; 9 were excluded for non-burn injury. The average age of the 87 with burns (55 males, 32 females) was 6.1 years (range, 6 mo–17 yr), with an average (range) percent total body surface area burn (%TBSA) of 46% (10.5–99.5%). The average initial dose was 73 ± 35 mg/kg/day, with dosing intervals of 6, 8 or 12 hours in 47%, 39%, and 14%, respectively. These regimens produced initial troughs of 6.7 ± 6.4 μg/ml. 50% of patients had initial troughs < 5 μg/ml and 84% < 10 μg/ml after the dosing regimen. Only about 20% of the variance in trough levels could be explained by the mg/kg/day dose. There was no significant relationship found between trough level and %TBSA burn. Renal function improved after initiation of vancomycin, with greatest improvements in those whom therapeutic trough concentrations were obtained.
Conclusion: This retrospective analysis demonstrated very high initial vancomycin dosing and variability in the resultant trough levels in pediatric burn patients. The significant number of patients with early subtherapeutic trough concentrations despite the high mg/kg/day dosages administered suggests the need for revised initial dosing regimens and prospective evaluation in pediatric burn patients. Multivariate analysis related to various outcome parameters is currently ongoing in an attempt to identify significant relationships that might better predict early dosing needs.

124. Retrospective evaluation of antibiotic prescribing with heart failure.
John Smith, Pharm.D.[1], Yasir Tasnif, Pharm.D.[2], Elena Guerra, Pharm.D. Candidate[3]; (1)Valley Baptist Medical Center, Harlingen, TX; (2)University of Texas at Pan American, Edinburg, TX; (3)University of Houston, Houston, TX

Purpose: Heart failure is the most common diagnosis for patients 65 years and older who are admitted to the hospital. The presentation of heart failure can mimic symptoms of pneumonia, resulting in inappropriate antibiotic usage. Inappropriate usage of antimicrobials has been associated with increased morbidity, mortality and health care costs. The purpose of our study was to evaluate the appropriateness of antibiotic usage in patients admitted with a primary diagnosis of heart failure.

Methods: We retrospectively reviewed patients admitted with a primary diagnosis of heart failure at our institution from April 2009 to June 2009. The following data was collected: whether or not the patient received antibiotics. In the patients that received antibiotics, we recorded the maximum and minimum white count and temperature in the 24 hours before and after starting antimicrobial therapy. We also looked to see if cultures were ordered prior to starting therapy, and if they were positive. If the patient had more than one infectious marker or a positive culture or obvious source of infection, we defined antibiotic use as appropriate. If the patient had one infectious marker but no positive cultures, we defined antibiotic use as likely appropriate. If the patient did not have infectious markers or positive cultures, we defined antibiotic use as likely inappropriate. If the patient did not have infectious markers and cultures were not ordered, we defined antibiotic use as inappropriate.
Results: Of the 106 patients admitted with heart failure, 40 received antibiotics. Among the patients who received antibiotics, 40% was appropriate, 30% was likely appropriate, 20% was likely inappropriate, and 10% was inappropriate.
Conclusion: Antibiotic use in this study did not consistently follow criteria defined by presence of infectious markers or positive cultures. The use of antibiotics in this disease state represents an opportunity for more study and improvement.

125. Use of single-agent vs multi-drug regimens as initial antibiotic therapy for community-acquired pneumonia (CAP) in US hospitals, 2000–2009.
Ariel Berger, MPH[1], John Edelsberg, M.D., M.P.H.[1], Gerry Oster, Ph.D.[1], Kenneth LaPensee, Ph.D., M.P.H.[2], David Weber, M.D., M.P.H.[3]; (1)Policy Analysis Inc., Brookline, MA; (2)Forest Research Institute, Jersey City, NJ; (3)University of North Carolina, Chapel Hill, NC

Purpose: Until relatively recently, single-agent therapy with beta-lactams or fluoroquinolones was the mainstay of treatment in patients hospitalized for CAP. Changes in US treatment guidelines and antimicrobial resistance may have led to a decline in use of single-agent regimens and a rise in multi-agent therapy. We examined this issue in our study.
Methods: Using a large US multi-hospital database, we identified all patients hospitalized for pneumonia between 1/1/2000 and 6/30/2009 who received parenteral antibiotics for ≥48 hours (except in the event of death) beginning ≤24 hours of hospital admission. Patients with healthcare-associated pneumonia were excluded, as feasible. Initial antibiotic therapy was defined as all parenteral antibiotics received ≤24 hours following hospital admission. Patients who received one antibiotic only during this period were deemed to have received single-agent therapy; all others, multi-drug regimens. Patients were stratified based on whether or not they were admitted to an intensive care unit (ICU) within first 24 hours ("ICU" and "non-ICU" cohorts, respectively). We examined use of single-agent versus multi-drug regimens on a calendar-year (CY) basis.
Results: We identified 50,713 patients admitted to hospital for CAP; mean (SD) age was 69 (17) years, and 50% were women. Among the non-ICU cohort (n=41,699), use of multi-drug regimens increased from 32.2% in CY2000 to 54.1% in CY2009, while use of single-agent regimens declined from 67.8% to 45.9% (p<0.01 using chi-square). Among the ICU cohort (n=9,014), use of multi-drug regimens increased from 48.1% to 70.1%, while use of single-agent regimens declined from 51.9% to 29.9% (p<0.01 using c[2]).
Conclusion: Use of multi-drug regimens in patients hospitalized for CAP has increased substantially over the last decade, possibly due to new treatment guidelines and/or patterns of antimicrobial resistance.

126E. Role of CgUPC2 in the susceptibility of *Candida glabrata* to fluconazole.
Kelly E. Caudle, Pharm.D., Ph.D.[1], Nathan P. Wiederhold, Pharm.D.[2], Katherine S. Barker, Ph.D.[1], P. David Rogers, Pharm.D., Ph.D.[1]; (1)The University of Tennessee Health Science Center, Memphis, TN; (2)The University of Texas Health Science Center at San Antonio, San Antonio, TX

Purpose: Azole antifungal resistance has emerged as a significant

problem in the management of infections caused by *Candida* species including *Candida glabrata*. Azoles act by inhibiting lanosterol demethylase, encoded by *ERG11*, which is a key enzyme in the ergosterol biosynthesis pathway. In *Saccharomyces cerevisiae*, the transcriptional regulators ScUpc2p and ScEcm22p regulate genes involved in this pathway. We identifed a single *ScUPC2/ScECM22* homolog in *C. glabrata*, *CgUPC2* (CAGL01199g) that influences azole susceptibility and expression of ergosterol biosynthesis genes.

Methods: *C. glabrata* strains SM1D*upc2* and SM3D*upc2* (and their revertants) were derived from the matched fluconazole (FLC)-susceptible and –resistant isolate set SM1 (FLC MIC = 16 µg /ml) and SM3 (FLC MIC >64 µg /ml), respectively. Fluconazole susceptibilities were determined by broth microdilution. SM1 and SM1D*upc2* were exposed to either medium alone or fluconazole at a concentration of 16 µg/mL for 3 hours. Total RNA was isolated and mRNA abundance for *ERG1, ERG2, ERG3, ERG4, ERG5, ERG6, ERG7, ERG11, ERG24,* and *ERG26* was measured by real-time RT-PCR.

Results: Deletion of *CgUPC2* in strains SM1 and SM3 increased susceptibility to fluconazole (FLC MIC = 2 and 16, respectively). In isolate SM1, fluconazole induced expression of all ergosterol biosynthesis genes tested. Disruption of *CgUPC2* also abrogated fluconazole-induced expression of these genes. Reintroduction of *CgUPC2* restored fluconazole susceptibility and ergosterol biosynthesis gene expression to baseline.

Conclusion: *CgUPC2* contributes directly to the susceptibility of *C. glabrata* to fluconazole and is essential for the fluconazole-induced expression of genes involved in the ergosterol biosynthesis pathway, including *ERG11*.

Presented at Interscience Conference of Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010.

127E. Comparative Immunoprofiling of Experimental Pneumonia Caused by Antibiotic Susceptible and Multi-Drug Resistant (MDR) *P. aeruginosa* (PA).
Cynthia Perez, Pharm.D.[1], Vincent H. Tam, Pharm.D.[1], Kimberly Ledesma, B.S.[1], K. Abdelraouf, B.S.[1], Dimitrios P. Kontoyiannis, M.D., Sc.D.[2], Russell E. Lewis, Pharm., D.[1]; (1)University of Houston College of Pharmacy, Houston, TX; (2)University of Texas M.D. Anderson Cancer Center, Houston, TX

Purpose: Pneumonia caused by MDR PA is often less fulminant than infections caused by antibiotic-susceptible strains; possibly due to reduced fitness of MDR isolates. We hypothesized that MDR PA may also display altered patterns of host immune system activation in vivo.

Methods: We compared disease patterns and the transcriptional response of 84 innate immune response genes in the lungs of immunocompetent Balb/C mice infected intratracheally with well–characterized isogenic WT and MDR (ΔMexR/ΔOprD PAO1) PA that display similar growth rates *in vitro*. At serial timepoints (1, 24 and 72 hrs) 5 mice were euthanized for isolation of total lung RNA (n=3) or histopathology (n=2). Control animals (n=5 per timepoint) were inoculated with sterile saline. Gene expression profiles were determined using commercial murine RT-PCR innate immune response array kits and analysis software provided the manufacturer (SA Biosciences).

Results: Compared to controls, infection with WT-PAO1 was associated with significant upregulation of genes involved in pathogen recognition (TLR2, Pglyrp1, Pglyrp3), inflammation (TNF, IL-1, IL-6, CCL1, CCL6), complement/collectin synthesis (C8a, Cfp, Dmbt1) and sepsis markers (Nos2, Protein C). Significantly lower expression levels of complement (C8a, Cfp, Dmbt1) and sepsis markers (Nos2, Protein C) were observed at 24h in animals infected with the MDR vs WT PA strain. Histology also revealed less extensive inflammation and consolidation in animals infected with MDR strain.

Conclusion: In this experimental model, isogenic WT and MDR PA strains elicited different patterns of immune system activation with marked differences in complement activation. These differences in host immune response to PA between WT and MDR strains may be important for the microevolution, evasion and persistence of MDR PA *in vivo*.

Presented at 50th Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA

128E. Activity of meropenem and colistin alone and in combination against mutlidrug resistant *Acinetobacter baumannii* in a pharmaco-kinetic-pharmacodynamic model.
Warunee Srisupha-olarn, Pharm.D, *David S. Burgess, Pharm.D., FCCP*; University of Texas at Austin College of Pharmacy and University of Texas Health Science Center San Antonio School of Medicine, San Antonio, TX

Purpose: Colistin (CST) has been used to treat multidrug resistant (MDR) *A. baumannii* but resistance to CST is being reported more frequently. Therefore the use of combination therapy must be evaluated to treat these MDR pathogens. Since for β-lactams the pharmacokinetic-pharmacodynamic (PK-PD) parameter that best predicts outcome is the time above the MIC, the objective of this study was to evaluate CST and continuous infusion (CI) meropenem (MEM) alone and in combination against MDR A. baumannii.

Methods: MICs were determined for 3 MDR A. baumannii according to the CLSI broth dilution guidelines. Next each isolate was exposed to 5 regimens consisting of CST 2.5 mg/kg q12h, MEM 3g and 6g CI over 24 hrs alone and in combination (i.e., CST plus MEM 3g and CST plus MEM 6g) using an in vitro PK-PD model. Samples were obtained at 7 time points over 24 hrs then incubated at 35C to determine colony count. All experiments were performed in duplicate. Bactericidal and synergy were defined using standard definitions.

Results: All isolates were susceptible to CST (MICs ranged from 0.5–1 µg/mL) but resistant to MEM (MICs ranged from 32–128 µg/mL). In the PK-PD model, MEM (3 g and 6 g) alone was unable to reach bactericidal activity for any isolate. While CST alone reached bactericidal activity within 4 hrs for all isolates, CST was unable to maintain this activity for the entire 24 hrs. The combination of CST plus CI MEM 3 g demonstrated synergy but still allowed regrowth to occur by 24 hrs. However the combination of CST plus CI MEM 6 g demonstrated both synergy and bactericidal activity over the entire 24 hrs for all isolates.

Conclusion: Colistin in combination with meropenem 6 g continuously infused over 24 hrs was highly active against MDR *A. baumannii* and should be further investigated in clinical studies.

Presented at the 50th Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 14, 2010.

129E. In vitro activity of carbapenems alone and in combination with amikacin against KPC-producing *K. pneumoniae* isolates.
David S. Burgess, Pharm.D., FCCP[1], Barbara McKee, MT, (ASCP)[2], Warunee Srisupha-olarn, Pharm.D.[3], Jennifer Le, Pharm.D., BCPS-ID[4]; (1)University of Texas at Austin College of Pharmacy and University of Texas Health Science Center School of Medicine, San Antonio, TX; (2)Long Beach Memorial Medical Center, Long Beach, CA; (3)University of Texas Health Science Center, San Antonio, TX; (4)University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla, CA

Purpose: Production of KPC β-lactamase in *K. pneumoniae* is alarmingly increasing and contribution to carbapenem resistance. With the current lack of antibiotics active against KPC-producing pathogens, one potential treatment modality is to optimize the use of combination therapy. Therefore the objective of this study was to evaluate the in vitro activity of carbapenems alone and in combination with amikacin against KPC-K. pneumoniae.

Methods: MICs were determined for ertapenem (ETP), imipenem (IPM), meropenem (MEM), and amikacin (AMK) against 4 non-duplicate KPC-K. pneumoniae using the Modified Hodge test (MHT). All isolates carried blakpc-3 and genes encoding TEM-1 and SHV-11/36 as previously described in the clinical outcomes evaluation (J Clin Microbiol 2010;48:623–5). Time-kill curves were performed with the following antibiotic concentrations (µg/mL) alone and in combination with AMK (20): ETP (2), IPM (4), and MEM (4). All experiments were performed in duplicate. Bacterial densities were determined at 0, 4, 8, 12, and 24 hrs. Standard definitions of bactericidal activity and synergy were used.

Results: All isolates were highly resistant to each carbapenem (ETP, IPM, and MEM MICs ranged 16–128 µg/mL) and AMK (MICs ranged 32–128 µg/mL). Monotherapy with AMK displayed some killing activity up to 8 hrs. However ETP monotherapy was the least

active of all agents. Synergy occurred in all combinations of IPM or MEM with AMK against all isolates. Bactericidal activity at 24 hrs was demonstrated for these combinations in 3 of 4 isolates.

Conclusion: IPM or MEM in combination with AMK were highly active against KPC-*K. pneumoniae* and warrants further investigation. Presented at the 50th Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 13, 2010.

130. Rapid phenotyping of two novel ganciclovir resistance mutations from human cytomegalovirus infections in liver transplant recipients.

Gregory Smallwood, Pharm.D.[1], Tim Barnett, Ph.D.[2], Katie Casper, M.S.[2], Thomas Heffron, M.D.[3]; (1)PCOM School of Pharmacy, Suwnee, GA; (2)Children's Healthcare of Atlanta, Atlanta, GA; (3)Emory Healthcare, Atlanta, GA

Purpose: Reduced susceptibility to the antiviral drug ganciclovir is increasingly observed in cytomegalovirus infections of liver transplant patients, greatly complicating treatment protocols and reducing prognosis. As we have previously reported, we have identified numerous mutations of the cytomegalovirus (CMV) from clinical isolates obtained from liver transplant recipients. Clinical outcomes associated with these isolates have been associated with "clinical resistance" to ganciclovir. Most research aimed at identifying ganciclovir-resistant CMV has centered on the identification of mutations in 2 genes, UL97 and UL54, and characterization of these mutations by a process called "recombinant phenotyping". In this study, we have developed an improved recombinant phenotyping method for CMV.

Methods: Using a reporter strain (Towne-SEAP) that is propagated in *Escherichia coli* as a Bacterial Artificial Chromosome, an individual mutation can be introduced into the UL97 gene in 1–2 weeks using rapid *E. coli* genetic techniques. Following transfection into host cells, recombinant virus particles are produced that contain two different reporter genes, Green Fluorescent Protein (GFP) and Secreted Alkaline Phosphatase (SEAP). Growth of recombinant virus in different concentrations of ganciclovir is monitored visually (via GFP) and antiviral susceptibility levels are calculated by measuring SEAP activity in culture supernatants which will be shown.

Results: With the introduction of 3 mutations from clinical isolates from liver transplant patients, a system has been developed that measures the degree of "clinical resistance" along with dose appropriate recommendations for clinical use. With the incorporation of known (A594V) and novel (N510S, N597Y) mutations into UL97, dose concentration curves required for viral kill are produced.

Conclusions: With the use of this engineered, reporter virus for antiviral resistance, quick identification of resistant CMV with dose recommendations are now possible. The reporter virus, Towne-SEAP, represents a dramatic improvement on existing methods with the ability to deliver a more comprehensive analysis of mutations affecting drug susceptibility of CMV.

131E. In vitro activity of MK-7655 in combination with imipenem (IPM) against carbapenem resistant Gram-negative bacteria.

Elizabeth B. Hirsch, Pharm.D.[1], Kimberly R. Ledesma, B.S.[1], Kai T. Chang, Ph.D.[1], Mary M. Motyl, Ph.D., D(ABMM)[2], Vincent H. Tam, Pharm.D.[1]; (1)Univ. of Houston, Houston, TX; (2)Merck & Co., Inc., Rahway, NJ

Purpose: Carbapenem resistant bacteria represent a significant treatment challenge due to the lack of active antimicrobials available. MK-7655 is a novel β-lactamase inhibitor under clinical development. We investigated the combined killing activity of IPM/MK-7655 against three IPM-resistant strains.

Methods: Time-kill studies (TKS) using approximately $1–5 \times 10^5$ CFU/ml were conducted with IPM and MK-7655 against one strain of KPC-2 producing *Klebsiella pneumoniae (*KP6339) and two strains of *Pseudomonas aeruginosa* (PA24226 and PA24227). TKS were performed using 25 clinically achievable concentration combinations in a 5 x 5 array. Bacterial burden at 24h was determined in triplicate by quantitative culture and mathematically modeled using a three-dimensional response surface. Volumes under the plane (VUP) of the observed and expected surfaces were computed by interpolation and

double integration, respectively. Synergy and antagonism were defined as an interaction index ($VUP_{observed}/VUP_{expected}$) of <1 and >1, respectively. The mathematical model assessment of KP6339 was validated experimentally using clinically relevant dosing regimens of IPM ± MK-7655 in a hollow-fiber infection model (HFIM).

Results: IPM MICs for KP6339, PA24226, and PA24227 were 128, 32, and 16 mg/L, respectively. In the presence of 4 mg/L of MK-7655, IPM MICs were reduced to 2 mg/L in all 3 strains. The combination of IPM/MK-7655 was synergistic for all strains examined. Interaction indices were as follows: KP6339 = 0.50 (95% CI 0.42–0.58), PA24226 = 0.60 (95% CI, 0.58–0.62), PA24227 = 0.70 (95% CI, 0.66–0.74). In HFIM, IPM alone failed to control KP6399 in 12h, but significant killing and sustained suppression was found using a simulated exposure of IPM/MK-7655 500 mg q6h over 72 h.

Conclusions: The addition of MK-7655 to IPM restores *in vitro* activity against IPM-resistant isolates. Further *in vitro* studies are ongoing to validate the mathematical model predictions.

Presented at Accepted for poster presentation at the 50th Interscience Conference on Antimicrobials and Chemotherpy (ICAAC), Boston, MA, September 12–15, 2010.

132E. Prospective validation of a model to predict mortality following *Pseudomonas aeruginosa* (PA) bacteremia.

Elizabeth B. Hirsch, Pharm.D.[1], Jessica M. Cottreau, Pharm.D.[1], Juan P. Caeiro, M.D.[2], Michael L. Johnson, Ph.D.[2], Vincent H. Tam, Pharm.D.[2]; (1)Univ. of Houston, Houston, TX; (2)St. Luke's Episcopal Hospital, Houston, TX

Purpose: Infections caused by PA are associated with significant morbidity and mortality. Models identifying mortality risk factors have been developed, but prospective validation of these models is lacking. We developed and validated a mathematical model to predict mortality in patients with PA bacteremia.

Methods: Adult patients with PA bacteremia from 1/2007 to 12/2009 were identified by the microbiology laboratory database, and pertinent clinical data (demographics, co-morbidities, APACHE II scores on the first day of positive culture, source of bacteremia, antibiotic susceptibility) were retrieved from electronic medical records. Risk factors for 30-day mortality were examined using 2007–08 patient data with multivariate logistic regression. The predicted probability of 30-day mortality was subsequently validated using patients in 2009, after conditioning the model by the identified risk factors. The predictive performance of the model was assessed by the ratio for observed versus expected (O/E) mortality.

Results: 115 episodes of PA bacteremia during 2007–08 were used to develop the model, 30-day mortality was found in 21 episodes (18.3%). Independent predictors of mortality were isolation of a multidrug-resistant strain (odds ratio [OR], 8.194; 95% CI, 1.723–38.961), APACHE II ≥ 23 (OR, 7.487; 95% CI, 2.147–26.106), immunosuppression (OR, 2.587; 95% CI, 0.881–7.598), and being diabetic (OR, 0.321; 95% CI 0.089–1.153). The model was validated by 50 episodes of PA bacteremia in 2009. The predicted probability of 30-day mortality was 16.6%, while the observed mortality was 18.0% (O/E ratio = 1.084; 95% CI, 0.376–1.792).

Conclusions: Our model was reasonable in predicting risk of 30-day mortality. Knowledge of patients at increased risk can be used to develop strategies to reduce mortality attributed to PA infections.

Presented at Accepted for poster presentation at the 50th Interscience Conference on Antimicrobials and Chemotherpy (ICAAC), Boston, MA, September 12–15, 2010.

133. Tuberculosis treatment outcomes: a retrospective cohort analysis of smoking versus non-smoking patients in the state of Penang, Malaysia.

Juman A. Dujaili, M.Pharm[1], Syed Azhar Syed Sulaiman, Pharm.D.[1], Ahmed Awaisu, Ph.D.[1], Abdul Razak Muttalif, M.Med.[2], Ali Q. Jaafar, M.Pharm[1]; (1)School of Pharmaceutical Science, Universiti Sains Malaysia, Minden, Malaysia; (2)Department of Respiratory Medicine, Penang Hospital, Jalan Residensi, Malaysia

Purpose: The association between tobacco smoking and tuberculosis (TB) is increasingly coming to light and the literature is laden with the evidence of this association. However, only a few observational

studies specifically investigated the association between smoking and TB treatment outcomes. The present study aims to compare the treatment outcomes between smoking and non-smoking TB patients.

Methods: A retrospective cohort study comparing smoking and non-smoking TB patients with regards to treatment outcomes was conducted. The data were extracted from medical records of newly diagnosed TB patients of both sexes, above 15 years of age whose smoking status was documented and who registered at a chest clinic of a tertiary care hospital in Penang, Malaysia from January 1 2006 to June 30 2008. Category II (TB relapse, treatment failure and treatment default), Category III (chronic cases) and HIV co-infected TB patients were excluded from the study. Furthermore, other Category I cases comprising of pregnant women, patients with diabetes and those with incomplete data were also excluded.

Results: Smoking was significantly associated with male gender, alcohol use, and intravenous drug use. Ever smokers had increased likelihood of treatment failure (OR=7.48; CI 0.93, 60.30), default (OR=7.17; CI 2.76, 18.62) and were less likely to be cured (OR=0.34; CI 0.21, 0.49). After controlling for the effects of confounders using multivariate logistic regression, ever smokers were still less likely to be cured (aOR=0.31; CI 0.17, 0.57) and more likely to default treatment (aOR=3.24; CI 1.01, 10.45). Dying from TB did not reach statistical significance.

Conclusion: This study further reaffirms that smoking is an independent predictor of poor TB treatment outcomes and prognosis. Therefore, smoking cessation interventions should be offered to all TB patients who are smokers when they are undergoing TB treatment.

134. Stability and compatibility of candidate antifungal lock solutions of micafungin.

P. Brandon Bookstaver, Pharm.D., BCPS(AQ-ID), AAHIVE, Jessic Harris, Pharm.D. Candidate, Mary B. Sides, B.S., M.S., Celeste N. Rudisill, Pharm.D.; South Carolina College of Pharmacy, USC Campus, Columbia, SC

Purpose: Studies investigating the utility of antifungal lock solutions in treatment or prophylaxis of catheter related bloodstream infections, specifically echinocandins, are limited. This study investigates the physical stability and compatibility of candidate micafungin lock solutions in combination with heparin or ethylenediaminetetraacetic acid (EDTA).

Methods: Candidate lock solutions included micafungin (MIC) at variable concentrations (0.001 mg/mL, 0.01mg/mL, 0.1 mg/mL, 1 mg/mL, and 2 mg/mL) alone and in combination with heparin (100 units/mL) or EDTA (30 mg/mL). Solutions were stored in light-protected casings at room temperature (22°C), refrigeration (4°C), and a heated environment (37°C). Physical stability and compatibility were measured by mean changes in turbidity, pH, and spectro-photometry over a 96 hour study period. Measurements were recorded for each sample at 0h, 4h, 12h, 24h, 48h, 72h, and 96h. Spectro-photometry was measured at baseline and daily. Each candidate lock solution was tested in quadruplicate. A 20 percent change in turbidity was deemed significant.

Results: Compatibility results based on significant changes in turbidity, pH, or visual changes are noted in the table below for the lock solutions in combination with heparin and EDTA at the 4°C temperature for 72 hours.

Lock Solutions	Heparin, EDTA		
	24 hours	48 hours	72 hours
MIC 0.001mg/mL	C, C	I[a], C	C, C
MIC 0.01mg/mL	C, C	I, C	I, I
MIC 0.1mg/mL	C, C	I, C	I, C
MIC 1.0mg/mL	C, C	C, C	C, I
MIC 2.0mg/mL	C, C	C, C	C, I

aSolution contamination; C=compatible; I=incompatible; At 96 hours, MIC 1.0 mg/mL and 2.0 mg/mL combined with heparin in solution was compatible.

Conclusion: Micafungin lock solutions in combination with heparin or EDTA were stable for 72-96 hours at refrigeration. Storage at room temperature or a high-temperature environment similar to a tunneled catheter resulted in at least 24-hour stability. Our results support bioactivity testing of micafungin lock solutions against biofilm producing *Candida* species.

135. Outcomes in obese patients on high doses of daptomycin (DAP): experience of fifteen institutions in the Southeastern United States.

P. Brandon Bookstaver, Pharm.D., BCPS(AQ-ID), AAHIVE[1], Christopher M. Bland, Pharm.D., BCPS[2], Carmen Faulkner, Pharm.D., BCPS(AQ-ID)[3], Charles E. Hartis, Pharm.D., BCPS[4], Benjamin Britt, Pharm.D.[5], Brianne Dunn, Pharm.D.[6], Celeste N. Rudisill, Pharm.D.[1], Brian Odle, Pharm.D.[7], Kathey Fulton, Pharm.D.[8], Linsey Hocker, Pharm.D.[7]; (1)South Carolina College of Pharmacy, USC Campus, Columbia, SC; (2)Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA; (3)Greenville Hospital System University Medical Center, Greenville, SC; (4)Forsyth Medical Center, Winston-Salem, NC; (5)Providence Hospital, Columbia, SC; (6)Medical University of South Carolina, Charleston, SC; (7)Bill Gatton College of Pharmacy, East Tennessee State University, Johnson City, TN; (8)Pitt County Memorial Hospital, Greenville, NC

Purpose: Safety and efficacy outcomes data of daptomycin (DAP) at high doses (>6mg/kg) and in obese patients are limited to case series and single center reports.

Methods: This was a retrospective, multicenter study of adult patients hospitalized from 2005-2009, who received a high-dose of DAP defined as >6 mg/kg or ≥ 550 mg daily for at least 7 consecutive days. The primary safety outcome was documented CPK elevations (Grade III or IV) or complaints of muscle pain/myalgias. Therapeutic failure was defined as meeting any of the following composite endpoint criteria: premature discontinuation of DAP; blood culture positive beyond 7 days; recurrence of bacteremia within 60 days; recurrent osteomyelitis within 6 months; and 30-day mortality post-DAP therapy. Correlation of obesity to safety and efficacy outcomes was analyzed. Chi-square or Fisher's exact test was applied to nominal data with a level of significance of 0.05.

Results: Based on completed data from 10 centers, 133 patients, 60% male with a mean age of 60 years, received an average DAP dose of 7.21 mg/kg for 20.69 days of therapy. The majority of patients, 50%, were obese (BMI>30 kg/m²), including 27 patients categorized as Class III or morbidly obese (BMI>40 kg/m²). The primary infection in these cases was bacteremia with or without endocarditis (65%) with Staphylococcus aureus as the primary pathogen. Four patients (3.0%) experienced a Grade III or IV CPK elevation without symptoms; 2 resulting in discontinuation of therapy. All four patients were Class II obese (BMI>35 kg/m²) or higher. Therapeutic success was achieved in 71% (n=95) of patients. No correlation between obesity and therapeutic success was noted (p=NS).

Conclusion: High doses of DAP in obese patients produce favorable clinical outcomes. As suggested in previous reports, protracted courses of DAP in an obese population may heighten the risk of CPK elevation without concurrent symptomatology.

136E. A multi-center study evaluating the impact of guideline-recommended empiric dosing of vancomycin in MRSA bacteremia.

Christopher A. Giuliano, Pharm.D.[1], Krystal K. Haase, Pharm.D., BCPS[1], Kathleen Hazelwood, Pharm.D.[2], Carlos A. Alvarez, Pharm.D., M.Sc.[3], Nicolas A. Forcade, Pharm.D.[4], Christopher R. Frei, Pharm.D., M.Sc., BCPS[4], Sara D. Brouse, Pharm.D.[3], Todd Bell, M.D.[1], Roger Bedimo, M.D., M.S.[5], Ronald G. Hall, Pharm.D., BCPS[3]; (1)Texas Tech University Health Sciences Center, Amarillo, TX; (2)The University of Wyoming School of Pharmacy, Laramie, WY; (3)Texas Tech University Health Sciences Center and the Dallas Veterans Affairs Medical Center, Dallas, TX; (4)The University of Texas at Austin and The University of Texas Health Science Center San Antonio, San Antonio, TX; (5)The University of Texas at Austin and The University of Texas Health Science Center San Antonio, Dallas, TX

Purpose: To evaluate the impact of guideline-based vancomycin dosing on mortality in patients with methicillin-resistant *S. aureus* bacteremia.

Methods: We conducted a multicenter, retrospective, cohort study of 337 patients admitted to three hospitals with methicillin-resistant *S. aureus* bacteremia and ≥48 hours of empiric vancomycin therapy. We compared hospital mortality for patients treated with the guideline-recommended vancomycin dose (≥15 mg/kg/dose) to those treated

with lower vancomycin doses (<15 mg/kg/dose). We used multivariable stepwise logistic regression analysis with variables identified by conceptual modeling and those found to be significant by univariable analysis.

Results: One-third of patients received empiric vancomycin at the guideline-recommended dose. Those patients had similar mortality to patients who received lower vancomycin doses (16% vs. 13%, OR 1.26 [95%CI 0.67–2.39]) in the univariable analysis and also were not significantly associated with mortality in the multivariable analysis (OR 0.9, 95%CI 0.39–2.31). The only factors that remained significant in the multivariable model were older age (4.5, 2.30–8.90), Pitt bacteremia score (4.14, 1.93–8.88), nephrotoxicity (3.49, 1.65–7.38), and length of stay (1.01, 1.00–1.02).

Conclusion: Use of guideline-recommended empiric vancomycin dosing was not associated with improved mortality in this multicenter study. These data warrant further investigation into vancomycin dosing practices. Presented at Interscience conference on Antimicrobial Agents and Chemotherapy (ICAAC) Boston, MA September 12–15, 2010

137. Is it time to change how outpatient urinary tract infections are treated?.

Davd A. Bookstaver, Pharm.D., Sary O. Beidas, M.D.; Eisenhower Army Medical Center, Fort Gordon, GA

Purpose: Empiric treatment of outpatient urinary tract infections (UTIs) needs to be reassessed due to increasing fluoroquinolone resistance among many species of bacteria. The purpose of the study was to assess current antimicrobial susceptibility patterns in bacteria isolated from the urinary tract in outpatient settings to determine the best alternatives to fluoroquinolones.

Methods: Microscan data were obtained to review all positive urine cultures from outpatient sites from January 2008 thru May 2010. The frequency of specific isolates was identified. A composite susceptibility percentage defined as the number of sensitive isolates divided by the total number of isolates for all organisms combined was calculated for agents typically used for UTIs. Chi-square was used to compare the percentages.

Results: A total of 3454 isolates from specimens submitted for urine culture were identified. The most common species identified were: *Escherichia coli* 2203 isolates (63%), *Klebsiella pneumoniae* 331 isolates (10%) and *Proteus mirabilis* 203 isolates (6%). The composite susceptibility for ciprofloxacin was 90% while nitrofurantoin susceptibility was 89% and these rates were not statistically different (p=0.21). Both rates were significantly greater than those of cefuroxime (85%), amoxicillin/clavulanate (82%) and trimethoprim/sulfamethoxazole (80%) (p<0.01). The composite rate for cefuroxime was significantly higher than that of amoxicillin/clavulanate and trimethoprim/sulfamethoxazole (p<0.01).

Conclusion: Nitrofurantoin had comparable composite susceptibility to ciprofloxacin and should be considered as first-line for treatment of acute cystitis to decrease fluoroquinolone usage. Cefuroxime appears to be an acceptable 2nd option. Empiric use of trimethoprim/sulfamethoxazole is discouraged at least in our institution.

138E. Daptomycin use in neutropenic patients with documented gram-positive infections.

Kenneth V. I. Rolston, M.D.[1], Scott A. McConnell, Pharm.D.[2], Dina Besece, Pharm.D.[2], *Kenneth C. Lamp, Pharm.D.*[2], MinJung Yoon, M.P.H.[2], Pamela White, Pharm.D.[2]; (1)University of Texas M D Anderson Cancer Center, Houston, TX; (2)Cubist Pharmaceuticals, Lexington, MA

Purpose: Infections occurring during neutropenia frequently involve resistant Gram-positive pathogens Vancomycin therapy is considered suboptimal by many clinicians. This analysis evaluated daptomycin in this setting.

Methods: All patients with neutropenia ($\leq$ 1000 cells/m³) and at least one documented gram positive culture were identified in CORE 2006–2009, a retrospective, multicenter, observational registry. Investigators assessed patient outcome (cured, improved, failed, nonevaluable) at the end of daptomycin therapy. The efficacy population (EP) was the cured, improved and failed patients. All patients were included in the safety analysis.

Results: The EP had 242 patients; 209 (86%) patients had either cure (n=132, 55%) or improved (n=77, 32%) as an outcome. Success rates (cure plus improved) by the lowest WBC during daptomycin were; 110/129 (85%) for $\leq$ 100 cells/m³, 70/79 (89%) for 101–499 cells/m³, and 29/34 (85%) for 500–1000 cells/m³, P=1.00. Most patients had a history of cancer; 162/200 (81%) had hematological malignancy, 29/200 (15%) had solid tumors and 9/200 (5%) had both. 55% were male, 26% were $\geq$66 yrs old, 12% had an initial CrCl <30 mL/min and 27% received daptomycin in an ICU. 84% of patients received antibiotics before daptomycin treatment; 67% vancomycin, of which 19% failed vancomycin. The most common infections were bacteremia (78%), SSTI (8%), and bone/joint (5%). The most common pathogens were vancomycin-resistant enterococci (45%), coagulase-negative staphylococci (26%), and MRSA (15%). The median (min, max) initial daptomycin dose was 6mg/kg (3, 8). The median (min, max) daptomycin duration of therapy was 14 days (1, 119). 17/283 patients (6%) experienced at least one possibly-related adverse event and 20 patients (7%) discontinued daptomycin due to AE.

Conclusion: The degree of neutropenia did not affect daptomycin success rates and overall daptomycin appeared useful and well tolerated in neutropenic patients. These data require confirmation via prospective clinical trials.

Presented at Presented at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010

139E. Guideline-concordant therapy is not associated with improved outcomes in healthcare-associated pneumonia.

Russell T. Attridge, Pharm.D., MSc, BCPS[1], Christopher R. Frei, Pharm.D., M.Sc., BCPS[2], Marcos I. Restrepo, M.D., M.Sc.[3], Kenneth A. Lawson, Ph.D.[4], Laurajo Ryan, Pharm.D., M.Sc., BCPS, CDE[2], Eric M. Mortensen, M.D., M.Sc.[3]; (1)University of the Incarnate Word Feik School of Pharmacy, San Antonio, TX; (2)The University of Texas at Austin and The University of Texas Health Science Center San Antonio, San Antonio, TX; (3)Univ. TX Health Sci. Ctr., Vet. Evidence-Based Res. Dissemination and Implementation Ctr., and South TX Vet. Health Care System, San Antonio, TX; (4)The University of Texas at Austin, Austin, TX

Purpose: Healthcare-associated pneumonia (HCAP) guidelines were first proposed in 2005 but have not been validated. The objective of this study was to compare 30-day mortality in HCAP patients treated with either guideline-concordant HCAP (GC-HCAP) therapy or guideline-concordant community-acquired pneumonia (GC-CAP) therapy.

Methods: We performed a population based cohort study of >150 hospitals in the Veterans Health Administration. Patients were included if they had $\geq$1 HCAP risk factor and received antibiotic therapy within 48 hours of admission. Critically-ill patients were excluded. We determined independent risk factors for 30-day mortality with a multivariable logistic regression model including baseline characteristics, HCAP risk factors, comorbidities, and organ failure as dichotomous covariates. Propensity scores were calculated for the probability to receive GC-HCAP therapy and incorporated into a second logistic regression model.

Results: A total of 15,071 patients met study criteria and received GC-HCAP therapy (8.0%), GC-CAP therapy (75.7%), or non-guideline-concordant therapy (16.3%). GC-HCAP patients were more likely to have neoplastic disease; whereas, GC-CAP patients had a higher prevalence of heart failure, chronic obstructive pulmonary disease, tobacco use, and recent medication use. In multivariable regression, recent hospital admission (OR 2.47, 95% CI 2.10–2.91) and GC-HCAP therapy (2.13, 1.82–2.48) were the strongest predictors of 30-day mortality. GC-HCAP therapy continued to be an independent risk factor for 30-day mortality (OR 2.12, 95% CI 1.82–2.47) in the propensity score analysis.

Conclusion: In non-severe HCAP patients, GC-HCAP therapy is not associated with improved survival compared to GC-CAP therapy. Presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010.

140E. Safety and clinical outcomes of daptomycin for

***Staphylococcus aureus* bacteremia in non-dialysis patients with renal insufficiency.**

Pamela A. Moise, Pharm.D.[1], Maria Amodio-Groton, Pharm.D.[1], Mohamad Rashid, M.D.[2], *Kenneth C. Lamp, Pharm.D.*[1], Holly Hoffman-Roberts, Pharm.D.[1], MinJung Yoon, M.P.H.[1], Ann Hernandez, B.S.[2], Suzanne Schweitzer, B.S.Pharm., M.P.H.[2], Anjay Rastogi, M.D., Ph.D.[2]; (1)Cubist Pharmaceuticals, Lexington, MA; (2)UCLA Division of Nephrology, Los Angeles, CA

Purpose: Daptomycin is approved for *Staphylococcus aureus* bacteremia (SAB), including right sided endocarditis. However, its safety and efficacy for SAB in patients with renal insufficiency (RI) has not been extensively examined and was the purpose of this study.
Methods: All non-dialysis patients with a baseline CrCl <50 ml/min who received daptomycin for SAB were identified in CORE (a retrospective, multicenter registry), 2005–2009 program years. All patients were evaluated for safety. Clinical outcomes (success [cure or improved], failure, nonevaluable) were assessed at the end of daptomycin using protocol-defined criteria. Nonevaluable patients were excluded from the efficacy analysis.
Results: 106 non-dialysis patients with CrCl <50 received daptomycin for SAB. 56% had a CrCl <30, 40% had diabetes, 59% were >66 yrs old, 33% were in an ICU, 21% had catheter-related bacteremia, 18% had endocarditis, 72% had MRSA, 60% received prior vancomycin, and 28% were community onset. The median daptomycin duration was 11 days (range, 1-265). The median dose was 6 mg/kg (range, 3-10). The dose was <6 mg/kg in 31% (18/59) with CrCl <30 and 15% (7/47) with CrCl 30–<50. Dosing frequency was q24h in 46% (27/59) with CrCl <30. 4/106 (4%) experienced ≥1 adverse events (AE) possibly related to daptomycin; in 2 patients (both CrCl 30–<50), the AE was an increase in creatine phosphokinase (resolved after stopping daptomycin). Success rates in the clinically evaluable population (n=80) was 81% (41% [33/80] cure + 40% [32/80] improved). Stratified by CrCl, success was 70% (31/44) in patients with a CrCl <30, and 94% (34/36) for CrCl 30–<50.
Conclusion: Daptomycin was well tolerated and effective for SAB in non-dialysis patients with a CrCl <50 ml/min. Lower success rates were seen for patients with CrCl <30 when compared to patients with CrCl 30–<50, consistent with other antimicrobial performance. Further prospective and comparative studies of daptomycin in patients with RI are warranted.
Presented at Presented at 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, Sep. 12–15, 2010

141E. FOCUS 1 and 2: randomized, double-blinded, multicenter phase 3 trials of the efficacy and safety of ceftaroline fosamil vs ceftriaxone in community-acquired pneumonia.

Paul Eckburg, M.D.[1], David Friedland, M.D., MBA[1], Jon Lee, .[1], Lily Llorens, Ph.D.[1], Ian Critchley, Ph.D.[1], Joseph B. Laudano, Pharm.D/[2], Charley Merrill, Ph.D., MBA[2], Dirk Thye, MD[1]; (1)Cerexa, Inc; a wholly owned subsidiary of Forest Laboratories, New York, NY; (2)Forest Research Institute, Jersey City, NJ

Purpose: Ceftaroline fosamil is the prodrug of ceftaroline, a novel, broad-spectrum cephalosporin with enhanced Gram-positive activity, including bactericidal activity against resistant *Streptococcus pneumoniae* and MRSA, as well as common gram-negative pathogens. The efficacy and safety of ceftaroline fosamil for CAP were evaluated in two randomized, double-blinded, multicenter, phase 3 trials.
Methods: Hospitalized adults with CAP (PORT risk class III or IV) requiring IV therapy received ceftaroline fosamil 600 mg q12h or ceftriaxone 1 g q24h for 5–7 days (randomized 1:1). Clinical and microbiological responses and adverse events (AEs) were assessed. The primary objective of both trials was to determine noninferiority (lower limit [LL] of 95% CI > -10%) in clinical cure rate of ceftaroline fosamil versus ceftriaxone 8–15 days posttherapy in clinically evaluable (CE) and modified intent-to-treat efficacy (MITTE) populations.
Results: Of 1228 treated patients, 614 received ceftaroline fosamil and 614 received ceftriaxone. Clinical cure rates for ceftaroline fosamil were higher vs ceftriaxone (Table); clinical success rates (microbiologically evaluable) were also higher (85.1%, 131/154) vs

ceftriaxone (75.5%, 111/147). Both agents were well tolerated; most common AEs for ceftaroline fosamil were diarrhea, headache, and insomnia (< 5% for each).

	Combined clinical cure, % (n/N)		
	Ceftaroline fosamil	Ceftriaxone	Difference (95% CI)
CE	84.3 (387/459)	77.7 (349/449)	6.7 (+1.6, 11.8)
MITTE	82.6 (479/580)	76.6 (439/573)	6.0 (+1.4, 10.7)
mMITTE			
S. pneumoniae	85.5 (59/69)	68.6 (48/70)	17.0 (2.9, 30.7)
S. aureus	72.0 (18/25)	60.0 (18/30)	12.7 (-13.1, 36.3)

mMITTE = microbiological MITTE.
Conclusion: Ceftaroline fosamil was noninferior to ceftriaxone in clinical cure rates in each FOCUS trial (CE; LL of 95% CI: +1.4 in FOCUS 1, -2.5 in FOCUS 2). The combined cure rate for ceftaroline fosamil was 6.7% higher than ceftriaxone. Ceftaroline fosamil was well tolerated with a safety profile similar to ceftriaxone, and has potential to be an effective well tolerated treatment option for CAP.
Presented at Presented at the 49th Annual Meeting of the Interscience Conference on Antimicrobial Agents & Chemotherapy, San Francisco, CA, September 12–15, 2009.

142. Initial antibiotic trends for the treatment of complicated skin and skin structure infections within a U.S. integrated health care system: a seven-year review.

Robert T. Adamson, Pharm.D.[1], Shilpa Amara, Pharm.D.[1], Ariel Berger, M.P.H.[2], Kenneth LaPensee, Ph.D., M.P.H.[3], Gerry Oster, Ph.D.[2]; (1)Saint Barnabas Health Care System, South Plainfield, NJ; (2)Policy Analysis Inc., Brookline, MA; (3)Forest Research Institute, Jersey City, NJ

Purpose: Empiric antibiotic therapy is typically administered to patients presenting with complicated skin and skin structure infections (cSSSI), but patterns of use have not been well documented. This retrospective study was conducted to assess changes in empiric cSSSI therapy over the past seven years within an integrated health care system.
Methods: The study was conducted at Saint Barnabas Health Care System, a 3,500-bed integrated health care delivery network with six acute-care facilities in New Jersey (3 teaching and 2 urban) ranging from 200 to 750 beds. Trendstar clinical billing and Cerner laboratory databases were used to identify patients hospitalized for cSSSI. Patients were stratified into three infection cohorts: acute (abscess and cellulitis), chronic/ulcerative (decubitus ulcer), and surgical-site infections. Data were collected on patients seen between January 1, 2003 and December 31, 2009 who received parenteral antibiotic therapy for ³48 hours, beginning within 24 hours of admission. We evaluated changing patterns in initial (i.e., within 24 hours of admission) antibiotic therapy over the course of the study.
Results: A total of 13,324 patients were included. Mean (SD) age was 59.9 (19.4) years, and 51.5% of patients were women. From 2003 to 2009, empiric vancomycin use as monotherapy or part of a multidrug regimen increased from 8.8% to 50.2%. These changes, stratified by cohort, were: 6.5% to 53.7%, 6.8% to 32.7%, and 19.5% to 45% for acute, chronic/ulcerative, and surgical-site infections, respectively. Empiric use of piperacillin/tazobactam also increased from 12.3% to 34.8% of all cSSSI admissions (12.1% to 33.6%, 18.5% to 37.7%, and 10.1% to 38.6% for acute infection, chronic/ulcerative infections, and surgical-site infections, respectively). All findings were statistically significant (chi-squared tests, *P*<0.001).
Conclusion: Initial empiric antibiotic therapy for the treatment of cSSSI has changed considerably over the past seven years. Notably, the use of vancomycin and piperacillin/tazobactam has increased significantly within the Health Care System.

143. Vancomycin: impact of a pharmacy consult service for guideline based therapeutic monitoring.

Jessica T. Clark, Pharm.D., Christy M. Vaughan, Pharm.D., BCPS; Methodist Dallas Medical Center, Dallas, TX

Purpose: The American Society of Health System Pharmacists (ASHP), Infectious Diseases Society of America (IDSA), and Society of Infectious Diseases Pharmacists (SIDP) developed concise

recommendations for vancomycin therapy to address concerns regarding efficacy, resistance and toxicity. These recommendations prompted a change in Methodist Dallas Medical Center's (MDMC) vancomycin dosing guidelines. This study was designed to evaluate the impact of a pharmacy consult service for therapeutic dosing and monitoring of vancomycin in adult hospitalized patients.

Methods: A retrospective chart review was conducted for quality assurance purposes of adult in-patients receiving vancomycin therapy for ≥ 3 days between August 2009 and December 2009. Patients were divided into two groups: those receiving vancomycin dosed per pharmacy protocol versus physician managed dosing. The frequency of appropriate dosing (loading and maintenance) and attainment of goal trough concentrations were compared between the two groups. The incidence of nephrotoxicity was evaluated as a secondary endpoint. Patients were excluded if they received any renal replacement therapy.

Results: Eighty patients were included in the analysis. When indicated for severe infections, loading doses were appropriately administered per protocol to 64% of pharmacist-dosed patients compared to only 35% of physician-dosed patients. Appropriate maintenance doses were prescribed to 80% of all pharmacist-dosed patients versus 60% of all physician-dosed patients. Only 29% of all patients' initial vancomycin trough level was within goal range (12 pharmacist-dosed patients versus 8 physician-dosed patients). Six (7.5%) patients developed nephrotoxicity during therapy.

Conclusion: In this study, it appeared that current physician and pharmacy protocol based dosing strategies are inadequate to achieve recommended vancomycin trough concentrations. This suggests that the MDMC pharmacy dosing protocol should be revised to employ higher doses, more similar to those recommended in the IDSA/ASHP/SIDP guidelines, to ensure attainment of therapeutic vancomycin concentrations, improve efficacy and prevent resistance.

144. Utility of fluconazole as de-escalation therapy in patients with fluconazole-susceptible candidemia.
Dhara N. Shah, Pharm.D.[1], Raymond W. Yau, Pharm.D.[2], Jaye Weston, M.S.[2], Todd Lasco, Ph.D.[2], Miguel Salazar, Phd, Pharm.D.[2], Hannah Palmer, Pharm.D.[2], Kevin W. Garey, Pharm.D., M.S.[1]; (1)University of Houston-College of Pharmacy, Houston, TX; (2)St. Luke's Episcopal Hospital, Houston, TX

Purpose: Fluconazole (FLU) or an echinocandin (ECH) are used for candidemia with ECH recommended for severe disease. Antifungal susceptibility testing may provide guidance on de-escalation to FLU in ECH-treated patients. The purpose of this study was to assess FLU de-escalation once antifungal susceptibility testing is reported.

Methods: Retrospective cohort study of hospitalized patients with candidemia from 2006–2009. Patients were evaluated for de-escalation to FLU stratified by APACHE II score and intensive care units (ICU) status. Susceptibility of *Candida* species was determined using automated susceptibility testing.

Results: One hundred forty-nine patients aged 59 ± 16 (male: 53%, Caucasian: 54%, Apache II ≥ 15: 46%, ICU: 52%) were identified of whom 126 patients (85%) had FLU-susceptible *Candida* species. Fifty of 126 (40%) were initiated on FLU and 76 on ECH. Twenty-one of 50 (42%) FLU-initiated patients were switched over to ECH prior to susceptibility report. Forty of 76 (53%) ECH-initiated patients were switched to FLU once susceptibility was reported. Five of 21 (24%) FLU-initiated patients who were switched to an ECH prior to susceptibility were de-escalated back to FLU (p=0.026 compared to ECH-initiated patients). For patients with APACHE II >15, none of the nine FLU-initiated patients were switched back to FLU from an ECH, while 16 out of 38 (42%) in the ECH-initiated group were de-escalated to FLU. In ICU patients, 2 of 13 patients (15%) were switched back to FLU from an ECH in the FLU-initiated group, while 19 (46%) were switched to FLU in the ECH-initiated group. The overall average duration of an ECH was 6.3 ± 4.9 days in FLU-initiated and 6.1 ± 5.1 in ECH-initiated groups (p=ns).

Conclusion: De-escalation to FLU is not commonly done once susceptibility is reported, especially in critically ill FLU-initiated patients changed to ECH before susceptibility is known. FLU-initiated patients receive similar days of ECH therapy during the treatment course.

145. Lack of Changes to Vancomycin Based on Microbiologic Culture Data: Possible Intervention for Antibiotic Stewardship Programs.
Euphemia Uhegbu, Pharm.D.[1], Kimberly Halton, Pharm.D.[2], Kristi Kuper, Pharm.D.[3], Kevin W. Garey, Pharm.D.[2], Harminder Sikand, Pharm.D.[1]; (1)Scripps Mercy Hospital, San Diego, CA; (2)University of Houston College of Pharmacy, Houston, TX; (3)Cardinal Health Pharmacy Services, Houston, TX

Purpose: Empiric vancomycin is very common in hospitalized patients due to high prevalence of methicillin-resistant *Staphylococcus* species (MRSS). Whether microbiologic cultures results are associated with changes to vancomycin therapy is not known. The purpose of this study was to evaluate vancomycin de-escalation or discontinuation based on 1) finalized culture results, and 2) methicillin-resistant S*taphylococcus aureus* (MRSA) nasal swab surveillance results.

Methods: Prospective cohort study of 199 non-trauma ICU patients >18 years given intravenous vancomycin at two large tertiary care medical centers. One hospital performed mandatory MRSA surveillance for every ICU patient. Demographics, MRSA surveillance and culture results were collected. Therapy was categorized into empiric versus definitive treatment with changes to vancomycin therapy within 48 hours after final culture results collected.

Results: One hundred forty- six of 199 patients (73%) received vancomycin empirically of whom 193 (97%) patients had at least one culture drawn within 24 hours of initiating vancomycin. Cultures were positive to MRSS in 43 of 193 (22%) patients. Vancomycin was discontinued in 83 of 150 (55%) patients with final non-MRSS culture results including 36 of 83 (43%) patients with Gram-negative only cultures. Vancomycin was not de-escalated to an MSSA antibiotic in 9 of 15 patients (60%) with MSSA only cultures. Ninety-eight patients were evaluated for MRSA surveillance swabs of whom 22 were MRSA positive. Four of 22 patients (18%) with positive MRSA surveillance results had final non-MRSA culture results were given vancomycin for up to 5 days of therapy.

Conclusion: Vancomycin is mainly given as empiric therapy with microbiologic cultures routinely obtained. However, treatment changes based on finalized culture results are not routinely done.

146. Relationship between vancomycin serum trough levels and clinical outcomes in a veteran population with methicillin-resistant Staphylococcus aureus bacteremia.
Kimberly Tamura, Pharm.D., *Thi Doan, Pharm.D.*, Ronald Brown, M.S., R.Ph.; Portland Veterans Affairs Medical Center, Portland, OR

Purpose: This retrospective cohort study examined if there is a relationship between vancomycin serum trough levels and clinical outcomes in veteran patients with methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia.

Methods: Medical records of 95 patients hospitalized between December 2006 and July 2009 for MRSA bacteremia and who received IV vancomycin therapy were reviewed. Twenty-eight day mortality and clinical response to therapy were documented. Safety endpoints, including nephrotoxicity, thrombocytopenia, and Red man syndrome were collected as well. Efficacy and safety outcomes were compared between patients who achieved higher serum vancomycin trough levels of ≥ 15 mg/L to 20 mg/L versus lower trough levels of 10 mg/L to < 15 mg/L.

Results: Of the patients reviewed, 68 met the study criteria and were evaluated. Thirty-three percent of those in the high vancomycin trough group and 18.2% in the low trough group died within 28 days of completing vancomycin therapy (p=0.268). There were no statistically significant differences observed between the high and low trough groups in regards to persistence of fever (4.2% vs. 2.3%, p=1) and persistence of leukocytosis (42.8% vs. 34.1%, p=0.722). A greater proportion of patients in the high trough group had persistence of blood cultures positive for MRSA compared to the low trough group (37.5% vs. 9.1%, p=0.008). No differences were observed for any of the safety outcomes.

Conclusion: Although we observed a greater proportion of patients in the higher trough group had persistence of blood cultures positive for MRSA, we were unable to detect a relationship between clinical outcomes and higher versus lower steady state serum vancomycin

trough levels in veteran patients hospitalized for MRSA bacteremia.

147. Relationship of microbiological and virulence characteristics to staphyloxanthin (STX) production in methicillin-resistant *Staphylococcus aureus* (MRSA).
Michael S. North, Pharm.D.[1], Brian Werth, Pharm.D.[1], Jora Sliwinski, Pharm.D. Candidate[1], Paulina Deming, Pharm.D.[1], George Sakoulas, M.D.[2], Renee C. Mercier, Pharm.D.[1]; (1)University of New Mexico Health Sciences Center, Albuquerque, NM; (2)University of Califoria San Diego, La Jolla, CA

Purpose: Staphyloxantin (STX) provides the golden pigmentation of *Staphylococcus aureus*. The microbiological significance of reduced or absent STX production is unknown but it may be a surrogate marker for strain virulence.
Methods: Bloodstream MRSA strains were collected from patients at the University of New Mexico Hospital between 2002 and 2009. Susceptibilities to vancomycin and daptomycin were determined by Etest. The functionality of *agr*, carriage of Panton-Valentine leukocidin (PVL), hemolysis, and STX production were determined. Colony color was evaluated by 3 investigators independently.
Results: MRSA strains were obtained from 146 patients. Colony colors were established as white (6), moderate-white (77), moderate-gold (51), and gold (12). The MIC_{90} of vancomycin was 2 [0.75-4] and 0.75 [0.047-3] for daptomycin. PVL carriage was positive in 77/146, loss of *agr* function in 27/146, and lack of hemolysis in 19/146. Bacteremia source was largely from endocardititis (29, 20%), catheter related (25, 17%), skin and soft-tissue infection (22, 15%), and osteomyelitis (21, 14%). White colonies were more likely to lack hemolysis ($p<0.05$) and more likely to have loss of *agr* function ($p<0.05$). Gold colonies were more likely to carry PVL ($p<0.05$). No correlation was found between colony color, bacteremia source or antimicrobial susceptibility.
Conclusion: Increased STX production yielding golden colonies is associated with PVL carriage and likely represents community-acquired MRSA. Lack of STX production and white colony phenotype are linked to a loss of *agr* function and lack of hemolysis. Visual inspection of colony color may serve as a qualitative marker of strain virulence in *S. aureus*.

148. Impact of novel UPC2 gain-of-function mutations on fluconazole resistance in *Candida albicans*.
Stephanie A. Flowers, PharmD.[1], Katherine Barker, Ph.D.[2], Joachim Morschhäuser, Ph.D.[3], P. David Rogers, Pharm.D., Ph.D.[1]; (1)University of Tennessee, Memphis, TN; (2)University of Tennessee Health Science Center, Memphis, TN; (3)Universität Würzburg, Würzburg, Germany

Purpose: Over expression of *ERG11*, which encodes the azole target lanosterol demethylase, contributes to azole-resistance. We have previously shown that a G648D or A643T gain-of-function mutation (GOF) in the transcription factor gene *UPC2* leads to increased *ERG11* expression and fluconazole (FLC) resistance. Our purpose was to determine if GOF mutations in *UPC2* represent a common mechanism of *ERG11* overexpression and FLC resistance in *C. albicans*.
Methods: We screened 27 FLC resistant isolates (MIC >16 μg/mL) of *C. albicans* for the overexpression of *ERG11* and *UPC2* by qRT-PCR. For isolates that overexpressed *ERG11* as compared to fluconazole susceptible isolates (MIC ≤ 2 μg/mL), *UPC2* was sequenced. Each novel mutation recovered was cloned and expressed in a strain in which both endogenous *UPC2* alleles had been disrupted. MICs were determined by CLSI methods. *ERG11* and *UPC2* expression was measured by qRT-PCR. *ERG11* was sequenced for isolates containing *UPC2* GOF mutations.
Results: Sixteen of the 27 isolates had increased *ERG11* expression. Of these, 7 overexpressed *UPC2*. Two isolates had mutations resulting in a G648D substitution, 3 in a G648S substitution, 3 in a W478C substitution, 2 in a G304R substitution and 1 in an A643V substitution. In 4 isolates, no unique mutations were found. When expressed in a susceptible strain, the G648S, A643V and G304R substitutions resulted in increased *ERG11* expression and FLC resistance. Five of the 7 isolates recovered with a *UPC2* GOF mutation also carried at

least 1 mutation in *ERG11* unique to resistant isolates.
Conclusion: These findings indicate that *ERG11* overexpression and *UPC2* GOF mutations are relatively common among FLC-resistant isolates. In many cases, isolates carrying a *UPC2* GOF mutation also carried *ERG11* mutations, which most likely results in a combined effect on FLC resistance. Interestingly, isolates without *UPC2* GOF mutations still overexpressed *ERG11* suggesting other mechanisms contribute to *ERG11* overexpression and FLC resistance.

149E. Development of a *Candida glabrata* PDR1 Mutation During Itraconazole Therapy for Oropharyngeal Candidiasis.
Philip Graves, M.S.[1], *Nathan P. Wiederhold, Pharm.D.*[2], Steven Mayen, B.A.[1], Steven D. Westbrook, DMD[1], Deborah K. Berg, BSN[1], William R. Kirkpatrick, M.S.[1], Spencer W. Redding, DDS[1], Thomas F. Patterson, M.D.[1]; (1)University of Texas Health Science Center at San Antonio, San Antonio, TX; (2)University of Texas at Austin, Austin, TX

Purpose: Gain of function mutations in transcription factors that regulate the expression of ABC-transporter genes in *Candida* species can confer azole resistance. In *C. glabrata*, these mutations occur within *PDR1* and are associated with fluconazole resistance in clinical isolates. We report the development of a point mutation in *C. glabrata PDR1* from a patient receiving itraconazole (200 mg PO BID) for oropharyngeal candidiasis (OPC) that was associated with increases in fluconazole but not itraconazole MIC values.
Methods: RAPD analysis was used to determine the isogenic status of the *C. glabrata* isolates collected during multiple clinic visits over a 4 month period. Microdilution susceptibility testing was performed by CLSI M27-A3 methodology. Sequence analysis of *PDR1* was performed by dideoxysequencing.
Results: The 4 *C. glabrata* isolates collected over the 4 month period were confirmed to be isogenic. Fluconazole MIC values increased from 2 mg/mL to 16 mg/mL over this period. However, there was no change in itraconazole susceptibility (0.25 mg/mL). Sequence analysis identified a point mutation within *PDR1* that resulted in a R293G amino acid substitution, which is at the same location as a similar amino acid substitution (R293I) previously reported to cause fluconazole resistance (Ferrari et al. *PLoS Pathog* 2009). The patient responded to itraconazole therapy with resolution of OPC, but remained colonized with the *C. glabrata* isolate harboring the *PDR1* mutation.
Conclusions: These data demonstrate that further studies are warranted to explore the potential for different azole susceptibility patterns associated with gain of function mutations in transcription factors that regulate efflux pumps.
Presented at 50th Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010

150. Variances in antibiotic utilization in 22 acute care hospitals (2008–2009).
Kristi Kuper, Pharm.D.[1], Alisa Goetz, PharmD[1], Amy Jackson, CPhT[1], Kevin W. Garey, Pharm.D., M.S.[2]; (1)Cardinal Health Pharmacy Solutions, Houston, TX; (2)University of Houston-College of Pharmacy, Houston, TX

Purpose: Antibiotic utilization provides an accurate measurement of consumption as compared to cost data. However, limitations in hospital IT and bioinformatics infrastructure makes this data difficult to obtain and institutional comparisons non-existent. This study characterizes antibiotic use over a 24-month period and provides a reference for other acute care facilities to use for antibiotic stewardship and future budget projections.
Methods: Antibiotic utilization data was collected from an inpatient dataset of 22 acute care hospitals (Cardinal Health, Houston,TX) for the period January 1, 2008 through December 31, 2009. Utilization was classified into 16 therapeutic classes for sub-analysis. All data was expressed in defined daily dose per 1000 patient days (DDD/1000 pt days) and reported by month. Antivirals, antiretrovirals and antifungals were excluded. The variance between cumulative 2008 and 2009 data was calculated and expressed as percent change. Variances were then classified into 1) minor increase [<15%] 2) moderate increase [15 to < 35%] or 3) major increase [≥35%].

Results: A total of 515,785 DDD/1000 pt days was assessed. Overall antibiotic utilization increased by 12% from 2008 to 2009. Minor increases in utilization were seen with second generation cephalosporins, anti-pseudomonal cephalosporins, narrow spectrum penicillins and quinolones. Anti-anaerobic agents (e.g., clindamycin) and monobactams were the only classes that showed a decrease in utilization. A moderate increase was seen in all other classes except for antibiotics used to treat resistant gram positive organisms. Major increases were seen with the anti-MRSA/VRE drugs and tetracyclines, with reported increases of 35% and 49%, respectively.
Conclusion: Annual comparison of antibiotic utilization between 2008 and 2009 for a large acute care hospital group revealed a 12% increase in overall utilization. Drugs used to treat resistant gram positive organisms showed the most significant growth.

151E. Successful Detection of Invasive Pulmonary Aspergillosis Using Lateral-Flow Device Tests of Bronchoalveolar Lavage Fluids.
Nathan P. Wiederhold, Pharm.D.[1], Christopher R. Thornton, Ph.D.[2], Laura K. Najvar, B.S.[3], Rosie Bocanegra, Research, Associate[3], William R. Kirkpatrick, M.S.[3], Thomas F. Patterson, M.D.[3]; (1)University of Texas at Austin, Austin, TX; (2)University of Exeter, Exeter, United Kingdom; (3)University of Texas Health Science Center at San Antonio, San Antonio, TX

Purpose: Studies have reported biomarker detection within bronchoalveolar lavage (BAL) fluid for the diagnosis of invasive pulmonary aspergillosis (IPA). We have demonstrated the potential utility of a lateral flow device (LFD) for the detection of a hyphal specific *Aspergillus* glycoprotein antigen within serum (Wiederhold et al. Clin Vaccine Immunol 2009). Our objective was to compare the time to positivity for the LFD compared to the (1-3)-β-D-Glucan (BG) and galactomannan (GM) assays within BAL fluid.
Methods: An established neutropenic guinea pig model of IPA was used for pulmonary inoculation with *Aspergillus fumigatus* 293. At predetermined time points (days 3, 5, and 7 post-inoculation) sera and BAL fluid were collected. The *Aspergillus* glycoprotein antigen was detected using an IgG monoclonal antibody-based LFD with 0.1 mL of sample applied to the device, and results were read within 15 minutes. GM and BG were measured using commercially available kits.
Results: The LFD detected the *Aspergillus* antigen early in both serum and BAL fluid with positive results occurring in the majority of samples on day 3 post-inoculation (60% and 67%, respectively). The LFD, BG, and GM assays each detected their respective biomarkers within the BAL fluid early during the course of infection (>80% for each assay by day 5 post-inoculation). However, only the LFD resulted in no false positives in uninfected animals. False positives were observed with both the GM and BG assays.
Conclusions: The time to positivity for the LFD was similar between BAL and serum and for the LFD, BG, and GM assays within the BAL. However, false positives were lowest for the LFD. These data demonstrate the potential utility of the LFD for the diagnosis of IPA using BAL fluid.
Presented at 50th Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010.

152. Steady-state pharmacokinetics and pharmacodynamics of cefepime, administered by prolonged infusion, in hospitalized patients.
S. Christian Cheatham, Pharm.D.[1], Katherine M. Shea, Pharm.D.[2], Melissa L. Humphrey, Pharm.D. Candidate[3], Megan R. Fleming, Pharm.D.[1], Daniel P. Healy, Pharm.D.[4], Matthew F. Wack, M.D.[5], David W. Smith, Pharm.D.[6], Kevin M. Sowinski, Pharm.D.[7], *Michael B. Kays, Pharm.D.*[7]; (1)St. Francis Hospitals and Health Centers, Beech Grove, IN; (2)University Medical Center at Brackenridge, Austin, TX; (3)Purdue University School of Pharmacy, West Lafayette, IN; (4)James Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH; (5)Infectious Diseases of Indiana, Indianapolis, IN; (6)Clarian Health Partners, Inc., Methodist Hospital, Indianapolis, IN; (7)Purdue University School of Pharmacy, Indianapolis, IN

Purpose: Prolonging the duration of the infusion is a strategy to optimize the pharmacokinetics and pharmacodynamics (PK/PD) of b-lactam antibiotics. Only a few studies have determined the actual pharmacokinetic profile of a β-lactam when administered by prolonged infusion. The purpose of this study was to evaluate the steady-state PK/PD of cefepime, administered by prolonged infusion, in hospitalized patients.
Methods: Patients with a suspected or proven bacterial infection and an estimated CLcr ≥ 50 ml/min were enrolled. Patients received cefepime 1 g IV q8h, and doses were infused over 4 h. Serial blood samples were collected at steady-state. Serum concentrations of cefepime were determined by HPLC, and PK parameters were determined. Monte Carlo simulations were performed to create serum concentration-time profiles for 5,000 patients. Using the PD target of 60% $fT>MIC$, the probability of target attainment (PTA) was calculated at MICs ranging from 0.5 to 32 µg/ml, and the cumulative fraction of response (CFR) was calculated using MIC distributions for 6 gram-negative pathogens (MYSTIC 2005-2007).
Results: 9 patients (7 male, 2 female) were studied. Mean ± SD age, weight, and CLcr were 51 ± 18 yr, 77 ± 17 kg, and 86 ± 31 ml/min, respectively. Cefepime PK parameters (mean ± SD) were as follows: C_{max} 32.5 ± 13.5 µg/ml; C_{min} 9.5 ± 5.2 µg/ml; CLs 6.7 ± 3.6 L/h; half-life 2.5 ± 0.8 h; V_{ss} 22.0 ± 7.3 L; V_b 22.5 ± 9.3 L. The PTA was 1.00, 0.91, 0.51, and 0.10 at MICs ≤ 4, 8, 16, and 32 µg/ml, respectively. The CFR was ≥ 91.1% for 5 species of Enterobacteriaceae and 89.0% for *Pseudomonas aeruginosa*.
Conclusions: In hospitalized patients, cefepime 1 g q8h, administered by prolonged infusion over 4 h, provides excellent PD exposures for organisms with MICs ≤ 8 µg/ml.

153. Concerning Discrepancies in Linezolid and Daptomycin Susceptibility Reporting for Enterococcus spp.
Natalie Boyd, Pharm.D., M.S.[1], Ellen Richards, MT[2], Chris Werth, Pharm.D.[1], Steve Young, Ph.D.[1], Renee C. Mercier, Pharm.D.[1]; (1)University of New Mexico Health Sciences Center, Albuquerque, NM; (2)Tricore Reference Laboratory, Albuquerque, NM

Purpose: An increasing number of linezolid (LZD)-intermediate *Enterococcus* isolates have been reported at Albuquerque area hospitals. This study evaluated different automated susceptibility testing panels and Etests to determine the validity of reported LZD-intermediate (LZD-I) *Enterococcus* isolates.
Methods: Automated susceptibility testing was performed with BD Phoenix (BDP), using the PMIC/ID-102 (BDP1) and PMIC/ID-107 (BDP2) panels, and Vitek2 (VTK), using the AST-GP67 card. LZD Etests were also utilized for determination of minimum inhibitory concentrations (MICs) and read by three separate investigators. Daptomycin (DAP) was included to determine presence of cross-resistance. DAP MICs were assessed using only BDP1 and BDP2.
Results: Twenty four clinical *Enterococcus* isolates (4 *E. faecium* and 20 *E. faecalis*) were evaluated. LZD-I resistance (MIC = 4 µg/ml) was reported by BDP1 for 23 of 24 isolates. Conversely, only 1 isolate was reported as LZD-I with BDP2 and VTK (not the same isolate). Eight LZD MICs (33.3%) differed by 2 or more dilutions between the two BDP cards. Ninety-six percent (23/24) of LZD MICs were 3 or 4 µg/ml as interpreted by Etests. BDP2 reported 2 isolates as DAP nonsusceptible (> 4 µg/ml), while BDP1 reported all isolates as susceptible (≤ 4µg/ml). Eleven DAP MICs (54%) differed by 1 or more dilutions when BDP1 was compared to BDP2.
Conclusions: The discordant LZD and DAP MICs observed between automated systems and Etests raises concern as to which method is reliable. These discrepancies must be resolved to prevent inappropriate selection of antibiotic treatment for enterococcal infections.

No. of *Enterococcus* isolates reported by each susceptibility testing method

Linezolid MIC (µg/ml)[a]	BDP1	BDP2	VTK	Etest
4	23	1	1	23[b]
2	1	15	23	1
≤ 1	0	8	0	0

[a]Susceptible ≤ 2 µg/ml
[b]Etest MICs of 3 µg/ml (n = 18) and 4 µg/ml (n = 5) were grouped together

154. Relationship between higher vancomycin trough levels and the incidence of nephrotoxicity.
Christine J. Yu, Pharm.D.[1], Howard K. Umemoto, Pharm.D.[2], Linh B. Van, Pharm.D., BCPS-AQ, ID[1]; (1)Kaiser Permanente Oakland Medical Center, Oakland, CA; (2)Kaiser Permanente Riverside Medical Center, Riverside, CA

Purpose: New recommendations to target vancomycin trough levels of 15–20 mg/L for patients with serious infections have prompted many institutions to increase their vancomycin target goals; however, limited data exists regarding the risk of nephrotoxicity at these higher levels. The objective of this study was to determine if high vancomycin troughs are associated with an increased risk of nephrotoxicity.
Methods: A multicenter retrospective study was conducted among adult patients treated with vancomycin at Kaiser Permanente Oakland Medical Center (KPOMC) and at Kaiser Permanente Riverside Medical Center (KPRMC). The incidence of nephrotoxicity was compared between patients who received vancomycin with low target troughs of 5–15 mg/L and those who received vancomycin with high target troughs of 15–20 mg/L. Nephrotoxicity was defined as either a serum creatinine increase of at least 0.5 mg/dL or at least 50% from baseline.
Results: There was no statistically significant difference in the incidence of nephrotoxicity between those treated with low vancomycin troughs compared to those treated with high vancomycin troughs (9.2% vs. 14.8%, respectively in KPOMC; p=0.1) and (9.2% vs. 15.8%, respectively in the combined facilities; p=0.051). A subanalysis performed in patients ≥ 60 years of age demonstrated that high vancomycin troughs did not increase the rate of nephrotoxicity in this population.
Conclusion: The data suggests that higher vancomycin levels may not be associated with an increased risk of nephrotoxicity.

155. Evaluation of the management of Clostrium difficile infection in hospitalized adult patients.
Kurt R. Winkler, Pharm.D., M.H.A., BCPS[1], Donna R. Burgess, B.S.[1], Tony Dasher, Pharm.D.[1], David S. Burgess, Pharm.D., FCCP[2]; (1)Methodist Hospital Department of Pharmacy, San Antonio, TX; (2)University of Texas at Austin College of Pharmacy and University of Texas Health Science Center School of Medicine, San Antonio, TX

Purpose: *C. difficile* infection (CDI) is a major infectious disease problem for many institutions. The study objective was to evaluate the current treatment of adult patients at our institution with CDI.
Methods: All medical records and hospital electronic databases for adult inpatients from January – April 2010 with CDI as noted by a positive enzyme immunoassay detection of glutamate dehydrogenase and PCR toxin were evaluated. Patient information collected was: patient demographics (age, sex), admission and discharge source, antimicrobial therapy, risk factors for CDI (e.g., antimicrobial therapy within past 28 days, GI surgery, etc.). In addition, each patient's disease severity based on their Zar score (Clin Infect Dis 2007;45:302–7) was determined to assess appropriateness of therapy.
Results: Overall, 57 episodes were evaluated with a frequency of 5.8 cases/1,000 patient admissions. The median age of patients was 75 yrs (range 18–102 yrs) with the majority (65%) being female. In fact, 65% of the patients were >65 yrs old. The majority of the patients were treated with metronidazole (72%) followed by vancomycin alone (12%), vancomycin in combination with metronidazole (12%), and no treatment (4%). The median length of stay was 9 days (range 4–61 days). While the majority of the patients were admitted from home (68%), only 47% were discharged to home. Based on the Zar score, 32% of the episodes were classified as mild and 68% as severe CDI. The appropriate therapy (e.g., metronidazole) for mild CDI was given 78% of the time; however, only 31% of the severe CDI were treated appropriately (e.g., vancomycin). The overall mortality was 7% with all patients having severe CDI and treated with metronidazole.
Conclusion: The understanding and classification of CDI disease severity and management must be emphasized for our healthcare team to provide better and appropriate treatment for patients with CDI.

156. Effect of the infusion time duration on the pharmaco-dynamics of piperacillin/tazobactam and cefepime.

Michael B. Kays, Pharm.D.[1], S. Christian Cheatham, Pharm.D.[2], Katherine M. Shea, Pharm.D.[3], Melissa L. Humphrey, Pharm.D. Candidate[4], Megan R. Fleming, Pharm.D.[2], Daniel P. Healy, Pharm.D.[5], David W. Smith, Pharm.D.[6], Matthew F. Wack, M.D.[7], Kevin M. Sowinski, Pharm.D.[1]; (1)Purdue University School of Pharmacy, Indianapolis, IN; (2)St. Francis Hospitals and Health Centers, Beech Grove, IN; (3)University Medical Center at Brackenridge, Austin, TX; (4)Purdue University School of Pharmacy, West Lafayette, IN; (5)James Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH; (6)Clarian Health Partners, Inc., Methodist Hospital, Indianapolis, IN; (7)Infectious Diseases of Indiana, Indianapolis, IN

Purpose: Prolonging the infusion time has been suggested to optimize b-lactam pharmacodynamics (PD). However, prolonged infusion times may not allow sufficient time to administer other medications. The purpose of this study was to evaluate the effect of varying infusion times on the PD of piperacillin/tazobactam (P/T) and cefepime (CEF).
Methods: Pharmacokinetic data for P/T and CEF in hospitalized patients were obtained. Patients received either P/T 4.5 g q8h or CEF 1 g q8h, and doses for both drugs were infused over 4 h. Monte Carlo simulations (5,000 patients) were performed to create serum concentration-time profiles for P/T 3.375 g q8h and 4.5 g q8h and for CEF 1 g q8h. Infusion times of 1, 2, 3, and 4 h were studied. The PD target was 50% fT>MIC for P/T and 60% fT>MIC for CEF. Probability of target attainment (PTA) was calculated at a range of MICs for both agents. Regimens were considered optimum if the PTA was ≥ 90%.
Results: For P/T, the PTA was > 90% for all of the infusion times for the 3.375 g and 4.5 g dosing regimens at MICs ≤ 8 µg/ml. At an MIC of 16 µg/ml, none of the infusion times achieved a PTA > 90% for the 3.375 g dose, and only the 3 h and 4 h infusions of the 4.5 g dose achieved a PTA > 90% at this MIC. For CEF, the PTA was > 90% for all infusion times at MICs ≤ 4 µg/ml; however, only the 4 h infusion achieved a PTA > 90% if the MIC was 8 µg/ml.
Conclusions: Empirically, the infusion time should be 3 h for P/T 4.5 g q8h and 4 h for CEF 1 g q8h. Shorter infusion times may be utilized after the MIC for the pathogen is known.

157. Evaluation of *Clostrium difficile* severity of illness.
Donna R. Burgess, B.S.[1], Kurt R. Winkler, Pharm.D., MHA, BCPS[1], Tony Dasher, Pharm.D.[1], David S. Burgess, Pharm.D., FCCP[2]; (1)Methodist Hospital Department of Pharmacy, San Antonio, TX; (2)University of Texas at Austin College of Pharmacy and University of Texas Health Science Center School of Medicine, San Antonio, TX

Purpose: In March 2010, the Society of Healthcare Epidemiology of America (SHEA) and the Infectious Disease Society of America (IDSA) provided new adult clinical practice guidelines for *C. difficile* infection (CDI). The definition of disease severity is different between SHEA/IDSA guidelines and the Zar score (Clin Infect Dis 2007;45:302–7). Our objective was to compare the CDI severity index using both methods.
Methods: From January–April 2010, all adult hospitalized patients with CDI diagnosed by a positive enzyme immunoassay detection of glutamate dehydrogenase and polymerase chain reaction toxin were evaluated. Patient information collected from the medical records and hospital electronic databases included patient demographics, antimicrobial therapy, and risk factors for CDI (e.g., antimicrobial therapy within past 28 days, GI surgery, etc.). All patients were classified for disease severity based on the Zar score and the SHEA/IDSA guidelines.
Results: Fifty-seven episodes (patient median age 75 yrs with a range of 18–102 yrs) were evaluated. The majority of the patients (72%) were treated with metronidazole and 24% received vancomycin alone or in combination with metronidazole. Comparing Zar scores and SHEA/IDSA guidelines for CDI, 32% and 44% of the episodes were classified as mild CDI and 68% and 56% as severe, respectively. Overall agreement between the Zar score and SHEA/IDSA guidelines for severity of disease was 63% (36/57 CDI, 11 mild CDI and 25 severe CDI), with more episodes being classified as severe based on the Zar score. This has a significant impact on the antimicrobial therapy prescribed since using the Zar score resuls in more patients

being treated with oral vancomycin for severe CDI.

Conclusion: Since disease severity majorly impacts antimicrobial therapy and currently two accepted methods for determining disease severity do not agree, additional studies are warranted to better understand and identify severity of CDI.

Medication Safety

158. Differences in complexity of medication regimens for males and females discharged from acute care following joint arthroplasty.
Megan Willson, Pharm.D.[1], Douglas L. Weeks, Ph.D.[2], Chris L. Greer, BPharm[3]; (1)Washington State University Spokane, Spokane, WA; (2)Washington State University, Inland Nortwest Health Services, Spokane, WA; (3)St. Luke's Rehabilitation Institute, Spokane, WA

Purpose: The purpose of this study was to determine whether discharge medication regimens of males and females discharged to home following lower extremity joint arthroplasty differed with respect to complexity of the medication regimen and number of medications.
Methods: A retrospective chart review of patients' records from a large urban acute care hospital was completed. Information was collected on patient demographics and discharge medication regimens for serial admitted patients with lower extremity joint arthoplasty. Complexity of discharge medication regimens was quantified with the Medication Regimen Complexity Index, which is a validated tool that calculates regimen complexity by factoring in dosage form, dosing frequency, number of medications, and additional directions.
Results: Two hundred seven patients were admitted with a lower extremity joint arthroplasty during the study period with osteoathrosis/ arthropathies as the main reason for admission. Hypertension was the most common secondary diagnosis followed by hyperlipidemia and diabetes. Females were discharged with significantly more medications to manage on their lists than males (mean 10.1 vs 8.2, p=0.006). Females also had a significantly more complex medication regimens at discharge than males (mean 26.8 vs. 23.5 p=0.047). Among the individual components contributing to regimen complexity, females had significantly larger dosing frequency scores than males (mean 19.3 vs 16.3, p=0.010). However, dosage form and additional direction components did not differ between males and females.
Conclusion: The significantly more complex regimen coupled with a larger number of medications to manage suggests that females may be at greater risk for an adverse drug event (ADE) when discharged to home than males. These finding suggests that providers should mindfully attempt to reduce complexity of the regimen for female arthroplasty patients by targeting dosing frequency. This may, in turn, bring down the relative complexity per medication, potentially reducing risk for an ADE.

159. Mechanism of echinocandin-induced cardiotoxicity.
Kayla R. Stover, Pharm.D., BCPS[1], John D. Cleary, Pharm.D.[2], Jerry Farley, Ph.D.[3], Glenn A. Hoskins, Researcher[4], March D. Ard, Ph.D.[2]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi Medical Center, Jackson, MS; (3)Univeristy of Mississippi Medical Center, Jackson, MS; (4)Univerisity of Mississippi Medical Center, Jackson, MS

Purpose: The echinocandins are a relatively new class of antifungal agents. Previous studies have demonstrated cardiotoxicity associated with anidulafungin (ANID) and caspofungin (CASP). Structural similarities to known mitochondrial toxins suggest that this may be the mechanism of toxicity. Our purpose was to isolate the mechanism of this antifungal cardiac toxicity.
Methods: *Ex vivo* live-heart studies (Langendorff) were performed using Harlan Sprague-Dawley rats. ANID 10–80 mcg/mL and CASP 12-48 mcg/mL were administered over 5 minutes. Krebs-Henseleit buffer (KHS) was used as a negative control and oligomycin (OLIG) 2–80 µg/mL was used as a positive control. Post-exposure, hearts were dissected into sections and evaluated macroscopically and microscopically. Select sections were immersion fixed in 2% buffered glutaraldehyde, post-fixed in 1% osmium tetroxide, stained en bloc with 2% uranyl acetate, and embedded in Embed 812 for evaluation

by electron microscopy (EM) on a Zeiss EM 906 transmission electron microscope. Sections post-stained with lead citrate were photographed to obtain longitudinally-sectioned cardiomyofibers.
Results: On EM, disintegrating myofibrils were evident in samples exposed to ANID, CASP, and OLIG, but not in hearts exposed to KHS only. Spaces emptied of myofibrils were filled by masses of mitochondria. In remaining myofibrils, Z bands were intact, and cardiomyocytes remained connected by intact intercalated discs.
Conclusion: Patterns of toxicity with ANID and CASP were similar to those caused by OLIG. The changes seen on EM confirm the cardiotoxicity seen in previous studies with ANID and CASP and suggest that the mechanism of toxicity is disintegration (depolymerization) of myofibrils.

160. Identification of the causes of medication errors in inpatients infected with human immunodeficiency virus.
Jessica L. Adams, Pharm.D.[1], Mark T. Sawkin, Pharm.D.[2], Rachel Chambers, Pharm.D.[3], Susan L. Davis, Pharm.D.[3], Megan Winegardner, Pharm.D.[3]; (1)University of North Carolina at Chapel Hill - Eshelman School of Pharmacy, Chapel Hill, NC; (2)University of Missouri - Kansas City, Kansas City Free Health Clinic, Kansas City, MO; (3)Henry Ford Hospital, Detroit, MI

Purpose: Previous studies have proven that HIV infected patients are at great risk for medication errors in regards to their antiretroviral regimens when they are hospitalized, but have failed to assess the reasons for these errors. The objectives of this study were to identify the types of medication errors involving antiretrovirals at Henry Ford Hospital in Detroit, MI, evaluate where in the medication use process the errors occurred and identify contributing factors in order to implement system based improvements.
Methods: This retrospective chart review evaluated any patient taking at least one antiretroviral medication between July 1, 2008 and July 1, 2009, with the first 50 patients at least 18 years old, with a confirmed HIV diagnosis, and who had been admitted for at least 24 hours included. The National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP) taxonomy was used to record types of errors incurred, node in the medication use process where the error occurred (prescribing, transcribing, dispensing or administration), and possible contributing factors. Data was analyzed using descriptive statistics.
Results: A total of 116 errors were identified. Prescribing errors made up 56%, dispensing errors 28.4%, administration errors 15.5% and there were no transcribing errors found. The most common prescribing error was wrong drug, the most common dispensing error was wrong timing of doses scheduled and the most common administration error was wrong timing of doses given. Examples of contributing factors included knowledge deficits, performance deficits and computer programming errors.
Conclusion: The results were used to identify and implement system based changes to formulary and computer programming that could prevent the errors found from occurring in future admissions of HIV infected inpatients. The methods used could be applied to other disease states and drug classes as well, to prevent additional error types.

161. Medication errors during medical emergencies in a large, tertiary care, academic medical center.
Roman Gokhman, Pharm.D.[1], Sandra L. Kane-Gill, Pharm.D., M.Sc.[2], Paul Phrampus, M.D.[1], Amy L. Seybert, PharmD[1]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh, Pittsburgh, PA

Purpose: There is a paucity of research on medication errors occurring during medical emergencies. We conducted the first prospective evaluation to assess the rate and type of medication errors made by the Medical Emergency Team (MET) at a large, tertiary-care, academic medical center during medical emergencies.
Methods: This was a quality improvement evaluation of 50 patients requiring care from a MET between March 2009 and February 2010. Data on medication use were collected using a direct-observation method whereby an observer documented drug information such as drug, dose, frequency, rate of administration and administration

technique. After data collection was completed, a team of three clinicians reviewed the data to assess the rate, type, and severity of medication errors using definitions consistent with the Unites States Pharmacopeia MEDMARX system.

Results: One hundred eighty six doses were observed for 36 unique medications. We identified a total of 296 errors; of these 196 errors (66%) were lack of aseptic technique. Of the remaining 100 errors, 46% were prescribing errors, 28% administration technique errors, 14% mislabeling errors and 10% drug preparation errors. Examples of errors included: 1) wrong medication preparation technique such as lack of filter needle use, 2) prescribing errors, 3) administration of wrong doses, 4) mislabeling, and 5) wrong administration technique such as not flushing intravenous medication through the intravenous access. The rate of medication administration errors was 1.6 errors per dose including aseptic technique and 0.5 errors per dose excluding aseptic technique. Majority (91%) were considered MEDMARX severity C meaning the error reached the patient but did not cause harm.

Conclusion: We found that 1 out of 2 doses were administered in error when we excluded the errors of using inappropriate aseptic technique. There is a need for education and systematic changes to prevent medication errors during medical emergencies.

162. Evaluation of a pharmacist-conducted medication reconciliation program upon admission in a medical center in Taiwan.
Yen-Ying Lee, M.S., PharmD, Tzu-Ying Wu, RPh, Mu-Lung Chen, M.S., Jing-Yi Hou, RPh, Hsiang-Yin Chen, M.S., Pharm.D.; Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan

Purpose: Studies have shown that medication reconciliation can improve patient safety. However, obtaining accurate medication history on admission can be challenging in Taiwan because patients usually are not familiar with the names of their drugs. This study evaluated the performance of a medication reconciliation program conducted by pharmacists with the aid of medication usage data provided by Bureau of National Health Insurance (BNHI).
Methods: Patients admitted between May 2008 and September 2009 and interviewed by pharmacists using medication usage data from BNHI on admissions were included. Type and class of medication discrepancies discovered by pharmacists, medication discrepancy rate, physician acceptance rate, and time taken for intervention were studied. Furthermore, the degrees of harm that could result from these discrepancies were evaluated by four pharmacists independently.
Results: Of the 3,026 patients interviewed, pharmacists were able to identify 243 patients (8%) with at least one medication discrepancy between patient medication history and admission orders. There were a total of 576 discrepancies discovered. Omission was the most common error and cardiovascular medications are the most frequently encountered drug class. About 19% of the errors prevented could have potentially caused moderate to severe harm. The average time for one intervention was 18 ± 9.8 minutes. The physicians' acceptance rate of pharmacist interventions was 98%.
Conclusion: This medication reconciliation program has been successfully conducted by pharmacists. There were more than 500 interventions regarding medication discrepancies in a 17-month period and the acceptance rate was high. The process of reconciling is made more efficient by using medication usage data from BNHI.

163. FMEA utilization to improve warfarin use at an urban teaching hospital.
Abir O. Kanaan, Pharm.D.[1], Kristin Tuiskula, Pharm.D.[1], Jason T. Andree, Pharm.D.[2], Matthew A. Silva, Pharm.D., BCPS[1], Michael J. Ditoro, Pharm.D.[2], V. Susan George, M.D., FACP[1], George Abraham, MD, MPH, FACP[1]; (1)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA; (2)St. Vincent Hospital, Worcester, MA

Purpose: Failure Mode and Effects Analysis (FMEA) proactively identifies failure modes associated with a product or process. This approach was utilized at our institution to evaluate the risks associated with warfarin use and develop corrective actions to optimize patient safety. An FMEA was performed based on observations from a pharmacist-led warfarin monitoring program. A warfarin order form was developed and a post-FMEA (postF) conducted to assess its effectiveness.

Methods: A multidisciplinary team of physicians, nurses, and pharmacists was identified. Sixteen process steps were adapted from a similar process conducted by the Institute for Safe Medication Practices. Posters were created to outline the severity, detectability and likelihood of occurrence scales with corresponding definitions and incidence. The Risk Priority Number (RPN) calculates the potential causes of failure (severity x occurrence x detection); a higher RPN indicates an increased risk associated with the process. Based on RPN results from the first FMEA (preF), a warfarin order form was developed. A postF was then conducted to assess the effectiveness of that form. Wilcoxon tests were selected for median scores based on non-normalized distributions.
Results: The overall median RPN preF was 175 compared to 45 postF (p<0.001). The preF medians for occurrence, detectability and severity were 6, 4, and 7 compared to 5, 3, and 3 postF (p=0.017, 0.009, < 0.0001 respectively). When allocating steps per discipline, the RPN did not vary between preF and postF for physicians and nurses (p=0.07, p=0.08 respectively); however, improvement was seen in pharmacy related failure modes (p=0.04). This was expected as the process did not dramatically affect physician and nursing practice. The total RPN was not driven by a specific process step nor did it vary between disciplines.
Conclusion: The FMEA process identified failure modes associated with warfarin use and was utilized to develop a warfarin order form.

164. Successful design, implementation, and quantification of a community-based medication collection program.
Laura Perry, Pharm.D.[1], Bradley W. Shinn, Pharm.D.[2], John S. Stanovich, B.S.[3]; (1)The University of Findlay College of Pharmacy, Findlay, OH; (2)University of Findlay School of Pharmacy, Finday, OH; (3)University of Findlay, Findlay, OH

Purpose: Statistical data show a growing problem with unused medications in the U.S. It is estimated that the elderly population alone wasted $1 billion of drugs in 2007. One of the most common sources of illicit pharmaceuticals is the home medicine cabinet. This study reports the design and successful implementation of an unused medication collection program that depended on the collaboration of government and community groups with the UF College of Pharmacy.
Methods: This initiative originated in March, 2008 when a community partnership focus group identified medication misuse and abuse as a problem within the local community. Over the next year, a structured process was designed by representatives from several local agencies and the UF College of Pharmacy. Final DEA approval was obtained in April, 2009. Thus far, three collection days (April 2009, October 2009, and April 2010) have been conducted with excellent community responses.
Results: A total of 319 cars dropped off medications during the three collection days. A total of 94,566 tablets and capsules were collected, of which 4.9% were controlled medications, 59.5% were uncontrolled prescription medications, and 35.6% were OTC medications. The most common medications collected were hydrocodone/APAP, propoxyphene/APAP, ibuprofen, furosemide, metoclopramide, calcium acetate, minocycline, and carvedilol. Based on AWP, the total estimated cost of medications collected is $208,858.84.
Conclusion: Through the implementation of a medication collection program, a large number of medications have been removed from the community. This program is unique in that all medications collected were inventoried. Pharmacy students were thoroughly involved with the process, which allowed the program to also serve as an educational experience. Furthermore, the quantification of unused medications may assist in identifying prescribing or compliance issues that might be addressed through future education programs. Current plans are to continue to offer this service at least two times each year.

165. Failure of risk evaluation and mitigation strategies with bosentan.
Lori A. Wilken, Pharm.D., Louis Kim, Pharm.D., Christopher Lee, B.S., JoAnn Stubbings, R.Ph., M.H.C.A., Juliana Chan, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL

Purpose: Advancements in pulmonary arterial hypertension (PAH) therapy have emerged to target key mediators, including endothelin

receptor antagonists, such as bosentan. However, bosentan is not free of adverse effects. Consequently, the FDA placed a black box warning on bosentan, informing prescribers of the increased risk of liver damage and birth defects. The FDA also approved a risk evaluation and mitigation strategy (REMS). It requires monthly liver function (LFTs) and pregnancy testing and that certified pharmacies confirm these tests were completed. The purpose of this study is to characterize the patient population and to determine if bosentan was monitored appropriately according to REMS requirements.
Methods: Patients receiving at least one bosentan prescription between 8/7/2009–5/28/2010 from the medical center were included in this retrospective study. Prescriptions were dispensed by outside certified pharmacies. Data collected include demographic information, WHO functional class, and treatment duration. Each patient's LFTs and pregnancy tests were obtained to determine if they were drawn on a monthly basis, as required by REMS.
Results: Nineteen patients met inclusion criteria. Three were excluded for not starting bosentan or stopping treatment before REMS implementation. Of the remaining 16 patients, the majority were African American (62.5%), female (87.5%) and older than 51 years old (62.5%). Fifty percent met WHO class III, while 75% were on bosentan for either less than 1 year or greater than 5 years. Since REMS initiation, 47.9% and 17.2% of the required monthly LFTs and pregnancy tests were performed, respectively.
Conclusion: REMS was developed to protect patients from potentially dangerous adverse effects. Implementation of current monitoring plans to meet the REMS requirements has been found to be ineffective. Clinical pharmacists can play a pivotal role in the management of drugs with REMS to minimize and to prevent adverse events and ultimately, to improve the quality of patient care.

166E. Extrapyramidal symptom and akathisia profile of iloperidone in schizophrenia clinical trials.
John Lauriello, M.D.[1], Joy Kainer, RPh, Pharm.D.[2], *Marla Hochfeld, M.D.*[2], Rosarelis Torres, Ph.D.[3], Curt D. Wolfgang, Ph.D.[3], John Feeney, M.D.[3]; (1)University of New Mexico, Albuquerque, NM; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3)Vanda Pharmaceuticals Inc., Rockville, MD

Purpose: Antipsychotic-induced akathisia and extrapyramidal symptoms (EPS) is physically uncomfortable and can influence functioning, quality of life, and treatment adherence. Iloperidone, a mixed D2/5-HT2 antagonist developed for the treatment of schizophrenia, has demonstrated a low incidence of these effects.
Methods: Nine phase II and III double-blind or open-label clinical trials of adults with schizophrenia were included in the analysis. Mean duration of iloperidone treatment was 230 ± 300.5 days; maximum treatment duration was 2 years. Reports of EPS and akathisia as adverse events and changes from baseline in Extrapyramidal Symptoms Rating Scale (ESRS) and Barnes Akathisia Scale (BAS) scores were evaluated.
Results: The pooled safety analysis comprised 4838 patients: 1225 iloperidone 4–8 mg/d; 1533 iloperidone 10–16 mg/d; 452 iloperidone 20–24 mg/d; 546 haloperidol 5–20 mg/d; 311 risperidone 4–8 mg/d; 184 ziprasidone 160 mg/d; and 587 placebo. Treatment-emergent EPS were reported in 18.0% (iloperidone 4–8 mg/d), 20.0% (iloperidone 10–16 mg/d), 15.9% (iloperidone 20–24 mg/d), 59.7% (haloperidol), 29.9% (risperidone), 24.5% (ziprasidone) and 11.6% (placebo) of patients. Mean changes in overall ESRS from baseline to endpoint were −0.7 (iloperidone 4–8 mg/d), −0.8 (iloperidone 10–16 mg/d), −0.1 (iloperidone 20–24 mg/d), 1.3 (haloperidol), −0.4 (risperidone), 0.2 (ziprasidone) and −0.3 (placebo). Treatment-emergent akathisia was reported in 4.2% (iloperidone 4–8 mg/d), 5.2% (iloperidone 10–16 mg/d), 3.3% (iloperidone 20–24 mg/d), 21.2% (haloperidol), 7.1% (risperidone), 8.2% (ziprasidone) and 2.7% (placebo) of patients. Worsening in BAS scores at endpoint were reported in 10.1% (iloperidone 4–8 mg/d), 8.8% (iloperidone 10–16 mg/d), 3.7% (iloperidone 20–24 mg/d), 18.5% (haloperidol), 13.9% (risperidone), 15.6% (ziprasidone) and 11.4% (placebo) of patients.
Conclusion: Iloperidone may have a lower propensity to cause EPS or akathisia than haloperidol, risperidone, or ziprasidone, offering a favorable treatment option for schizophrenia. Vanda Pharmaceuticals sponsored this study.

167E. The metabolic profile of iloperidone: summary of phase II and III schizophrenia trials.
Stephen M. Stahl, M.D., Ph.D.[1], *Joy Kainer, RPh, Pharm.D.*[2], Marla Hochfeld, M.D.[2], Paolo Baroldi, M.D., Ph.D.[3], John Feeney, M.D.[3], Curt D. Wolfgang, Ph.D.[3]; (1)University of California, San Diego, La Jolla, CA; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3)Vanda Pharmaceuticals Inc, Rockville, MD

Purpose: Many atypical antipsychotics are associated with adverse effects on metabolic parameters that may increase diabetes and cardiovascular disease risk. Iloperidone is a mixed D2/5-HT2 antagonist developed for the treatment of schizophrenia. Body weight, blood glucose, cholesterol, triglyceride, and prolactin level changes were assessed in a pooled analysis of iloperidone clinical data.
Methods: Nine phase II and III double-blind or open-label clinical trials of adults previously diagnosed with schizophrenia were identified and included in the analysis. Mean duration of iloperidone treatment was 230 days. Maximum treatment duration was 2 years. Weight gain and metabolic parameters were evaluated.
Results: A total of 4838 patients (iloperidone 4–24 mg/day, n=3210; haloperidol 5–20 mg/day, n=546; risperidone 4–8 mg/day, n=311; ziprasidone 160 mg/day, n=184; placebo, n=587) were included in the pooled safety analysis. Mean changes from baseline to endpoint in body weight were +2.1, +0.8, +1.7, +1.1, and −0.1 kg, respectively. Respective mean changes at endpoint in blood glucose levels were +5.4, +1.8, +1.8, +9.0, and 0.0 mg/dL. Mean changes at endpoint in total cholesterol were −3.9, 0.0, −7.7, +3.9, and −7.7 mg/dL, and mean changes at endpoint in triglycerides were −17.7, 0.0, −35.4, +8.8, and −26.5 mg/dL, respectively. Respective mean changes at endpoint in prolactin levels were −1.8, +23.1, +34.5, +2.0, and −8.0 ng/mL.
Conclusion: Pooled analysis results indicate that iloperidone has a favorable metabolic profile with clinically neutral values or reductions on key parameters often associated with atypical antipsychotics. Vanda Pharmaceuticals sponsored this analysis.

168. Use of a computerized on-screen alert to reduce weight-entry errors in an electronic medical record at a large community health system.
Danny McNatty, Pharm.D., BCPS, John M Silverberg, Pharm.D., BCNSP, Brenda S Stoffer, RN, Nick Sindorf, MT, CLE, Joel D McAlduff, M.D.; Banner Health, Phoenix, AZ

Purpose: Inaccurate weight documentation in the electronic medical record has the potential to lead to significant medication dosing errors. Common weight entry errors include confusing pounds and kilograms, inappropriate estimation of weight, and decimal point errors. The purpose of this trial was to examine the effectiveness of an automated computerized alert in reducing weight-entry errors in an electronic medical record at a large community health system. A reduction in weight-entry errors has the potential to improve medication safety in the inpatient setting.
Methods: A computerized on-screen warning was developed to alert users when a patient weight is charted that represents greater than a 20% change from a previous weight. The warning interrupts the user during weight documentation and requires a modification or acknowledgement to continue with charting. Incidence of weight entry representing greater than a 20% change during a two-week period pre-alert was compared with a two-week period post-alert using χ^2 test.
Results: A similar number of patients were admitted during the pre-alert (n=9999) and post-alert (n=9813) time periods. A 71% reduction in weight-entry errors was seen during the two weeks after implementation of the alert compared to the pre-alert period (2.5% versus 8.6%, p<0.001).
Conclusion: Implementation of a computerized on-screen alert is an effective way to reduce weight-entry errors in the electronic medical record. Ensuring accurate documentation of patient weight is one way to help optimize medication safety in the inpatient population.

169. Evaluation of the immunogenicity and safety of recombinant human thrombin after subsequent surgical re-exposure.
W. Allan Alexander, M.D.[1], Antonios P. Gasparis, M.D.[2], Kaj Johansen, M.D.[3], Jeffrey L. Ballard, M.D.[4], Neil K. Singla, M.D.[5]; (1)ZymoGenetics, Inc., Seattle, WA; (2)Stonybrook University Hospital, Stony Brook, NY; (3)Swedish Medical Center, Seattle, WA; (4)Vascular and Interventional Specialists of Orange County, Orange, CA; (5)Lotus Clinical Research, Inc., Pasadena, CA

Purpose: In clinical trials with recombinant human thrombin (rThrombin), anti-product antibodies were observed in 0.9% (5/552) of patients. There are clinical concerns regarding the risk of anti-product antibody and/or inhibitor formation following repeat application of xenogenic thrombin. This study evaluated the immunogenicity and safety of rThrombin in patients with prior exposure to rThrombin undergoing a subsequent surgical procedure.
Methods: This Phase 4, open-label, single group, multisite study included 31 patients ≥18 years of age with documented prior exposure to rThrombin who were undergoing a surgical procedure in which topical rThrombin application was planned. Immunogenicity was evaluated by enzyme-linked immunosorbent assay at baseline and Day 29. Adverse events (AEs) were collected through Day 29. Safety evaluations included incidence/severity of AEs and incidence/grade of clinical laboratory abnormalities.
Results: Immunogenicity and safety results from 19 patients are available. Mean age was 57.1 years (SD, 12.9; range, 22–80 years). Surgical procedure types included: spine, 74% of patients; vascular, 21%; other, 5%. Median applied rThrombin activity was 15,000 IU (range, 5000–60,000 IU). Complete immunogenicity data are available for 19 subjects. All patients were seronegative for anti-rThrombin product antibodies at baseline, and no patients developed anti-product antibodies through Day 29. Topical application of rThrombin was well tolerated. Common AEs and laboratory changes were consistent with the post-surgical setting and surgery type and prior studies of rThrombin. Serious adverse events (SAEs) were observed in 4 patients. No AEs or SAEs were considered by the investigators to be treatment-related.
Conclusions: No anti-rThrombin product antibody formation was observed through Day 29 in patients previously treated with rThrombin who were re-exposed during a subsequent surgical procedure. rThrombin appears to be well tolerated when used as an aid to hemostasis in patients previously treated with the product.

Nephrology

170E. Effects of Intravenous Iron Products in the Pathogenesis of Pulmonary Edema.
Amy Pai, Pharm.D., George R. Bailie, Pharm.D., Arnold Johnson, PhD; Albany College of Pharmacy and Health Sciences, Albany, NY

Purpose: Fluid retention and pulmonary edema are major complications associated with significant morbidity, mortality and hospitalization costs in maintenance HD patients. IV iron induces oxidative stress and may affect intracellular reactive oxygen species (ROS) generation, but is unknown if this affects lung permeability.
Methods: A lung permeability model was used in the 1st experiment. Rat lung microvessel endothelial cell (RLMEC) monolayers were cultured and treated with iron sucrose (IS), sodium ferric gluconate (SFG), ferumoxytol (FMX), low MW iron dextran (ID) and ferric carboxymaltose (FCM) at 0.05 mg/mL for 24 hours and permeability was determined by clearance rate of Evans Blue-labeled albumin between the luminal and abluminal compartments between 10 and 60 mins. Experiments were conducted in quadruplicate. ROS were quantitated in a 2nd experiment. RLMEC treated with iron products (0.05 mg/mL) for 30 minutes were incubated with dihydroethidium (a fluorescent probe for ROS) (10 μM, 0.5 h at 37°C). Sonicated cell suspensions were added to microplates (100 μl/well) in quadruplicate. Fluorescence was measured using excitation and emission wavelengths of 490 and 605 nm.
Results: Incubation of RLMECM with SFG, IS and FCM induced greater endothelial barrier dysfunction compared to controls, FMX and ID ($p < 0.05$ for all comparisons, Figure 1). Endothelial permeability after treatment with FMX and ID was not significantly

different from control. All IV iron products induced ROS production, with 14, 22, 44 and 85% increases in detected O_2^- for SFG, ID, FMX and IS, respectively vs. untreated controls ($p < 0.05$ for FMX and IS vs. controls).
Conclusion: Albumin clearance indicated highest RLMEC permeability for SFG, IS and FCM. All IV iron products induced ROS production. More data are needed to explore intracellular free iron generation and disruption of intracellular signaling. These data indicate that IV iron produces oxidative stress leading to potential for lung injury and adverse clinical outcomes.
Presented at European Dialysis and Transplant Association, June 28, 2010, Munich, Germany

171. Anemia management in hemodialysis: cost-savings, epoetin alfa, and target hemoglobin level.
Timothy V. Nguyen, Pharm.D.[1], David S. Goldfarb, M.D.[2]; (1)Arnold & Marie Schwartz College of Pharmacy, Long Island University and The Mount Sinai Medical Center, Brooklyn, NY; (2)NYU School of Medicine and NY Harbor VA Medical Center, New York City, NY

Purpose: Effective correction of anemia in hemodialysis (HD) patients has recently become one of the most controversial aspects of patient care. The latest trials indicate that higher risks of heart attack, stroke and death were associated with higher target hemoglobin (Hb) levels in epoetin alfa (EPO)-treated patients. We hypothesized that reducing target Hb level would reduce the percentage of patients having Hb above 12 g/dL and at the same time, lead to cost-savings associated with EPO reduction therapy.
Methods: A hemodialysis unit treated 35–42 chronic adult patients, who received EPO via subcutaneous injection either weekly or twice weekly to target Hb levels 9–11 g/dL in 2009 compared to target Hb levels 11–12 g/dL in 2007. IV iron ferric gluconate was administered to maintain transferrin saturation (TSAT) >20% and ferritin >200 ng/mL. Retrospective data analysis compared those two periods with respect to: EPO dose, Hb, TSAT and ferritin levels.
Results: The mean weekly EPO dose decreased from 8,300 units in 2007 to 6,800 units in 2009 (18% decreased). The mean Hb levels in 2007 ranged 10.9 to 11.7 g/dL with 28% of patients having Hb>12 g/dL and 10% >13g/dL. The mean Hb levels in 2009 ranged from 10.6 to 11.2 g/dL with 10% of patients having Hb >12 g/dL and 1.6% of patients having Hb >13 g/dL. The resulting change in EPO dose, which cost $9.1 per 1000 units, represents a cost-savings of approximately $25,000 in 2009 compared to 2007. More than 80% of patients had TSAT>20% and ferritin level >200 ng/mL throughout the entire period.
Conclusion: Careful management of anemia in HD patients is crucial to improve patient care, reduce risks associated with EPO therapy, and avoid Hb levels rising above recommended ranges. Significant cost-reduction and cost-savings play important roles in this setting as well.

Neurology

172E. Prospective Evaluation of Labetalol vs. Nicardipine for Blood Pressure Management in Patients with Acute Stroke.
Denise H. Rhoney, Pharm.D.[1], Xi Liu-DeRyke, Pharm.D.[2], Dennis Parker, Jr., Pharm.D.[1], Benjamin Atkinson, M.D.[1], William Coplin, MD[1], Phillip Levy, MD[1]; (1)Wayne State University, Detroit, MI; (2)Orlando Regional Medical Center, Orlando, FL

Purpose: Labetalol (L) and nicardipine (NIC) are used for blood pressure (BP) following cerebrovascular emergencies but there is limited clinical data comparing them. The purpose of this study is to compare therapeutic response, overall patient outcomes, and adverse events between L and NIC following acute stroke.
Methods: This is a prospective, randomized, trial of acute stroke patients requiring BP management. L or NIC was continued for 24 hours post-randomization and therapeutic response was assessed by achievement of goal BP (defined by published guidelines), percentage of time within goal BP, and ease of administration.
Results: A total of 47 patients were enrolled (L=22; NIC=25) with a mean of 26 ± 5 total BP measurements per patient in the 24-hour

period. The majority of patients had intracerebral hemorrhage(L=46%; NIC= 60%: p=0.40) and baseline clinical characteristics (including BP and heart rate) were similar between groups. All 25 patients who received NIC achieved goal BP during stuyd compared to only 15(68%) in the L group(p<0.001). Additionally, a significantly greater proportion of NIC treated patients were within goal BP by 1-hour compared to those treated with L(88% vs. 32%; p<0.001). The mean NIC infusion at time of goal achievement was 5 (range: 2.5–15) mg/hr while total mean cumulative dose to goal achievement of L was 50 (range: 10–280) mg. During the 24-hour study period, patients in the NIC group were at goal 82.5% (± 19.6) of time while those who received L were in goal only 48.5% (± 30.0) of the time(p<0.001). "Rescue therapy" was given to 73% of the L group compared with 0% of NIC patients(p<0.001). There was no difference in adverse effects, ICU/hospital length of stay, Glasgow outcome score at discharge, or in-hospital mortality.

Conclusion: Therapeutic response to NIC was superior to L for management of acute hypertension following stroke with no demonstrable difference in adverse effects or patient outcomes.
Published in Crit Care Med. 2009;37(12):A161. Abstract 342.

Oncology

173. Evaluation of osteoporosis risk assessment in veterans receiving androgen deprivation therapy.
Valerie A. D¢Alesio, Pharm.D.[1], T. Neal Fourakre, Pharm.D.[2], Brent E. Salvig, Pharm.D.[2]; (1)VA Tennessee Valley Healthcare System, Nashville, TN; (2)VA Tennessee Valley Healthcare System, Murfreesboro, TN

Purpose: This study sought to determine whether veterans receiving androgen deprivation therapy (ADT) with goserelin or leuprolide for prostate cancer were screened at any time for bone mass measurement more or less than rates from previous literature. Secondary objectives included identifying if calcium, vitamin D, or antiresorptive therapy with calcitonin or bisphosphonates were prescribed to prevent or treat osteoporosis in these patients. We also utilized the Osteoporosis Screening Tool (OST) to determine if veterans may have been candidates for bone mineral density (BMD) testing independent of therapy.
Methods: We retrospectively reviewed the electronic medical records of all male veterans who received at least one dose of goserelin or leuprolide within the fiscal years October 1, 2005 through September 30, 2009. Descriptive statistics were used to analyze all primary and secondary endpoints. Chi-square analysis was used to determine the rate of BMD testing in our patients compared to results found in the literature. Sample size was determined based on a 95% confidence interval with a desired confidence interval precision of 0.10. Based on these variables, to detect a 10% difference a sample size of 219 patients was calculated.
Results: Of the 219 patients included in the analysis, 50 patients (22.8%) had a documented BMD test. This was statistically significant when compared to results found in previous literature.
Conclusion: Although rates of BMD testing were higher at VA-TVHS compared to previous literature, this rate is still low given the well known risk of accelerated osteoporosis associated with ADT. The results of our study indicate there is a significant opportunity to improve osteoporosis prevention among men receiving ADT.

Pain Management/Analgesia

174E. Gaps in the initial management of postherpetic neuralgia: the BASIK PHN survey.
Gregory D. Salinas, Ph.D.[1], Terry A. Glauser, M.D.[1], Mark S. Wallace, M.D.[2], Chad Williamson, M.S.[1]; (1)CE Outcomes, LLC, Birmingham, AL; (2)University of California San Diego Medical Center, La Jolla, CA

Purpose: Postherpetic neuralgia (PHN) is continued pain due to herpes zoster for >3 months after resolution of the dermatomal rash. While annual incidence of PHN in the United States is 100,000–180,000, there is a lack of published information regarding the knowledge, attitudes, and practice patterns of U.S. physicians on their management of PHN.
Methods: To identify needs of physicians managing patients with PHN, we distributed a case-vignette survey (BASIK PHN: Behaviors, Attitudes, Skills, Identified gaps and Knowledge of Postherpetic Neuralgia) to a nationally representative sample of US-practicing primary care physicians (PCPs) and neurologists. The total sample included 150 PCPs and 76 neurologists. The survey presented typical patients with PHN to assess how the patient would be managed. Additional questions assessed attitudes concerning available treatment and barriers to optimal patient care.
Results: Less than 1 in 10 respondents indicated that they were "very satisfied" with currently available PHN treatments. Only 1 in 5 physicians were "very confident" that an initial treatment would control the patient's pain. 1 in 3 PCPs and 1 in 5 neurologists do not specifically tell a patient that they have "postherpetic neuralgia" when initially diagnosed. PCPs were more likely than neurologists to include gabapentin in initial therapy choice (p=0.004). Neurologists were more likely to recommend pregabalin (p=0.007). Few PCPs would refer a patient with PHN to a specialist. Major barriers to managing patients with PHN include patients' high expectations about the level of pain relief and dose-limiting side effects.
Conclusion: Most respondents have not had positive experiences managing patients with PHN and are not very confident in the ability of available therapies to treat PHN pain. Information on best ways to communicate with patients about the reason for their pain as well as expected outcomes and side effects of treatment may be useful to physicians.
Presented at the American Association of Pain Management meeting, Las Vegas, NV, 2010

175E. Gaps in the patient perception of PHN management.
Gregory D. Salinas, Ph.D.[1], Terry A. Glauser, M.D.[1], Mark S. Wallace, M.D.[2], Chad Williamson, M.S.[1]; (1)CE Outcomes, LLC, Birmingham, AL; (2)University of California San Diego Medical Center, La Jolla, CA

Purpose: Postherpetic neuralgia (PHN), continued pain due to herpes zoster for >3 months after resolution of the dermatomal rash, has an expected annual incidence in the United States of 100,000–180,000. However, there is a lack of published information on US physician practice patterns and the perceptions of patients with PHN on the management of their condition.
Methods: To identify differences in perceptions of PHN care between patients and physicians, we distributed a survey to US adults who had been diagnosed with herpes zoster and prescribed medications for pain. The survey assessed patients' level of agreement with statements regarding their PHN management, as well as their level of pain, what types of medications they were prescribed, and satisfaction with prescribed medications and care.
Results: A total of 142 eligible patient respondents were included in the study. Responses were compared to the 150 PCPs and 76 neurologist respondents from the BASIK PHN (Behaviors, Attitudes, Skills, Identified gaps and Knowledge of Postherpetic Neuralgia) study. Few patients and physicians indicated satisfaction with the currently available PHN treatments. While physicians indicated that they did discuss the cause of PHN with their patients, 23% of patients indicated that their physician did not. 25% of patients were not aware of the duration of PHN, the side effects of treatment, or what to expect from treatment; however, few physicians indicated that these issues were not discussed. 42% of patients indicated their physician had never discussed how PHN treatments may affect their quality of life, while almost all physicians reported discussing this with their patients.
Conclusion: Physicians and patients have similar perceptions regarding PHN treatment options. However, certain gaps were evident which may be attributable to physician knowledge and communication skills. Strategies to improve outcomes and communicating side effects of treatment may be useful to physicians.
Presented at American Association of Pain Management meeting, Las Vegas, NV, 2010

176. Evaluation of continuous subcutaneous anesthetic infusion usage in coronary artery bypass graft patients.

Anastasia L. Roberts, Pharm.D., Karen O. Petros, Pharm.D., Melissa L. Rinehart, Pharm.D.; West Virginia University Hospitals, Morgantown, WV

Purpose: The primary objective of this study was to determine whether a continuous subcutaneous anesthetic infusion delivered to sternotomy site decreases opioid requirements in surgical patients who have undergone coronary artery bypass grafts (CABG).

Methods: A retrospective chart review of 100 patients was performed comparing pain medication requirements of patients who received a subcutaneous anesthetic infusion post-operatively with those who received usual analgesic regimen. Patients included received a CABG from March to December 2009. Patients were excluded if they remained intubated longer than twenty-four hours or required additional surgery in the first ninety-six hours. Repeated Measures Analysis of Variance (ANOVA) was used to compare opioid use in twenty-four hour increments. A power analysis was performed and found >99.9% power to detect a 30mg morphine-equivalent difference in groups.

Results:

Drug	Mean dose in pump patients (mg) (N=50)	Mean dose in traditional pain control patients (mg) (N=50)	P value
Acetaminophen	801	1000	0.134
Ketorolac	8.0	9.6	0.586
Opioids (Morphine Equivalents)	8.2	10.3	0.107

Conclusions: Use of subcutaneous anesthetic infusion did not show a statistically significant reduction in the use of analgesic medications in post-CABG patients.

Pediatrics

177. Pediatric warfarin therapy – a children's hospital's experience and pursuit of the goal.

Lee Bernard, Pharm.D.[1], Joshua E. LaBrin, M.D.[2], Kevin K. Graner, R.Ph.[1], Chad K Brands, M.D.[1]; (1)Mayo Clinic, Rochester, MN; (2)Vanderbilt University, Nashville, TN

Purpose: Despite the increasing pediatric usage of warfarin therapy, there are still few published dosing experiences and even fewer standardized clinical protocols. This study aimed to critically examine pediatric warfarin dose and response data over a 2 year period in all pediatric hospitalized patients. The objective was to develop a day by day evidence- and practice-based pediatric warfarin therapy clinical protocol.

Methods: Retrospective medical records review included physician and nursing notes, medication administration records, laboratory and pharmacy records of consecutive pediatric patients (< 18 years) hospitalized at Mayo Children's Hospital between 1/1/2007 and 12/31/2008. Evidence of research authorization was confirmed before inclusion.

Results: 135 patients representing 176 inpatient courses of warfarin were elucidated from the observation period. Among 121 newly initiated courses, the average starting dose was 0.078 mg/kg (range 0.014–0.377 mg/kg, SD 0.047 mg/kg) with 57 (47.11%) reaching goal INR requiring a mean of 5.35 days to achieve. For every 0.1 mg/kg/dose of warfarin, a 0.12 (7.5%), 0.57 (34.3%), 0.39 (23.7%), 0.33 (20.2%) and 0.29 (19.6%) change in INR from the previous day on days 1–5, respectively, was observed. In addition, when patients were further analyzed by age (infants $\leq$ 1 year, children 1–13 years and adolescents $\geq$ 13 years) and weight (less than versus $\geq$ 50 kg) subgroups, the dose response data drastically diversified revealing increased dose requirements and varied INR response in younger and lighter patients. Among the 55 non-naïve patients, despite having used warfarin within 7 days prior, a 0.264 (15.8%) change in INR was observed after hospital day 1.

Conclusion: Highly variable dosing and monitoring regimens resulted in inconsistent outcomes for warfarin therapy in a highly diversified, multi-factored pediatric population. Our data strongly indicated the need for and subsequent development of a weight based, standardized pediatric daily warfarin dosing protocol.

178E. Efficacy of metformin in pediatric patients with type-1 diabetes mellitus.

Jamie L. McCarrell, Pharm.D., Thomas M. Parker, Pharm.D., Krystal K. Haase, Pharm.D., BCPS; Texas Tech University Health Sciences Center, Amarillo, TX

Purpose: The aim of this study was to determine if pediatric subjects with type-1 diabetes experienced a change in glycemic control as a result of metformin being added to their current insulin regimens.

Methods: Demographics, medication use, insulin sensitivity markers, and laboratory values were obtained from subject medical records. Reduction in A1C was the primary objective, while insulin sensitivity/usage, BMI, glycemic excursions, and safety were secondary objectives. The paired t-test was used to compare data for all objectives.

Results: Of the 18 subjects who met study criteria, 78% were female, 39% were on an insulin pump, and 61% were managed with multiple daily injections. The average age at initiation of metformin was 11.8 ± 3.4 (range 5.8–16.3 years). Significant reductions in A1C were seen at first follow-up after metformin initiation (10.8 ± 1.8% vs. 9.3 ± 1.1%, P=0.001) and remained significantly lower over the 12 month follow-up. Average maximal reduction in A1C per patient was 2.5% ± 1.3%. The percentage of hyperglycemic excursions decreased (13.9% vs. 3.0%, P=0.002) without an increase in hypoglycemic excursions (1.2% vs. 3.7%, P=0.272). Insulin sensitivity and dosage requirements did not change over the study period. BMI increases were seen over 12 months despite improved glycemic control.

Conclusion: Pediatric patients with type-1 diabetes had a significant and sustained reduction in A1C and hyperglycemic excursions after metformin initiation. These improvements in glycemic control were observed in the absence of an increase in the total daily insulin dose or an improvement in insulin sensitivity, indicating that the benefit demonstrated in this age group is more likely related to metformin's effect on halting hepatic gluconeogenesis than increasing insulin sensitivity.

To be presented at the 19th Annual Pediatric Pharmacy Conference and Annual Meeting (Pediatric Pharmacy Advocacy Group-PPAG) in St. Charles, MO, October 7–10, 2010.

179. Cytomegalovirus infection in the pediatric liver transplant recipient.

Gregory Smallwood, Pharm.D.[1], Tim Barnett, Ph.D.[2], Katie Casper, M.S.[2], Thomas Heffron, M.D.[3]; (1)PCOM School of Pharmacy, Suwnee, GA; (2)Children's Healthcare of Atlanta, Atlanta, GA; (3)Emory Healthcare, Atlanta, GA

Purpose: Reduced susceptibility to the antiviral drug ganciclovir is increasingly observed in cytomegalovirus infections of liver transplant patients. In the "Victor Trial", as many as 10% of the treated population demonstrated CMV resistant characteristics, greatly complicating treatment protocols and reducing prognosis.

Aim: To evaluate CMV infections in the pediatric liver transplant population in relation to clinical resistance.

Methods: This is a prospective, IRB approved, biosafety approved, consented/assented, single center study evaluating CMV viremia within the pediatric liver transplant population. Following liver transplantation, at time of CMV seroconversion, samples of blood are drawn, serially, for genomic evaluation of the CMV virus and then compared to clinical outcomes.

Results: From May 2007, 31 consecutive pediatric liver transplant recipients were consented, 16 (51.6%) seroconverted by PCR for CMV with 5 (31.2%) demonstrating clinical resistance. Patient's clinically resistant had similar days to CMV (23.2 ± 4.5 vs. 25.3 ± 14.9 days; p=0.765) with longer initial days of viremia (39.2 ± 9.7 vs. 22.0 ± 11.0 days; p=0.009) and longer total days of viremia (65.8 ± 26.8 vs. 34.7 ± 24.8 days; p=0.040). Patients with multiple episodes of CMV viremia were similar [4/5(80%) vs. 6/11(54.5%); p=0.588]. Patients with biopsy proven rejection were more likely to have resistance [4/5(80%) vs. 1/11(9.1%): p=0.013]. Co-infection with EBV was associated with CMV seroconversion [81.2% (13/16) vs. 33.3% (5/15); p=0.011] with no relationship to rejection or resistance (p=0.631). 60% of clinical resistant patients had point mutations identified as S655L, N685S, A88T, N898D, A688V, and S896L.

Conclusion: Inherent differences are noted with patients being treated for clinically resistant CMV. These differences are demonstrated by increased time of viremia, total viremic days, co-infection with EBV, rates of biopsy proven rejection and mutations in the UL54 CMV gene. Additional work should be conducted in this important group of patients.

180. An evaluation of levetiracetam use in critically ill pediatric patients.
Allison M. Chung, Pharm.D., BCPS, AE-C[1], Ashley M. McIntyre, Pharm.D.[2], *MaryAnn Birch, Pharm.D. Candidate*[3]; (1)Auburn University, Department of Pharmacy Practice; University of South Alabama, Department of Pediatrics, Mobile, AL; (2)Lexington Veteran's Affairs Medical Center, Lexington, KY; (3)Auburn University, Harrison School of Pharmacy, Mobile, AL

Purpose: Levetiracetam is a new generation antiepileptic drug (AED) which has a favorable pharmacokinetic profile and few adverse events compared to other AEDs. Since levetiracetam is available as an intravenous formulation and an oral formulation, it is an ideal agent for termination of acute seizures or seizure prophylaxis in critically ill patients. Although its use is increasing in the pediatric intensive care unit (PICU), its safety and efficacy in this setting has not been well documented. The objective of this study was to evaluate the use of levetiracetam in PICU patients for treatment of acute seizures and for seizure prophylaxis.
Methods: A retrospective analysis was conducted on critically ill pediatric patients who were treated with levetiracetam while in a 15-bed PICU over one year. Patients on levetiracetam and in the PICU were identified via the pharmacy database. Charts were reviewed for information on demographics, diagnosis, levetiracetam dosages, concomitant AEDs, outcomes and adverse effects. Descriptive statistics were utilized.
Results: Fifty nine pediatric patients were identified to have received levetiracetam. Sixty three percent were male, 49% were 0–2 years of age (range 0–18 years), 68% had a prior seizure disorder, and 63% had levetiracetam as a home medication. The most common diagnosis upon admit was respiratory distress (13.6%), head trauma (10%) or status epilepticus (8%). Doses ranged from 3-132mg/kg/day (mean=67 mg/kg/day). Levetiracetam monotherapy was administered to 20% of the patients with a mean dose of 54 mg/kg/day. A majority of patients (49%) were on levetiracetam plus 2 other AEDs. Patients were on levetiracetam for acute seizures, prophylaxis and maintenance. Most patients (96%) obtained good clinical outcomes. No significant adverse events were attributed to levetiracetam.
Conclusion: This single center experience of levetiracetam use in the PICU demonstrated it as a safe and effective option in this population.

181. Single versus Double Gram Negative Coverage Empiric Antibiotic Therapy of Febrile Neutropenia in Pediatric Patients.
Shane Pawluk, BSC, (Pharm), Roxane Carr, Pharm D; BC Children's Hospital, Surrey, BC, Canada
Background: In adult patient with febrile neutropenia, there is no difference in efficacy between single and double gram negative coverage antibiotic regimens. Outcome comparisons of these different antibiotic regimens have not been assessed in the pediatric population.
Purpose: To compare the effectiveness and safety of a double coverage gram negative antibiotic regimen to a single coverage gram negative antibiotic regimen in pediatric febrile neutropenia patients.
Methods: Retrospective review of patients who received piperacillin-tazobactam with or without gentamicin. Data collected using a standardized data collection form. Wilcoxon Rank-Sum Test was used to compare duration of fever and change in serum creatinine between the two treatment groups.
Results: A total of 60 patients were included in this study. Mean duration of fever was 3.5 days in the double coverage group and 3.1 days in the single coverage group (p=0.5). Addition of vancomycin was similar in double and single coverage groups (16.7% vs. 13.3%). Addition of gram negative coverage antibiotics occurred more frequently in the single coverage group. Mean percent increase in serum creatinine was 25% in the double coverage group and 10% in the single coverage group (p=0.03).
Conclusion: A similar duration of fever was observed in both

treatment groups. The single coverage group received additional gram negative antibiotics more frequently than the double coverage group. Although statistically significant, the change in serum creatinine in the double gram negative coverage group compared to the single coverage group was not clinically significant.

182. Safety and efficacy of high-dose levetiracetam in the treatment of various pediatric seizure disorders.
Debora Castañeda, Pharm.D., Dana Kirk, Pharm.D., Rana Said, M.D., Kelly R. Pulte, Pharm.D., Sean T. Nguyen, Pharm.D., BCPS; Children's Medical Center Dallas, Dallas, TX; University of Texas Southwestern Medical Center, Dallas, TX

Purpose: The objective of this study was to evaluate the safety and efficacy of levetiracetam (LEV) doses > 60 mg/kg/day in children diagnosed with a variety of seizure disorders.
Methods: A retrospective review of pediatric patients who received high dose LEV as either monotherapy or adjunctive therapy between January 1, 2006 through November 25, 2009 was performed. Primary endpoints were evaluated at 3, 6, 12 and 24 months after initiation of high dose LEV therapy. Safety was determined by the frequency of reported adverse events and discontinuation of LEV secondary to adverse drug reactions. Efficacy was evaluated based on the response to LEV therapy as determined by seizure frequency. Descriptive statistics were used to analyze the data.
Results: Of the 676 patients identified to have received LEV, 58 patients met inclusion criteria. At baseline, the age ranged from 8 months to 17 years (median 5 years) with a median dose of 72.5 mg/kg/day. Seven patients were receiving LEV as monotherapy at baseline. Over a 2-year period, there was an increase in the percent of patients achieving seizure freedom and reduction (29.3% to 56.3%). However, all patients were receiving adjunctive therapy at the end of the study period with a median LEV dose of 80.2 mg/kg/day. All adolescent patients had a documented intractable epilepsy diagnosis requiring LEV adjunctive therapy, none of which achieved seizure freedom at 3, 12 and 24 months. Two (3.4%) patients were discontinued from LEV secondary to adverse events.
Conclusion: Levetiracetam doses > 60 mg/kg/day in pediatric patients are well tolerated with few adverse events. High daily doses of LEV may be beneficial in adjuvant therapy except for those patients with refractory seizures. Monotherapy of high dose LEV does not appear to be beneficial in pediatric patients diagnosed with several seizure disorders.

183. Topical recombinant human thrombin (rThrombin) is well-tolerated in pediatric patients undergoing synchronous burn wound excision and skin grafting.
Kevin N. Foster, M.D., MBA, FACS[1], David G. Greenhalgh, M.D., FACS[2], Paul Glat, M.D.[3], Paul Fredlund, M.D.[4], John Pribble, Pharm.D.[4], *W. Allan Alexander, M.D.*[4]; (1)The Arizona Burn Center, Phoenix, AZ; (2)Shriner's Hospital for Children, Sacramento, CA; (3)St. Christopher's Hospital for Children, Philadelphia, PA; (4)ZymoGenetics, Inc., Seattle, WA

Purpose: rThrombin is a topical hemostat; its safety, immunogenicity, and efficacy have been evaluated in clinical studies with adults. In this study, rThrombin safety and immunogenicity were evaluated in pediatric patients.
Methods: This Phase 4 open-label, single-group, multisite study included children ages newborn through 17 years undergoing synchronous burn wound excision and skin grafting who required topical rThrombin to aid hemostasis. At least 3 children were enrolled per age category (0–2 years; 3-6 years; 7-11 years; 12-17 years). Safety evaluations included incidence/severity of adverse events (AEs) and incidence/grade of clinical laboratory abnormalities. Immunogenicity was evaluated at baseline and Day 29.
Results: Thirty subjects received rThrombin. Eleven subjects were 0–2 years, 8 were 3–6 years, 3 were 7–11 years, and 8 were 12–17 years. Of the 30 subjects receiving rThrombin, 28 (93.3%) completed the study. Flame, scald, and thermal etiologies accounted for 56.6% (n=17/30) of burns. Mean (SD) percent total body surface area (TBSA) burned was 5.58% (4.88). Median estimated thrombin activity applied/TBSA ranged from 6000–13,600 IU/m². AEs and changes in

laboratory parameters were consistent with prior rThrombin studies in adult burn patients. One subject had serious adverse events (skin graft infection, skin graft failure). There were no deaths. No AEs were considered to be treatment-related by investigators. Complete immunogenicity data are available for 27 subjects; none developed anti-rThrombin product antibodies at Day 29. One subject had pre-existing anti-rThrombin antibodies at baseline, but had no antibody response at Day 29.

Conclusions: rThrombin was well tolerated over a range of age groups in pediatric patients undergoing synchronous burn wound excision and skin grafting. There was no evidence of immunogenicity of rThrombin product in this study, consistent with the low incidence of immunogenicity observed in adults.

Pharmacoeconomics/Outcomes

184. Trends in infliximab utilization: An analysis of data from 60 United States commercial payers.
Lorie Ellis, Ph.D., Denise Zomorrodian, RN, R. Scott McKenzie, M.D., Samir H. Mody, Pharm.D., MBA; Centocor Ortho Biotech Services, LLC, Horsham, PA

Purpose: To report recent infliximab (IFX) vial utilization patterns by therapeutic indication in U.S. commercially insured patients. IFX utilization patterns are poorly understood since IFX vial utilization is difficult to discern from medical claims data.
Methods: IFX claims between 1/1/2008 and 12/21/2009 were analyzed from data provided by 60 U.S. commercial insurers representing approximately 180,000,000 U.S. lives. IFX claims were identified by J Code (1745) and ICD-9 codes (Ankylosing Spondylitis -720.x; Crohn's Disease (CD)-555.x; Ulcerative Colitis-556.x; Rheumatoid Arthritis (RA)-714.x; Psoriatic Arthritis- 696.0; Psoriasis-696.1). Number of IFX vials per infusion (VPI) was derived from Healthcare Procedure Code System entries and verified by associated charges. Mean VPI and proportion of infusions at various IFX dose ranges were analyzed.
Results: Claims for 921,764 IFX infusions (441,905, 2008; 479,860, 2009) were analyzed. Results indicate mean IFX utilization was stable over time (2008: 4.9 VPI; 2009: 5.0 VPI). Approximately 75% of IFX infusions occurred in RA and CD. A higher proportion of RA infusions (approximately 60%) utilized 1–4 VPI vs other indications. Overall, approximately 90% of infusions utilized ≤ 7 VPI (Table).
Table: IFX Utilization Summary

Indication	Proportion (%) of Infusions Infusions N (%)		MEAN VPI	
YEAR	2008	2009	2008	2009
ALL	441,905 (100%)	479,860 (100%)	4.8	5.0
CD	117,773 (27%)	125,460 (26%)	4.7	4.9
RA	221,346 (50%)	226,455 (47%)	4.4	4.5

Table (continued)

Indication	1-4VPI		5-7VPI		$\geq$8VPI	
YEAR	2008	2009	2008	2009	2008	2009
ALL	55%	52%	37%	39%	8%	10%
CD	54%	52%	36%	36%	10%	12%
RA	60%	57%	34%	35%	7%	7%

Column totals may not add to 100% due to rounding
Conclusion: This study evaluated the majority of U.S. commercially reimbursed IFX infusions occurring between 2008 and 2009. These findings demonstrate stable IFX-dosing across all indications over time, with the minority of infusions using $\geq$8 IFX VPI. These data confirm studies from commercial database populations showing stability of IFX utilization.

185. Compliance and persistence to single-tablet levodopa/carbidopa/entacapone compound versus levodopa/carbidopa in idiopathic Parkinson's Disease.
Mark A. Stacy, M.D.[1], François Laliberté, M.A.[2], Amit S. Kulkarni, Ph.D.[3], Monique Somogyi, M.D.[3], Francis Vekeman, M.A.[2], Mei-Sheng Duh, MPH, Sc.D.[4], *Patrick Lefebvre, M.A.*[2]; (1)Duke University Medical Center, Durham, NC; (2)Groupe d'analyse, Ltée, Montréal, QC, Canada; (3)Novartis Pharmaceuticals Corporation, East

Hanover, NJ; (4)Analysis Group, Inc, Boston, MA

Purpose: To quantify adherence to the single-tablet levodopa/carbidopa/entacapone (L/C/E) versus levodopa/carbidopa (L/C) combination in patients with idiopathic Parkinson's disease (PD).
Methods: Using MarketScan database (January 2004 through June 2008), PD patients naïve to L/C and with continuous insurance coverage newly initiated on single-tablet L/C/E or L/C combination, and with $\geq$2 dispensings and $\geq$1 diagnosis for PD were analyzed for compliance and persistence of tablet usage. Compliance was estimated using medication possession ratio (MPR) over the first year of therapy. Persistence was defined as continuous drug use without a gap of >30 days of medication supply or a switch to another PD medication.
Results: A total of 738 subjects on L/C/E single-tablet and 10,240 subjects on L/C combination were identified. Mean MPR during first year of observation was significantly higher in the single-tablet L/C/E group compared to the L/C combination (0.73 vs. 0.67; $P<0.05$). Kaplan-Meier rates of persistence after 6, 12 and 24 months of treatment initiation for single-tablet L/C/E and L/C combination were 60.4% vs. 55.4% ($P<0.05$), 48.1% vs. 40.1% ($P<0.05$), and 35.3% vs. 25.5% ($P<0.05$) respectively. Median time to drug discontinuation for L/C/E and L/C, was 315 and 229 days ($P<0.05$).
Conclusion: This large cohort of patients naïve to levodopa/carbidopa indicates that when initiated with single-tablet levodopa/carbidopa/entacapone, patients have greater drug compliance and remain on therapy longer than when beginning levodopa/carbidopa combination.

186. Impact of levodopa/carbidopa/entacapone compound versus levodopa/carbidopa on hospitalization rates in patients with idiopathic Parkinson's Disease.
Mark A. Stacy, M.D.[1], François Laliberté, M.A.[2], Amit S. Kulkarni, Ph.D[3], Monique Somogyi, M.D.[3], Francis Vekeman, M.A[2], Mei-Sheng Duh, MPH, Sc.D.[4], *Patrick Lefebvre, M.A.*[2]; (1)Duke University Medical Center, Durham, NC; (2)Groupe d'analyse, Ltée., Montréal, QC, Canada; (3)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (4)Analysis Group, Inc, Boston, MA

Purpose: To investigate whether levodopa/carbidopa/entacapone (L/C/E) reduced the risk of hospitalization compared with levodopa/carbidopa (L/C) in patients with idiopathic Parkinson's disease (PD).
Methods: Using MarketScan database (January 2004 through June 2008), PD patients naïve to L/C, with continuous insurance coverage newly initiated on L/C/E or L/C, and with $\geq$2 dispensings and $\geq$1 diagnosis for PD were included were analyzed. The incidence rate ratio (IRR) was used to compare the rates of all hospitalizations, PD-related hospitalizations, and special care requirements, including skilled nursing facility, nursing home, custodial, hospice, and inpatient psychiatric facility, for patients treated with L/C/E versus L/C based on two approaches: (1) all hospitalizations (number of inpatient visits or services), and (2) first hospitalization (censored observation at the first event). Univariate and multivariate (adjusted for age, gender, baseline L/C dosage, concurrent PD medications, health plan, and region) analyses were conducted.
Results: A total of 738 on L/C/E and 10,193 on L/C subjects were studied. The IRR for L/C/E relative to L/C of all hospitalizations was 0.73 (95% CI: 0.64–0.82, $P<0.001$). When considering only the first hospitalization event, L/C/E reduced the risk of hospitalization by 28% (IRR: 0.72, 95% CI: 0.62–0.84, $P<0.001$) compared to L/C. Similar findings were observed for PD-related hospitalizations (any events: IRR: 0.70, 95% CI: 0.56–0.87, $P=0.002$; first event: IRR: 0.76, 95% CI: 0.60–0.96, $P=0.023$) and special care requirements (any events: IRR: 0.56, 95% CI: 0.48–0.65, $P<0.001$; first event: IRR: 0.62, 95% CI: 0.48–0.81, $P<0.001$). After adjusting for confounders, L/C/E remained associated with statistically significant reduced risks of all hospitalizations and special care requirements compared to L/C.
Conclusion: This study based on a large cohort suggests that patients initiated with levodopa/carbidopa/entacapone have lower risks of hospitalizations and special care requirements than patients receiving levodopa/carbidopa.

187E. Estimating resource utilization in patients with suspected

immune-mediated coagulopathy associated with exposure to topical bovine thrombin: a novel approach.

M. Scot Maxon, Pharm.D.[1], Anthony B. Russell, Ph.D.[1], Karen Wisont, M.S.[1], Stephen Stemkowski, M.H.A., Ph.D.[2], Bernadette H. Johnson, B.S., M.B.A.[2], George M. Rodgers, M.D., Ph.D.[3]; (1)ZymoGenetics, Inc., Seattle, WA; (2)Premier, Inc., Charlotte, NC; (3)University of Utah Health Sciences Center, Salt Lake City, UT

Purpose: Exposure to topical bovine-derived thrombin has been associated with post-operative immune-mediated coagulopathy (IMC) in some patients. IMC may be associated with poor outcomes and clinical and financial burden. Characterization of the resource utilization and pharmacoeconomic impact of bovine thrombin-associated IMC may be useful to formulary decision makers and third party payers. The goal of this descriptive study was to develop a novel approach using administrative data to estimate economic burden and resource utilization in patients where IMC was suspected.

Methods: Data for bovine thrombin-exposed patients discharged between January 2005 and March 2009 were extracted from Premier's Perspective® database. Given the lack of a diagnostic code for IMC, suspected IMC cases were identified utilizing a clinical algorithm based on laboratory tests/consultations consistent with investigation of IMC. Criteria for identifying suspected IMC were: a coagulation test and a mixing study ordered in conjunction with either a thrombin time or Factor V activity assay or hematology/pathology consult during the index or subsequent hospitalization. The first observed use of bovine thrombin and suspected IMC in the study period was designated the index hospitalization. Length of stay (LOS), ICU LOS, total, and departmental costs/patient (2009 dollars) were calculated for the index hospitalization and any subsequent hospitalization with suspected coagulopathy.

Results: 475 of 561,963 patients exposed to bovine thrombin met the criteria for suspected IMC during their index hospitalization. The estimated median total (non-incremental) cost (range) associated with the index and subsequent hospitalizations was $44,002 ($1,385–$924,397), including costs in pharmacy $4,892 ($79–451,032), laboratory $4,287 ($221–250,718), and blood bank $2,046 ($14–264,943). Total hospital LOS [median (range)] was 15 days (1–204), with ICU LOS of 11 days (2–161).

Conclusion: Application of this algorithm to a large in-patient database provides a new method for identifying patients with suspected IMC and estimating total hospital costs associated with patient management.

Presented at The International Society of Pharmacoeconomics and Outcomes Research Annual Meeting, Atlanta, GA, May 15–19, 2010.

188. Health outcomes experienced by daptomycin treated patients with MRSA infections.

Debra A. Goff, Pharm.D., FCCP[1], Peggy S. McKinnon, Pharm.D.[2], *Amanda J. Boening, Pharm.D.*[2], Thomas P. Lodise, Pharm.D.[3]; (1)The Ohio State University Medical Center, Columbus, OH; (2)Cubist Pharmaceuticals, Lexington, MA; (3)Albany College of Pharmacy, Albany, NY

Purpose: MRSA is associated with high cost of care; hospital length of stay (LOS) is a key cost driver. Little is known about DAP outcomes such as time to response or antibiotic related-LOS (AR-LOS) in pts with MRSA infections.

Methods: MRSA patients were identified in CORE 2007–2009, a retrospective, multicenter, observational registry. Investigators assessed pt outcome (cured, improved, failed or non-evaluable) at the end of DAP therapy (efficacy population); non-evaluable pts were excluded. All pts were included in the safety analysis.

Results: 382 MRSA pts were identified: 55% male, 70% <65yo, 32% diabetic, 17% CrCL<30ml/min, of pts w/VAN MICs 29% were ≥2. Median DAP dose: 6 mg/kg for all infections. 84% had prior antibiotics (75% of prior treatment was VAN). Success occurred in 89.5% (342/382), overall and was 87% (first line DAP), 90% (second line DAP) and 85% in prior VAN failures. Time to response ranged from 3d (SKIN, BAC) to 5d (IE, OST); AR-LOS was 5d (SKIN), 9d (OST), 10d (BAC) & 14d (IE). 43/520 pts (8.3%) had AEs possibly related to DAP; discontinuation due to AE was 5.6% (29/520).

Health Outcomes	Clinical success rate (cure + improved), n (%)	Time to clinical response, days (med, IQR)
SKIN, n=137	129 (94.2)	3 (2–5), n=97
IE, n=37	30 (81.1)	5 (3–7), n=20
BACTEREMIA, n=113	103 (91.2)	3 (2–5), n=79
OSTEO, n=95	80 (84.2)	5 (3–14), n=55

Table (continued)

Health Outcomes	AR-LOS, days (med, IQR)	Total treatment duration, days* (med, IQR)
SKIN, n=137	5 (3–8)	9 (4–17)
IE, n=37	14 (6–22)	28 (8–43)
BACTEREMIA, n=113	10 (5–15)	14 (8–30)
OSTEO, n=95	9 (4–15)	37 (15–44)

*includes inpatient and outpatient days

Conclusions: LOS is a key cost driver. Time to response and AR-LOS are important outcomes in managing infection-related healthcare costs and provide meaningful information about real-world outcomes for DAP pts with various MRSA infections. Further studies are warranted to evaluate optimal resource utilization in MRSA pts.

Pharmacoepidemiology

189. Impact of generic substitution of lamotrigine in a state Medicaid population: a retrospective crossover cohort study.

Daniel Hartung, Pharm.D., M.P.H.[1], Leanne Svoboda, Pharm.D.[2], Luke Middleton, B.S.[1], Jessina C. McGregor, Ph.D.[3]; (1)Oregon State University, Portland, OR; (2)Oregon Health & Science University, Portland, OR; (3)Oregon State University/Oregon Health & Science University College of Pharmacy, Portland, OR

Purpose: The objective of this study was to evaluate the association between generic substitution of lamotrigine and adverse consequences in a diverse Medicaid population.

Methods: A retrospective crossover cohort design was employed using administrative Medicaid claims data from the state of Oregon between June 2006 and July 2009. Subjects were included in the cohort if they had converted from branded to generic lamotrigine, had sustained lamotrigine therapy for at least two years, and had three years of continuous Medicaid enrollment prior to conversion. Following generic conversion, the frequency of emergency department (ED) visits, hospitalizations, and indication-specific ED visits or hospitalizations (e.g. ED encounter for epilepsy) were compared to a randomly selected control period prior to the subject's generic conversion. Univariate and multivariate conditional logistic regression were used to quantify the association between generic conversion and health services utilization adjusting for current dose and concurrent therapy. Separate models were developed for subjects with and without epilepsy.

Results: Of the 516 unique subjects included in this analysis, epilepsy was the most common diagnosis (44%), followed by bipolar disorder (34%), pain (30%), and depression (18%). Conversion to generic lamotrigine was not associated with a statistically significant increase in the risk of an ED visit (adjusted OR [AOR]=1.23; 95% confidence interval [CI] 0.83–1.84; p=0.30), hospitalization (AOR=1.17; 95% CI 0.54–2.52; p=0.70), or indication-specific encounter (AOR 1.333; 95% CI 0.68–2.6; p=0.39). Associations were similar among patients with and without a diagnosis of epilepsy.

Conclusions: In contrast to previous studies conducted solely among epilepsy patients, we identified no significant increase in ED visits, hospitalizations, or indication-specific encounters following the switch from brand to generic lamotrigine. This study builds on previous research by including a broader population of lamotrigine users and employing a crossover cohort design to better control for severity of disease.

190. Comparing clinician opinion and proprietary database severity ratings for drug-drug interactions.

Pamela L. Smithburger, Pharm.D., Sandra L. Kane-Gill, Pharm.D., M.Sc., FCCM, FCCP, Neal J. Benedict, Pharm.D., Bonnie A.

Falcone, Pharm.D., BCPS, Amy L. Seybert, Pharm.D.; University of Pittsburgh School of Pharmacy, Pittsburgh, PA

Purpose: Clinical decision support software that alerts clinicians to the presence of drug-drug interactions has the potential to prevent medication-related errors. This software also has a major limitation; if the alert sensitivity is to too high then clinicians may receive numerous DDI alerts with low clinical significance leading to "alert fatigue". A tiered DDI alert system based on severity rankings has shown to be effective in reducing alert fatigue; however, the optimal method to assess severity has not been established. The purpose of this study is to compare the severity ranking of proprietary databases to clinician assessment for DDIs occurring in critically ill patients.
Methods: This prospective, observational study was conducted over an 8-week time period in the cardiothoracic and cardiac intensive care units (ICU). Patients' medication profiles were screened for the presence of DDIs. A severity evaluation was conducted using rankings from 2 proprietary databases and clinician opinion assisted by a published 4-item DDI severity assessment tool. The number and drug combinations of DDIs considered severe by both evaluation methods was compared.
Results: 400 patient medication profiles were evaluated and a total of 1150 DDIs were identified containing 458 were unique drug pairs. Based upon proprietary databases ratings, 7.4 % (34/458) were considered a severe interaction. The assessment by clinicians ranked 6.6% (30/458) of the unique DDIs as severe. Only 3 interactions, aspirin/warfarin, atazanavir/tenofovir, and atazanavir/simvastatin, were considered severe by both evaluation methods.
Conclusion: Due to the disagreement concerning severe DDIs between proprietary databases and clinician assessments, the development of a knowledgebase for a DDI alert system in critically ill patients likely requires proprietary database information in conjunction with clinical opinion.

191. Medication adherence in Medicaid patients with dyslipidemia.
Michael W. Daly, Pharm.D.[1], Terry Seaton, Pharm.D.[1], Nathan Moore, B.S.[2], Frances Wang, B.S.[2], Adam Ralko, M.D.[2], Thomas Bailey, M.D.[2]; (1)St. Louis College of Pharmacy, St. Louis, MO; (2)Washington University, St. Louis, MO

Purpose: To evaluate the use of an adapted version of the Modified Morisky Adherence Scale (MMAS) as a screening tool for identifying patients who have been nonadherent with statin medications in Medicaid patients.
Methods: We conducted a cross-sectional study using a convenience sample of 76 medicine clinic patients. Eligible patients were 18 years or older who had received a statin within the previous 3 months. We surveyed them with an adapted 8-item MMAS during a face-to-face interview while waiting for a scheduled apointment. Claims data were used to calculate each patient's medication possession ratio (MPR) and nonadherence was defined as a value of less than 0.8. MMAS adherence was categorized as high, medium, and low (for scores of 8, 6 to <8, and <6, respectively).
Results: Overall, patients were categorized as having low (26%), medium (35%) and high (39%) medication adherence according to the MMAS. Of the 50 patients who were adherent by the MPR, 86% were categorized as medium or high by the MMAS (p=0.002). Correlation between the MMAS and the MPR was fair (r=0.48, p<0.001) and the internal consistency reliability was moderate (alpha=0.64). Of the 26 patients who were nonadherent by MPR, only 4 (15%) had an MMAS=8. In contrast, of the 50 patients who were adherent by MPR, 26 (52%) had an MMAS=8 (p=0.002). While the positive predictive value of a MMAS score of 8 for adherence by MPR was 87%, the positive predictive value for non-adherence for a MMAS score less than 8 was 48%, with a sensitivity of 85%.
Conclusions: An adapted MMAS is significantly correlated with statin drug refill adherence for Medicaid patients. Although further validation of the MMAS is needed in this population, it may be a useful tool for identifying patients who are nonadherent with statins.

Pharmacogenomics/Pharmacogenetics

192. Genetic Predictors of Valproic Acid Response in Patients with Bipolar Disorder.
Kelly C. Lee, Pharm.D., BCPP[1], Tanya Shekhtman, B.S.[2], Rebecca McKinney, B.S.[2], John R. Kelsoe, M.D.[2]; (1)University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla, CA; (2)University of California, San Diego Department of Psychiatry, La Jolla, CA

Purpose: Bipolar disorder is a chronic, debilitating psychiatric disorder with significant clinical, social and economic implications. There is currently lack of literature to indicate which genetic and clinical factors may predict good response to a specific mood stabilizer.
Methods: A retrospective sample of 181 subjects who received valproic acid (VPA) was identified from a large genetic linkage study for bipolar disorder. Each subject was assessed for lifetime VPA response using lifechart method, patient subjective ratings, and medical records. Thirteen single-nucleotide polymorphisms (SNPs) of six genes (PDE11A, NTRK2, GK3B, IMPA1, GNB3 and GRK3) were genotyped using Taq-man assays. The genes were selected based upon previous lithium pharmacogenomic studies. The following clinical predictors were also compared based upon VPA response: dysphoric mania, mixed mania, BP I vs BP II, rapid cycling, suicide attempts, PTSD, panic attacks, panic disorder, alcohol and substance abuse. The specific aims of this study were to 1) to test whether gene variants that influence lithium also influence response to valproic acid and 2) identify clinical and biological predictors of drug response.
Results: Out of 850 medication trials, 181 unique subjects who received VPA were identified. Thirteen subjects were excluded due to poor quality of DNA. Due to concern for heterogeneity of sample, 28 non-Caucasians were excluded. Therefore, 75 subjects had good response to VPA and 65 subjects had poor response to VPA. The 13 selected SNPs were not found to be significantly associated with response to VPA. The clinical predictors that were selected based upon previous lithium studies were also not associated with response to VPA.
Conclusion: Genetic and clinical factors that have been previously associated with response to lithium do not appear to predict response to VPA. Limitations include small number of SNPs as well as small sample size.

193. A Survey of Public Attitudes towards Pharmacogenetic Testing.
Susanne B. Haga, Ph.D.[1], Julianne O'Daniel, M.S.[1], Genevieve M. Tindall, B.A.[1], Robert Agans, Ph.D.[2]; (1)Institute for Genome Sciences & Policy, Duke University, Durham, NC; (2)Survey Research Unit, University of North Carolina, Chapel Hill, NC

Purpose: Pharmacogenetic (PGx) testing is considered one of the most promising clinical applications resulting from genomics research, with the potential to reduce adverse drug responses and improve drug efficacy. However, despite its potential to improve health outcomes, knowledge regarding public attitudes towards PGx testing is limited in the U.S.
Methods: To address this gap, we conducted an anonymous, random-digit-dial phone survey of the U.S. public, achieving an overall response rate of 42% (n=1139).
Results: Respondents were predominantly female (61%), White (84%), and 55 years and older (51%). Nearly 78% of respondents had heard of genetic testing in general, although respondents ages 55+ were less likely to be aware of genetic testing (vs. ages 18-34). Most respondents were 'not very' or 'not at all' likely to have a PGx test if there was a chance their DNA sample (79%) or test result (78%) could be shared without their permission. However, the potential risks did not appear to affect respondents' overall interest as 65% indicated they would be 'extremely' or 'somewhat likely' to have a PGx test. The majority of respondents expressed interest in PGx testing to predict mild or serious side effects (71% and 84%, respectively), guide dosing (91%) and assist with drug selection (92%). Younger individuals (ages 18-34) were more likely to be interested in PGx testing to predict serious side effects (vs. ages 55+) as well as Whites, those with a college degree, and those who had experienced side effects.
Conclusion: We found public interest in PGx testing to be high, in particular regarding its ability to predict serious side effects,

particularly from respondents who had experienced side effects. Lower interest from non-White and less educated groups confirms prior studies on disease-related genetic testing, suggesting the need for targeted education and engagement of the broader public.

194. Comparison of warfarin pharmacogenetic dosing algorithms.
Diana X. Cao, Pharm.D., Jaekyu Shin, Pharm.D.; University of California, San Francisco, San Francisco, CA

Background: *CYP2C9* and *VKORC1* polymorphisms significantly impact inter-patient variability in warfarin dose requirements. In addition, warfarin pharmacogenetic tests approved by the Food and Drug Administration (FDA) are available for clinical use. Although multiple warfarin pharmacogenetic dosing algorithms have been described in the literature, direct comparisons of their performance are limited.
Purpose: To compare the performance of available warfarin pharmacogenetic dosing algorithms.
Methods: Warfarin pharmacogenetic dosing algorithms suitable for using FDA-approved test results were identified using the PubMed database. Patient information from the International Warfarin Pharmacogenetics Consortium (IWPC) database, including genetic- and non-genetic variables, was used to predict stable weekly dose according to each algorithm. The performance of algorithms was compared for percentage of patients whose predicted warfarin dose falls within 20% of actual dose (primary endpoint) and absolute error (secondary endpoint). The performance of algorithms was also compared by race and dose range.
Results: 21 algorithms were eligible for our study. 1952 patients had complete genetic and non-genetic variables available: mean age 64 ± 14.5 years, 60% male, 63% Caucasian, 20% Asian, and 16% African American. Most algorithms demonstrated similar performance in predicting stable weekly warfarin dose. The algorithm that performed best was www.warfarindosing.org, with 51 percent of patients having a predicted warfarin dose within 20% of actual dose. African American population had higher absolute error when compared with other races; however, the same trend was not observed in the primary endpoint. In general, the predictive value of algorithms was higher in the low (≤ 21 mg/wk) and medium dose (> 21 mg/wk to 49 mg/wk) group compared to the high dose (≥ 49 mg/wk) group.
Conclusion: Overall, published warfarin pharmacogenetic dosing algorithms had similar performance in predicting stable warfarin dose.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

195. A comparison of tacrolimus pharmacokinetics in Hispanic vs non-Hispanic pediatric renal transplant patients.
Myrna Y. Munar, Pharm.D.[1], Ganesh Cherala, Ph.D.[1], Amira Al-Uzri, M.D.[2]; (1)*Department of Pharmacy Practice, Oregon State University / Oregon Health & Science University College of Pharmacy, Portland, OR; (2)Department of Pediatrics, Division of Pediatric Kidney Services and Hypertension, Oregon Health & Science University, Portland, OR

Purpose: Limited data reported in the literature shows that age and ethnicity play a role in P-gp, CYP3A4 and CYP3A5 polymorphisms that may affect tacrolimus pharmacokinetics (PK). The purpose of this study was to compare tacrolimus PK in Hispanic vs non-Hispanic pediatric transplant patients.
Methods: Fourteen pediatric renal transplant patients receiving chronic tacrolimus immunosuppressive therapy were studied. Serial blood samples were obtained at 0, 1, 2, 4, and 6 hours following an oral tacrolimus dose. Plasma tacrolimus concentration-time data were analyzed by noncompartmental methods (WinNonLin 5.2, Pharsight Inc., Mountain View, CA). Data between Hispanic vs non-Hispanic patients were compared using the Student's *t*-test. Pearson-Product Correlations (R) were used to determine the relationship between demographic and laboratory data and tacrolimus PK parameters. Statistical significance was defined at *P*<0.05 (SigmaPlot 11, Systat Software Inc., San Jose, CA).
Results: Data were normally distributed. Age (12.4 ± 1.4 vs 12.9 ± 4.2 years), weight (50.3 ± 11.0 vs 46.8 ± 19.1 kg), and serum creatinine

(1.2 ± 0.4 vs 1.0 ± 0.5 mg/dL) were not significantly different between Hispanic (n = 4; 2 females, 2 males) vs non-Hispanic (n = 10; 3 females, 7 males) patients, respectively. When standardized to dose, both the average C_{max} (4.9 ± 2.4 vs 6.4 ± 4.0 ng/mL/mg) and $AUC_{0-\infty}$ (32.54 ± 11.50 vs 56.56 ± 32.17 ng/mL×hr/mg) were lower in Hispanic vs non-Hispanic patients. V_D was higher in Hispanic vs non-Hispanic patients (193464 ± 88665 vs 169852 ± 111904 mL). Oral tacrolimus clearance was faster in Hispanic vs non-Hispanic patients (34622.9 ± 10851.2 vs 25135.5 ± 14658.8 mL/hr), resulting in a shorter half-life (3.9 ± 1.5 vs 7.9 ± 12.7 hrs) which correlated with eGFR ($R^2 = 0.8976$, *P*<0.05).
Conclusion: Our data suggests a need for frequent (tid vs bid) dosing of tacrolimus in Hispanic pediatric renal transplant patients.

196. Pharmacokinetics of mycophenolate and its glucuronidated metabolites in stable renal transplant recipients on a steroid-free regimen.
Eric Poulin, B.Sc.(Pharm)[1], Erica D. Greanya, B.Sc.(Pharm), Pharm.D., ACPR[1], Nilufar Partovi, B.Sc.(Pharm), Pharm.D.[2], R.Jean Shapiro, M.D., FRCPC[3], Mai Al-khatib, B.Sc.(Pharm), M.Sc.(Pharm)[4], *Mary HH Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS*[5]; (1)Vancouver General Hospital, Vancouver, BC, Canada; (2)University of British Columbia and Vancouver General Hospital, Vancouver, BC, Canada; (3)University of British Columbia, Vancouver General Hospital, Vancouver; (4)University of British Columbia, Vancouver, BC, Canada; (5)University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

Purpose: The purpose of this study was to characterize the pharmacokinetics of mycophenolic acid (MPA) and its glucuronidated metabolites, MPAG (phenolic-glucuronide) and AcMPAG (acyl-glucuronide), in stable renal transplant recipients on a tacrolimus-based steroid-free regimen.
Methods: Twenty-eight subjects enrolled into this open-label study following written informed consent. Upon administration of a steady-state morning mycophenolate mofetil (MMF) dose, blood samples were collected at 0, 0.5, 1, 2, 4, 6, 8, 10, and 12 hours post-dose. MPA, MPAG, and AcMPAG concentrations were measured by validated high-performance liquid chromatography (HPLC) with ultraviolet detection and pharmacokinetic parameters were analyzed by conventional non-compartmental modeling.
Results: (Data are in mean ± SD). Subjects included 17 females and 11 males who were 2.5 ± 1.9 years post-transplant. Age was 47.4 ± 12.5 years and weight 70.4 ± 15.9 kg. Serum albumin concentration was 4.3 ± 0.4 g/dL, serum creatinine was 1.2 ± 0.3 mg/dL, and eGRF was 60.8 ± 15.4 mL/min. Daily MMF dosage was 1321.4 ± 508.5 mg. Pharmacokinetic parameters for MPA were: area-under-the-curve [$AUC_{(0-12h)}$] 31.46 ± 11.48 μg*hr/mL; dose-normalized (to 1 g) $AUC_{(0-12h)}$ 26.91 ± 13.20 μg*hr/mL/g; maximal concentration (C_{max}) 10.56 ± 5.39 μg/mL/g; time to C_{max} (t_{max}) 0.88 ± 0.60 h; minimum concentration (Cmin) 0.88 ± 0.50 μg/mL/g; and MPA free fraction $1.76 \pm 0.65\%$. AUC ratios of MPAG:MPA and AcMPAG:MPA were 12.97 ± 5.77 and 0.14 ± 0.24, respectively. When stratified according to time post-transplant, patients within the first year had lower exposure [dose-normalized $AUC_{(0-12h)}$ 18.6 ± 5.4 μg*hr/mL/g] compared with patients greater than one year post-transplant [dose-normalized $AUC_{(0-12h)}$ 30.3 ± 13.9 μg*hr/mL/g].
Conclusion: To our knowledge, this is the first study to determine the pharmacokinetics of MPA and two of its glucuronidated metabolites in renal transplant recipients on steroid-free regimens. Similar to steroid-based renal transplant populations, wide interpatient variability in MPA, MPAG, and AcMPAG pharmacokinetic parameters was observed in this population. Likewise, MPA exposure increased with time post-transplant. Thus, time post-transplant is a critical factor in designing future studies that evaluate the impact of steroids on MPA disposition.

197. Evaluation of a revised vancomycin dosing strategy to meet new guideline recommendations.
Tina H. Denetclaw, Pharm.D., BCPS[1], Bogdan H. Wapniarski, Pharm.D.[2], Douglas T. Steinke, Ph.D.[3]; (1)University of California at San Francisco School of Pharmacy, San Francisco, CA; (2)Marin General Hospital, Greenbrae, CA; (3)UKHealthCare, Lexington, KY

Purpose: To evaluate a revised vancomycin dosing strategy in attaining target trough levels within 24 hours of initiation, while avoiding overshooting target range and any measured trough <10 mg/mL.

Methods: Two hundred fifty-six patients were dosed per vancomycin pharmacy protocol with 1st tough level drawn just before the 3rd dose; 151 patients were dosed with the revised protocol; 105 patients were dosed with the traditional protocol. Data were collected from protocol monitoring sheets from November 2008 through January 2010 as a retrospective medical record review..

Results: Patient characteristics were similar in both groups, however, women were more likely to be dosed with the revised protocol (p=0.001). Patients dosed with the revised protocol were 15 times more likely to have 1st trough levels within the target range (odds ratio [OR]=15.09). This advantage held, regardless of gender (p<0.001). Patients dosed with the old protocol were 8 times more likely to have 1st trough levels <10 mg/mL (OR=7.83). Forty-six percent of revised protocol patients with 1st trough level below target range also had serum creatinine (SCr) <1 mg/dL. Most (83%) of these cases would have attained target range if the actual SCr had been used to estimate creatinine clearance (CrCl), rather than rounding to 1. Remaining patients dosed with revised protocol and 1st trough level below target range exhibited improving renal function, or already received every six-hour dosing, and dose adjustments were made in response.

Conclusion: The revised vancomycin dosing strategy reliably attains measured trough levels in the target range within 24 hours of initial dosing. It avoids any measured trough <10 mg/mL, as long as actual SCr is used to calculate estimated CrCl. It allows patients with rapid renal function improvement to be reassessed and adjusted based on measured levels within 12-to-24 hours of initiation.

198. Cyclophosphamide pharmacokinetics in glomerulonephritis.
Melanie S. Joy, Pharm.D., Ph.D.[1], Mary La, B.S., (in, progress)[2], Jinzhao Wang, B.S.[2], Arlene S. Bridges, Ph.D.[2], Yichun Hu, M.S.[2], Susan L. Hogan, MPH, Ph.D.[2], Reginald F. Frye, Pharm.D., Ph.D.[3], Joyce A. Blaisdell, B.S.[4], Joyce A. Goldstein, Ph.D.[4], Mary Anne Dooley, M.D., MPH[2], Kim L.R. Brouwer, Pharm.D., Ph.D.[5], Ronald J. Falk, M.D.[2]; (1)University of North Carolina, Schools of Medicine and Pharmacy, Chapel Hill, NC; (2)University of North Carolina, School of Medicine, Chapel Hill, NC; (3)College of Pharmacy and Center for Pharmacogenomics, University of Florida, Gainesville, FL; (4)NIH NIEHS, Research Triangle Park, NC; (5)University of North Carolina, School of Pharmacy, Chapel Hill, NC

Purpose: Cyclophosphamide is used to treat active glomerulonephritis despite limited pharmacokinetics data. The primary objective for this research was to characterize the pharmacokinetics of cyclophosphamide and 4-hydroxycyclophosphamide in patients with glomerulonephritis. Secondary objectives were to evaluate relationships between pharmacokinetics and laboratory values, race, gender, and variants in cytochrome P450 (*CYP2B6, CYP2C9, CYP3A4*) and multidrug-resistance transporter (*ABCB1/MDR1*).

Methods: Glomerulonephritis patients (n=23) prescribed intravenous cyclophosphamide consented to a cyclophosphamide/4-hydroxy-cyclophosphamide pharmacokinetics study. Blood was collected predose, and 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 18, and 24 hours after a dose and analyzed by LC/MS. Analyses included noncompart-mental pharmacokinetics (WinNonlin®) and parametric/non-parametric statistical analyses.

Results: Pharmacokinetic parameters for cyclophosphamide and 4-hydroxycyclophosphamide are shown in the Table (mean ± SD).

Cyclophosphamide			
Lambda (hr-1)	0.13 ± 0.06	0.13 ± 0.05	0.13 ± 0.06
T_{max} (hr)	1.7 ± 1.3	1.4 ± 0.9	1.8 ± 1.4
C_{max} (ng/mL)[a]	7793 ± 5268	8231 ± 3835	7601 ± 5890
V_z (L/70kg)	102 ± 33	97 ± 33	104 ± 35
V_{ss} (L/70kg)	111 ± 31	109 ± 39	112 ± 28
Cl (L/hr/70kg)	12.0 ± 4.7	12.7 ± 6.1	11.7 ± 4.1
$AUC_{0-\infty}$ (ng hr/mL)[a]	74000 ± 26100	77800 ± 34100	72300 ± 23000
MRT (hr)	10.2 ± 4.3	9.3 ± 3.2	10.6 ± 4.8

4-Hydroxycyclophosphamide

Lambda (hr-1)	0.13 ± 0.11	0.10 ± 0.02	0.14 ± 0.13
T_{max} (hr)	2.1 ± 2.5	3.3 ± 4.0	1.5 ± 1.3
C_{max} (ng/mL)	296 ± 137	271 ± 116	307 ± 148
$AUC_{0-\infty}$ (ng hr/mL)	3553 ± 1967	3260 ± 1209	3682 ± 2243
MRT (hr)	13.7 ± 6.9	11.6 ± 1.4	14.6 ± 8.1
Metabolic Ratio %	5.6 ± 3.7	5.2 ± 3.6	5.7 ± 3.9

[a]normalized to 1 g dose

Significant covariate relationships with cyclophosphamide included; decreased serum albumin and increased lambda, increased UP:Cr and increased $AUC_{0-\infty}$, increased C_{max}, and decreased plasma clearance. For 4-hydroxycyclophosphamide, significant relationships included increased serum albumin and increased half-life and $AUC_{0-\infty}$. Regarding pharmacogenomics; 1)*CYP2B6*(*G516T*) variants had decreased lambda, increased Vd, and decreased cyclophosphamide C_{max}, 2)*CYP3A4*(*A-392C*) variants had decreased cyclophosphamide lambda, and 3)*ABCB1/MDR1*(*C3435T*) variants had decreased cyclophosphamide lambda.

Conclusions: Glomerular disease severity (defined by serum albumin and urinary protein excretion) and genetic variants in *CYP2B6*, *CYP3A4*, and *ABCB1/MDR1* alter the pharmacokinetics of cyclophosphamide and 4-hydroxycyclophosphamide. This research serves as data toward individualizing cyclophosphamide therapy in glomerulonephritis.

199. Concentration dependent protein binding of tigecycline in adult diabetic patients.
Catharine C. Bulik, Pharm.D., Dora E. Wiskirchen, Pharm.D., Christina A. Sutherland, B.S., Joseph L. Kuti, Pharm.D., David P. Nicolau, Pharm.D., FCCP, FIDSA; Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, CT

Purpose: It is generally agreed that only the unbound fraction (F_u) of an antibiotic is available for activity. Previous human studies have reported tigecycline F_u ranging between 53-64%, while a study by our group demonstrated that tigecycline F_u was dose dependent over a range of concentrations in a murine thigh infection model. Currently, *in vivo* data are lacking concerning the protein binding (PB) of tigecycline over time and over changing concentrations in the same patient.

Methods: Eight adult diabetic (DM) patients enrolled in a tissue penetration study were administered tigecycline 100mg followed by 50mg IV twice daily for 3–5 doses. Plasma samples for PB studies were collected in each patient at 1, 6 and 12h after the last dose and centrifuged prior to plasma separation. PB studies were conducted in triplicate using ultrafiltration devices with 30,000 molecular weight cutoff filters. Samples were stored at -80°C until tigecycline concentrations were determined using HPLC in both the plasma and ultrafiltrate samples. Regression analyses were employed to fit the F_u over the concentration range.

Results: Tigecycline F_u increased with decreasing plasma concentrations in each patient. Mean ± SD F_u was 35.6 ± 8.22%, 80.3 ± 23.05%, and 100 ± 34.5% at time 1, 6, and 12h, respectively. These percentages correspond to mean plasma concentration of 0.61, 0.14, and 0.10μg/ml, respectively. F_u versus concentration fit the following polynomial with r^2=0.783:

$y=y_0+a/x+b/x^2+c/x^3$ where y=% unbound, y_0=9.0896, a=15.339, b=-0.999, c=0.0232, and x=plasma concentration.

Conclusion: These observations are in agreement with the previous murine work by our group demonstrating an increase in tigecycline F_u concentrations. This is the first study to describe this PB alteration *in vivo* in patients. These data may be used to correct for Fu over a concentration-time profile. The clinical significance of this finding is unknown but may help to explain some of the agent's lesser known pharmacokinetic and pharmacodynamic characteristics.

200. Evaluation of Renal Function Estimation Methods to Predict Vancomycin Clearance.
Thomas C. Dowling, Pharm.D, Ph.D[1], Steven L. Allison, Pharm.D.[2]; (1)University of Maryland, School of Pharmacy, Baltimore, MD; (2)Pitt County Memorial Hospital, Greenville, NC

Purpose: Renal function estimation is a critical aspect of

individualized regimen design for vancomycin. Vancomycin clearance is most frequently estimated a priori using creatinine clearance algorithms. The ability of newer equations that estimate glomerular filtration rate (GFR), such as the Modification of Diet in Renal Disease (MDRD4), to predict vancomycin clearance in population pharmacokinetic models is unknown.

Methods: Patients receiving vancomycin in a general medicine ward with stable renal function were evaluated. Vancomycin serum drug concentrations (SDC) were analyzed using individualized Bayesian adaptive control as implemented in the MM-USC*PACK software. Creatinine clearance was estimated using the Cockcroft-Gault (CG) equation with ideal body weight (IBW) or actual body weight (ABW), and GFR was estimated using the MDRD4 equation. All serum creatinine values were analyzed by IDMS calibration.

Results: A total of 109 serum creatinine concentrations and 47 SDC were analyzed from 20 patients receiving vancomycin. The CG-IBW, CG-ABW and MDRD values were 52 ± 27 mL/min, 75 ± 35 mL/min and 70 ± 38 mL/min, respectively. A priori vancomycin clearance estimates by MDRD were 34.7% higher than CG-IBW (95%CI: 1.28-1.42) and 8.4% lower than CG-ABW (95%CI: 0.88-0.95). The CG-ABW had the highest correlation with fitted vancomycin clearance compared to CG-IBW and MDRD.

Conclusion: Significant differences in vancomycin prediction and modeled clearance exist among creatinine clearance and GFR estimation approaches. Use of creatinine clearance estimated by CG-ABW provided the best prediction of vancomycin clearance obtained by an individualized Bayesian model.

Psychiatry

201E. Efficacy and safety of lisdexamfetamine dimesylate in adults with attention-deficit/hyperactivity disorder in the simulated adult workplace environment.

Timothy Wigal, Ph.D.[1], Joseph Gao, Ph.D.[2], Maria Gasior, M.D.[2], John Giblin, M.D.[3], *Steve Valliere, Pharm.D.*[2], Matthew Brams, M.D.[4]; (1)University of California, Irvine Child Development Center, Irvine, CA; (2)Shire Development Inc., Wayne, PA; (3)Clinical Study Centers, LLC, Little Rock, AR; (4)Bayou City Research, Houston, TX

Purpose: Safety and efficacy of lisdexamfetamine dimesylate (LDX), a long-acting prodrug stimulant, indicated for attention-deficit/hyperactivity disorder (ADHD) in children (6–12 years) and adults were evaluated in adults with ADHD using a simulated adult workplace environment (AWE).

Methods: Subjects (18–55 years) entered a 4-week open-label dose-optimization phase (LDX 30–70 mg/d) and were then randomized to a 2-week, double-blind, placebo-controlled crossover phase. Efficacy assessments included the Permanent Product Measure of Performance (PERMP) total score (attempted + correct) measured predose and 2, 4, 8, 10, 12, and 14 hours postdose, averaged across postdose sessions (primary) and at each time point vs placebo (secondary). PERMP is a validated, time-sensitive, skill-adjusted math test that evaluates ability to attend, initiate, and complete written seatwork. The ADHD Rating Scale IV (ADHD-RS-IV) with adult prompts was administered at baseline and in both phases. Safety assessments included treatment-emergent adverse events (TEAEs), vital signs, and electrocardiogram.

Results: A total of 127 subjects were randomized (105 in the intention-to-treat cohort; 103 completed the study). Least squares (LS) mean (SE) PERMP total scores per session were higher for subjects on LDX vs placebo when averaged across postdose sessions (312.9 [8.59] vs 289.5 [8.59]; *P*<0.0001) and at all time points from 2 to 14 hours postdose (*P*≤0.0017 for each). During the crossover phase, ADHD-RS-IV mean (SD) scores were 18.2 (9.52) for LDX vs 29.6 (10.14) for placebo; LS mean difference (LDX-placebo) (95% CI) was -11.5 (-14.2, -8.9) (*P*<0.0001). TEAEs (>10%) during dose-optimization were decreased appetite, dry mouth, headache, and insomnia. No TEAEs >10% were reported during the crossover phase with LDX.

Conclusion: In adults with ADHD, LDX improved and maintained math test performance in the simulated AWE from 2 hours to 14 hours postdose vs placebo. LDX demonstrated a safety profile consistent with long-acting stimulant use.

Presented at 2009 New Clinical Drug Evaluation Unit (NCDEU) Meeting, Hollywood, Florida, June 29–July 2, 2009

Pulmonary

202E. Omalizumab may normalize IgE production rate in patients with moderate-to-severe atopic asthma.

Philip Lowe, Ph.D.[1], Stacey Tannenbaum, Ph.D.[2], Aurelie Gautier, M.A.[1], *Marc Massanari, Pharm.D.*[2]; (1)Novartis Pharma AG, Basel, Switzerland; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ

Purpose: Long-term anti-IgE therapy may attenuate the excess IgE expression observed in atopic individuals.

Methods: We investigated and quantified the timescale over which IgE production could be normalized using a direct-binding model incorporating both dissociation constants and kinetic parameters for omalizumab, IgE and omalizumab-IgE complexes. This was written into a nonlinear mixed effect PK/PD model accounting for inter- and intra-patient variability. Input data were total serum omalizumab (sum of free and complex), free and total IgE from 1682 individuals with allergic asthma or rhinitis in four clinical studies of omalizumab. Two versions of the model were fitted: one with constant parameters; the other where IgE production rate could change over time. Normal IgE production was defined as 264 μg/day.

Results: Each model allowed relatively precise parameter estimation (maximum residual error, 25% coefficient of variation [CV]). The time-changing IgE production model gave a highly significant 2067-point decrease in log-likelihood objective function versus the constant IgE expression version. The estimated mean initial IgE production rate was 1840 μg/day (inter-patient CV, 29%). In control patients, IgE production appears to increase slowly at an average rate of 3.6% per year. IgE production rate decreased in omalizumab-treated patients and was projected to stabilize, ultimately, at 132 μg/day (168% CV). The apparent half-life of this change was 1.6 years (80% CV) providing a testable hypothesis that atopic patients may achieve normal IgE expression after 3-4 half-lives.

Conclusion: PK/PD models based on total and free IgE data suggest that, over the long term, omalizumab reduces IgE production towards normal (non-atopic) rates.

Published in PJ Lowe, S Tannenbaum, A Gautier, M Massanari, Z Panahloo. Omalizumab (Xolair) may normalize IgE production rate in patients with moderate-to-severe atopic asthma. J Allergy Clin Immunol. 2009;123(2 Suppl.):S152.

Rheumatology

203E. Gout Subjects With Hyperuricemia and Renal Impairment Treated With Febuxostat or Allopurinol for 6 Months.

Andrew Whelton, M.D.[1], Michael A. Becker, M.D.[2], Patricia MacDonald, NP[3], Barbara J. Hunt, M.S.[3], Robert L. Jackson, M.D.[3]; (1)UCRC Inc. & Johns Hopkins University School of Medicine, Hunt Valley, MD; (2)University of Chicago, Pritzker School of Medicine, Chicago, IL; (3)Takeda Global Research & Development Center, Inc., Deerfield, IL

Purpose: To compare urate-lowering efficacy and safety of febuxostat (FEB) and allopurinol (ALLO) in subjects with hyperuricemia and gout who have normal or impaired renal function.

Methods: Subjects received FEB (40 or 80 mg) or ALLO (200/300 mg, based on estimated creatinine clearance [eCLcr]; Table). Efficacy endpoints included proportion of subjects (N=2,269) with final serum urate level (sUA) <6.0 mg/dL and mild/moderate renal impairment subjects with final sUA <6.0 mg/dL. Safety was evaluated based on baseline renal status.

Results: In the FEB 40 mg, ALLO, and FEB 80 mg groups, respectively, 45%, 42%, and 67% of subjects achieved target sUA. More mild/moderate subjects with renal impairment achieved target sUA in the FEB 80 mg group compared to FEB 40 mg or ALLO. However, FEB 40 mg showed greater efficacy than ALLO (p=0.021). AE rates were similar regardless of renal function and across treatment groups. The most frequently reported AEs were URIs, liver function test analyses, and diarrhea. Five deaths occurred: 1 in each FEB group and 3 in the ALLO group.

Conclusion: With overall lowering of sUA to <6.0 mg/dL, FEB 80 mg is superior to FEB 40 mg and ALLO 200/300 mg, with FEB 40 mg

similar to ALLO 200/300 mg. In subjects with mild/moderate renal impairment, both FEB doses are significantly more effective than ALLO. In addition, FEB dosing does not require adjustment in mild/moderate renal impairment. Safety was similar for FEB and ALLO.

Subjects With Final sUA <6.0 mg/dL by Treatment and Renal Function

	FEB 40 mg, N (%)	FEB 80 mg[a], N (%)	ALLO 200/300 mg, N (%)
Renal Function (eCLcr)			
Normal (≥90 mL/min)	278 (37)	253 (58)	254 (42)
Mild Impairment (60–89 mL/min)	349 (52)	367 (72)	365 (46)
Moderate Impairment (30–59 mL/min)	130 (43)	136 (71)	136 (32)[b]

[a]p<0.001 vs FEB 40 mg and/or ALLO.
[b]*Moderate renally impaired subjects received 200 mg ALLO.*
Presented at ASN Renal Week 2009

204. Multiple-dose colchicine administration, as prescribed for prophylactic treatment of gout, has no effect on single-dose theophylline plasma concentrations in healthy volunteers.
Matthew Davis, M.D., RPh[1], Suman Wason, M.D., M.B.A.[1], Jennifer DiGiacinto, Pharm.D.[2]; (1)URL Pharma, Inc., Philadelphia, PA; (2)Salamandra, LLC, Bethesda, MD

Purpose: Colchicine downregulates CYP1A2 activity *in vitro*. This phase 1 drug-drug interaction study was conducted to assess risk for clinically significant interactions following coadministration of colchicine and theophylline, the *in vivo* CYP1A2 substrate probe recommended by the FDA.
Methods: Healthy adult volunteers (30 enrolled, 27 completed) received 300mg theophylline on Day 1, 0.6 mg colchicine at 12-hour intervals on Days 5–18, and theophylline plus colchicine on Day 19, with an additional colchicine dose 12 hours later. Blood samples for pharmacokinetics analysis were collected before dosing and 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0, 16.0, 24.0, 36.0, and 48.0 hours postdose on Days 1 and 19.
Results: Twenty-two (73%) volunteers experienced a total of 70 adverse events (AEs); all were mild to moderate in severity. Approximately 26% of all AEs were reported by volunteers following theophylline, ~59% following colchicine, and ~16% following theophylline and colchicine coadministration. There were 3 discontinuations because of AEs (diarrhea n=2; vomiting n=1). The most common AEs with treatment were gastrointestinal symptoms, headache, and dizziness.
Table. Geometric Means, Ratio-of-Means, and 90% Confidence Intervals: Natural Logarithm-Transformed Data

	Colchicine + theophylline	Theophylline	% Ratio (90% CI)
AUC_{0-t} (μg·hr/mL)	115.5	114.7	100.7 (96.3, 105.3)
$AUC_{0-\infty}$ (μg·hr/mL)	122.8	120.7	101.7 (97.2, 106.4)
C_{max} (μg/mL)	9.6	9.5	101.1 (97.7, 104.6)

Confidence intervals (CIs) around the ratios of the means for maximal concentration (Cmax), area under the curve from time zero to time of measurement (AUC0–t), and AUC from time zero to infinity (AUC0–∞) were within the prespecified range (80–125%), indicating there was no statistically significant drug-drug interaction between colchicine and theophylline.
Conclusions: These pharmacokinetic and safety analyses indicate no drug interaction is present; therefore, no dose modification is required for coadministration of colchicine and theophylline. These data from healthy volunteers should prove applicable to the patient with gout.

Transplant/Immunology

205. Development and validation of limited sampling strategies for tacrolimus and mycophenolate in steroid-free renal transplant regimens.
Eric Poulin, B.Sc.(Pharm)[1], Erica D. Greanya, B.Sc.(Pharm), Pharm.D., ACPR[1], Nilufar Partovi, B.Sc.(Pharm), Pharm.D.[2], R. Jean Shapiro, M.D., FRCPC[3], Mai Al-khatib, B.Sc.(Pharm), M.Sc.(Pharm)[4], *Mary H.H. Ensom, Pharm.D., FASHP, FCCP, FCSHP,*

FCAHS[5]; (1)Vancouver General Hospital, Vancouver, BC, Canada; (2)University of British Columbia and Vancouver General Hospital, Vancouver, BC, Canada; (3)University of British Columbia, Vancouver General Hospital, Vancouver, BC, Canada; (4)University of British Columbia, Vancouver, BC, Canada; (5)University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

Purpose: (1)Develop and validate limited sampling strategies (LSSs) for tacrolimus (TAC) and mycophenolic acid (MPA) in a renal transplant population not receiving corticosteroids; (2)Evaluate predictive performance of published LSSs (for steroid-based regimens) in our renal transplant population.
Methods: Following written informed consent and upon administration of steady-state morning TAC and mycophenolate mofetil doses, blood samples were collected at 0, 0.5, 1, 2, 4, 6, 8, 10, and 12 h from 28 stable renal transplant recipients; concentrations were measured by validated high-performance liquid chromatography methods and area-under-the-curve (AUC) by trapezoidal rule. TAC LSSs were developed and validated via multiple regression analysis (MRA) using the 2-group method (index n=18;validation n=10) and MPA LSSs using the jackknife method (n=28). Potential LSSs were restricted to ones having $r^2{\geq}0.80$ and ≤3 time points within 4h post-dose. Derived equations were validated for predictive performance, with preset criteria for bias and precision of within ± 15%. Other TAC and MPA LSSs [including the one commonly used in practice (Pawinski,2002)] were tested using our data.
Results: For TAC, three 3-concentration, one 2-concentration, and one 1-concentration model using concentrations from 0–2h met pre-specified criteria. The best equations were:

TAC $AUC=10.338+7.739C0+3.589C2$
(r^2=0.956,bias=-3.37%,precision=4.65%)
and
TAC $AUC=29.479+5.016C2$
(r^2=0.862,bias=3.15%,precision=9.72%).

For MPA, only one model identified for MPA met pre-specified criteria:

MPA $AUC=9.328+1.311C1+1.455C2+2.901C4$
(r^2=0.838,bias=-3.78%,precision=14.89).

One published TAC (and no MPA) LSS in renal transplant recipients on steroid-based regimens met preset criteria for bias and precision.
Conclusion: To our knowledge, this was the first study to develop and validate LSSs for TAC and MPA in steroid-free renal transplant recipients. These LSSs can be used to accurately predict TAC and MPA AUCs for patients on a steroid-free regimen. The commonly used MPA LSS is based on a steroid regimen and was not predictive for our steroid-free patients. Corticosteroids may have an impact on predictive performance of MPA LSSs and these hypotheses-generating results warrant further study.

206. Pharmacokinetics of tacrolimus in stable renal transplant recipients on a steroid-free regimen.
Eric Poulin, B.Sc.(Pharm)[1], Erica D. Greanya, B.Sc.(Pharm), Pharm.D., ACPR[1], Nilufar Partovi, B.Sc.(Pharm), Pharm.D.[2], R. Jean Shapiro, M.D., FRCPC[3], Mai Al-khatib, B.Sc.(Pharm), M.Sc.(Pharm)[4], *Mary H.H. Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS*[5]; (1)Vancouver General Hospital, Vancouver, BC, Canada; (2)University of British Columbia and Vancouver General Hospital, Vancouver, BC, Canada; (3)University of British Columbia, Vancouver General Hospital, Vancouver; (4)University of British Columbia, Vancouver, BC, Canada; (5)University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

Purpose: The purpose of this study was to characterize the pharmacokinetics of tacrolimus in stable renal transplant recipients on a mycophenolate-based steroid-free regimen.
Methods: Twenty-eight subjects were entered into this open-label study following written informed consent. Upon administration of a steady-state morning tacrolimus dose, blood samples were collected at 0, 0.5, 1, 2, 4, 6, 8, 10, and 12 hours post-dose. Whole blood concentrations of tacrolimus were measured by a validated liquid chromato-

graphy-tandem mass spectrometry method and pharmacokinetic parameters analyzed by conventional non-compartmental modeling.
Results: (Data are in mean ± SD). Subjects included 17 females and 11 males who were 2.5 ± 1.9 years post-transplant. Age was 47.4 ± 12.5 years and weight 70.4 ± 15.9 kg. Serum albumin concentration was 4.3 ± 0.4 g/dL, serum creatinine was 1.2 ± 0.3 mg/dL, and estimated glomerular filtration rate (eGFR) was 60.8 ± 15.4 mL/min. Daily tacrolimus dosage was 2.71 ± 1.51 mg. Tacrolimus pharmacokinetic parameters were: area-under-the-curve [$AUC_{(0-12h)}$] 116.04 ± 30.97 µg*hr/L; dose-normalized (to 1 mg) $AUC_{(0-12h)}$ 52.57 ± 24.75 µg*hr/L/mg; dose-normalized maximal concentration (C_{max}) 8.01 ± 3.31 µg/L/mg; time to C_{max} (t_{max}) 1.75 ± 1.00 h; and dose-normalized minimum concentration (C_{min}) 2.63 ± 1.41µg/L/mg.
Conclusion: Prednisone is known to interact with tacrolimus and may reduce tacrolimus exposure by inducing cytochrome (CYP) 3A and/or P-glycoprotein. In renal transplant recipients on a prednisone-based protocol, average dose-adjusted tacrolimus AUC, C_{max}, and C_{min} have been reported as 30–50 µg*hr/L/mg, 3–6 µg/L/mg, and 2–3.5 µg/L/mg. In our prednisone-free patients, while (as expected) C_{max} was higher, the AUC and C_{min} values were similar to those of patients on prednisone-based regimens. Large variability in pharmacokinetic parameters has been reported in prednisone-based protocols. Given the variability also seen in our cohort and different C_{max} values despite similar overall drug exposure, special attention must be paid to tacrolimus dosing for patients in whom prednisone is being removed or added to immunosuppressive regimens.

207. Immunosuppressants adherence rates in the Mycophenolic Acid Observational Renal Transplant (MORE) Registry.
Marie Chisholm-Burns, Pharm.D., M.P.H.[1], Anne Wiland, Pharm.D., BCPS[2], Demetra Tsapepas, Pharm.D.[3]; (1)The University of Arizona College of Pharmacy, Tucson, AZ; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ; (3)NY-Presbyterian Hospital-Columbia University Medical Center, New York, NY

Purpose: Adherence with immunosuppressant medications is an important determinant of graft outcome in renal transplantation.
Methods: The MORE registry is a prospective, observational study of *de novo* renal transplant patients receiving enteric-coated mycophenolate sodium (EC-MPS) or mycophenolate mofetil (MMF) at 40 US transplant sites. Adherence was assessed using the Immunosuppressant Therapy Adherence Scale (ITAS); a validated, self-report, four-item questionnaire. Patient adherence with immuno-suppressant medications was evaluated and an analysis of factors influencing early non-adherence (total ITAS score < 12) was conducted.
Results: At January 2010, 744 patients were analyzed (Mean age = 51.4 years, 63% male, 25% African American (AA), 41% Living Donor Transplant Recipients) and 77% completed the ITAS at 3, 61% at 6 and 52% at 12 months. Majority of patients received tacrolimus (95%) and corticosteroids (59%). The mean (SD) total ITAS score [Range 0–12] at 3, 6 and 12 months were 11.5 (1.0), 11.3 (1.3) and 11.3 (1.2). Non-adherence rates were greater at 6 and 12 months versus 3 months (34%, 34%, 27%, respectively). Factors independently associated with non-adherence included living vs. deceased donor (Odds ratio [OR]=1.55; 95% confidence interval [CI] = 1.10–2.17; p=0.013) and AA vs. Caucasian recipient (OR=1.52; 95% CI = 1.05–2.20; p=0.027). A trend for non- adherence was observed in patients with no delayed graft function (OR=1.47; 95% CI = 0.93–2.32; p=0.096). No significant differences were observed for EC-MPS vs. MMF, gender, expanded criteria donor or reason for end-stage renal disease.
Conclusion: Despite the importance of adherence to immuno-suppressant medications, many patients are non-adherent to therapy. AA and living donor renal transplant recipients were identified as especially non-adherent and we will focus on these populations for comparative outcomes analyses and potential improvement strategies.

208. Early outcome analysis of the Mycophenolic Acid Observational Renal Transplant (MORE) Registry: initial comparisons of enteric-coated mycophenolate sodium and mycophenolate mofetil.
Ali Olyaei, Pharm.D., BCPS[1], Anne Wiland, Pharm.D., BCPS[2], Kimi Ueda Stevenson, Pharm.D., BCPS[3]; (1)Oregon State University/Oregon Health and Sciences University, Portland, OR; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ; (3)California Pacific Medical Center, San Francisco, CA

Purpose: The MORE Registry is a prospective, observational study of de novo adult renal transplant patients receiving mycophenolic acid (MPA) therapy designed to determine effectiveness, tolerability and safety of enteric-coated mycophenolate sodium (EC-MPS) versus mycophenolate mofetil (MMF)-based immunosuppressive regimens.
Methods: Based on standard-of-care at 40 US sites, outcomes analyzed included: graft survival, patient survival, first biopsy-proven acute rejection (BPAR), mean serum creatinine, adverse event (AE) rates, and percentages of patients maintained on at least full recommended MPA dose (1440 or 2000 mg/day, EC-MPS or MMF respectively). Preliminary data from 688 patients receiving tacrolimus were analyzed.
Results: Interim results at 1, 3, 6 and 12 months from 468 EC-MPS and 220 MMF patients showed that more EC-MPS patients were maintained on at least full recommended dose of MPA (EC-MPS/MMF: 80.2/71.0%, p=0.01; 72.0/59.7%, p<0.01; 56.7/45.7%, p=0.02; 48.6/42.9%, p=0.30). Comparable 6-month clinical outcomes were achieved for effectiveness outcomes, tolerability and safety for both EC-MPS and MMF respectively. There were no significant differences in graft survival (98.9/99.0%, p=0.44), patient survival (99.5/99.0%, p=0.37), BPAR (6.7/6.1%, p=0.51), mean serum creatinine (1.44/1.56 mg/dL, p=0.16) or cumulative incidence of early AEs by organ system, infections or neoplasia. Gastrointestinal AEs were reported in 59.9% EC-MPS and 66.8% MMF patients (p=0.09).
Conclusion: These results show that the majority of renal transplant patients are maintained on at least full recommended doses of MPA. Early dosing differences are seen between EC-MPS and MMF which may impact outcomes at later time points in this study.

209. Predictors of recurrent hepatitis C treatment success in liver transplantation.
Shirley M. Tsunoda, Pharm.D.[1], Mo Cui, Pharm.D.[1], Judy Hsiao, Pharm.D.[1], Rachel Sperling, Pharm.D.[1], Tarek I. Hassanein, M.D.[2]; (1)UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla, CA; (2)University of California, San Diego, San Diego, CA

Purpose: Recurrent hepatitis C post-liver transplant occurs universally with approximately 30% of patients progressing to cirrhosis as early as 5 years post-transplant. Treatment success is highly variable with sustained viral response (SVR) rates of 20–45% post-transplant. The purpose of our study was to determine SVR rates in our patient population and to identify predictors of treatment success using SVR as the primary outcome.
Methods: A retrospective data analysis was conducted in 374 liver transplants performed over 10 years at our institution. Inclusion criteria included adult liver transplant patients transplanted for hepatitis C, post-transplant hepatitis C treatment with pegylated interferon and ribavirin, and continuous follow-up data for 6 months after treatment initiation. Data collected included demographics, SVR, early virological response (EVR) rates, rapid virological response (RVR) rates, and immunosuppressive regimen. Statistical analysis was performed using the Pearson's χ^2 test and logistic regression.
Results: A total of 40 liver transplant patients treated with 43 courses of hepatitis C therapy met our inclusion criteria and were analyzed. RVR and EVR were significantly correlated to SVR, p=0.008 and 0.001, respectively. Treatment duration of pegylated interferon and ribavirin was not significantly correlated to SVR, p=0.857. Patients taking sirolimus were more likely to have achieved an SVR, OR 4.33 (0.91, 20.6), p=0.065. Other variables such as baseline serum creatinine, HCV RNA levels, HCV genotype, and immunosuppression with mycophenolate were not significantly correlated to SVR.
Conclusions: RVR and EVR can be used as early indicators of treatment success with pegylated interferon and ribavirin in hepatitis C post-liver transplant. Immunosuppression with sirolimus may provide an advantage towards SVR in patients treated for hepatitis C post-transplant; however, further studies are needed to confirm this result.

210. Mycophenolate sodium vs. mycophenolate mofetil in kidney transplant recipients withdrawn from corticosteroids: an analysis

of the Mycophenolic Acid Observational Renal Transplant Registry (MORE).
Kimi Ueda Stevenson, Pharm.D., BCPS[1], Anne Wiland, Pharm.D., BCPS[2], Ali Olyaei, Pharm.D., BCPS[3], V. Ram Peddi, M.D.[1]; (1)California Pacific Medical Center, San Francisco, CA; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ; (3)Oregon State University/Oregon Health and Sciences University, Portland, OR

Purpose: This analysis evaluates tolerability and efficacy of enteric-coated mycophenolate sodium (EC-MPS) vs. mycophenolate mofetil (MMF) using data from the MORE registry in subjects who were withdrawn from corticosteroids.
Methods: The MORE registry is a prospective observational study of adult renal transplant recipients receiving EC-MPS or MMF as part of their immunosuppression regimen. Standard-of-care was determined by local clinical practice in 40 US sites. Corticosteroid withdrawal (CSW) was defined as no longer taking corticosteroids at 3 months post-kidney transplantation.
Results: A total of 267 subjects were analyzed. In patients withdrawn from corticosteroids, there was no significant difference in patients tolerating full dose MPA (adjusted to MMF dose). Percentage of Subjects tolerating $\geq$ 2000mg/day.

	EC-MPS	MMF
Month 1	71.8	62.8
Month 3	59.5	48.3
Month 6	38.6	37.0
Month 12	35.5	40.0

(p=NS at all time points) Furthermore, there was no difference in biopsy-proven acute rejection, patient and graft survival, infections, cardiovascular events, bone, hematologic events, malignancies, and mean serum creatinine level. Reported adverse effects for GI toxicity were however, higher in subjects taking MMF (69.8% vs. 57.9%, p=0.0656). When overall tolerability of MPA was compared in 267 patients withdrawn from corticosteroids vs. those 378 who continued on corticosteroids, the use of corticosteroids allowed for better tolerability of higher doses of MPA. Percentage of subjects tolerating $\geq$ 2000 mg/day.

	CSW group	Corticosteroid group	p value
Month 1	68.6	85.0	<0.0001
Month 3	55.6	77.0	<0.0001
Month 6	38.1	63.6	<0.0001
Month 12	37.1	54.1	0.0007

Hematologic adverse events were reported in 57.7% v. 26.2% (p<0.0001) in the CSWD and corticosteroid group.
Conclusion: In patients withdrawn from corticosteroids, EC-MPS and MMF offer equivalent efficacy and safety in kidney transplant recipients. Continued use of corticosteroids permits therapy with standard doses of MPA, perhaps related to less hematologic toxicity.

---

211. Patient self-efficacy and satisfaction after medication education following solid organ transplantation.
Seth D. Heldenbrand, Pharm.D.[1], Lindsey E. Turnbow, Pharm.D.[1], Nalin Payakachat, Ph.D.[2]; (1)University of Arkansas for Medical Sciences, Little Rock, AR; (2)University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR

Purpose: Most renal or liver transplant patients are discharged in less than 1 week following transplantation. Therefore, to achieve maximum patient benefit, transplant medication education must be intensive and effective. This pilot study was designed to assess medication self-efficacy and patient satisfaction following pharmacist-led transplant medication education in the immediate post-solid organ transplant (SOT) setting.
Methods: A prospective cross-sectional study was conducted in de novo SOT patients over a 5 month period. All patients received standardized pharmacist-provided transplant medication education following transplantation. Prior to hospital discharge, patients completed a 51-item questionnaire to determine self-efficacy (27 questions) and satisfaction with the educational process (24 questions). All responses were measured using 5-point Likert scales (1=strongly disagree; 5=strongly agree). Data were analyzed using descriptive and Student *t*-test statistics.

Results: Twenty-one SOT patients (14 renal; 7 liver) completed the study (67% female) with a mean age 49 ± 12 years. Mean composite scores for self-efficacy and satisfaction were 4.5 ± 0.53 and 4.72 ± 0.64, respectively. Self-efficacy scores relating to the patient taking medications when nauseated, when the purpose of the medication was unknown, or in the absence of medication aids (pillboxes, calendars, medication lists) were significantly lower than others (p<0.05). Liver transplant recipients displayed significantly higher self-efficacy scores compared to renal transplant recipients (4.94 v. 4.60 p<0.05). Patients reported lower satisfaction with pain immediately following transplant surgery, but this was not significantly different from the mean.
Conclusion: Patients reported high self-efficacy, suggesting they were well-prepared to self-administer their medications. Additionally, patients were highly satisfied with the transplant medication education process. However, differences in self-efficacy scores indicate the need to tailor the medication education process to meet patient-specific needs of renal and liver transplant recipients.

---

212. Impact of Post-Operative Hyperglycemia on Clinical Outcomes in Non-Diabetic Renal Transplant Recipients.
Steven Gabardi, Pharm.D.[1], Michele Campolieto, Pharm.D.[2]; (1)Pharmacy Department & Renal Division, Brigham and Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA; (2)Department of Pharmacy Services, Brigham and Women's Hospital, Boston, MA

Purpose: Post-operative hyperglycemia occurs frequently after renal transplantation. Many factors contribute to hyperglycemia including induced insulin resistance, increased levels of endogenous glucocorticoids, and the use of diabetogenic immunosuppressive drugs. Current analyses of post-operative glucose control and clinical outcomes in renal transplant recipients (RTR) are limited and contradictory. This is the first study to evaluate clinical outcomes of post-operative hyperglycemia in non-diabetic RTR receiving tacrolimus-based immunosuppression.
Methods: A retrospective study was conducted of consecutive adult RTR between September 2008 and September 2009. Patients with pre-existing diabetes, primary graft failure or graft loss due to technical complications were excluded. As standard of care, all patients received every six-hour finger stick blood glucose (both fasting and post-prandial) monitoring following renal transplant. Mean blood glucose (MBG) values were calculated for post-operative days 0–5. We defined hyperglycemia as a MBG >140 mg/dL. Patients were divided into two groups, those with normoglycemic MBG values (n=18) or hyperglycemic MBG values (n=24). The primary endpoints were the incidence of cellular rejection, antibody-mediated rejection (AMR), graft loss, or death. Secondary endpoints included an analysis of infectious complications, renal function, delayed graft function (DGF) and new onset diabetes after transplant (NODAT). Patients were followed for 30 days after transplant.
Results: Demographics, transplant characteristics and immuno-suppressive regimens were comparable between the two groups. For the primary end points of cellular rejection, AMR, graft loss or death there were no differences between the normoglycemic and hyperglycemic groups. For the secondary endpoints of infection, serum creatinine, DGF, and NODAT there were no differences between the normoglycemic and hypoglycemic groups.
Conclusion: This analysis revealed no difference in transplant-related outcomes at 30 days when comparing five-day post-operative MBG values above and below 140 mg/dL. Interestingly, acute rejection rates and serum creatinine levels were numerically higher in the normoglycemic group, but did not reach statistical significance.

---

213. Evaluation of atovaquone versus sulfamethoxazole-trimethorpim as *Pneumocystis jiroveci* pneumonia prophylaxis following renal transplantation.
Steven Gabardi, Pharm.D.; Pharmacy Department & Renal Division, Brigham and Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA

Purpose: *Pneumocystis jiroveci* pneumonia (PCP) remains an important pathogen in transplantation despite effective antimicrobial strategies. Anti-*Pneumocystis* prophylaxis is commonplace after renal

transplantation. Sulfamethoxazole-trimethoprim (SMZ-TMP) is the prophylaxis agent of choice. However, due to allergy, intolerance or G6PD deficiency, some patients are not good candidates for SMZ-TMP therapy. Atovaquone is an alternative to SMZ-TMP for PCP prophylaxis, but it has never been studied in renal transplant recipients (RTR). This is the first study to evaluate atovaquone vs. SMZ-TMP as PCP prophylaxis in RTR.

Methods: A retrospective study was conducted of adult renal transplant recipients between January 2004 and December 2008. At our center we use 12-months of sulfamethoxazole/trimethoprim (SMZ/TMP) for *Pneumocystis* prophylaxis. In our sulfa-allergic patients we use 12-months of atovaquone and one-month of a fluoroquinolone. The fluoroquinolone is added for urinary tract and incision site prophylaxis. Patients were divided into two groups, depending on their prophylaxis regimen; SMZ/TMP (n=160) and atovaquone/fluoroquinolone (n=25). All patients received induction therapy with either basiliximab or thymoglobulin and maintenance immunosuppression using tacrolimus, mycophenolate ± corticosteroids. The primary endpoint was the incidence of PCP.

Results: Demographics were comparable between the two groups. There were no cases of PCP in either group at one-year post transplant. However, the incidence of BK viremia was also evaluated and found to be significantly higher in the SMZ/TMP group (p=0.03)

Conclusions: This analysis revealed that atovaquone is as efficacious at preventing PCP as SMZ-TMP in RTR. Possibly more importantly was the protective effect against BK viremia seen with the combination of atovaquone and a fluoroquinolone antibiotic.

214. Evaluation of early corticosteroid cessation therapy in standard criteria donor versus expanded criteria donor renal transplant recipients.

Steven Gabardi, Pharm.D.; Pharmacy Department & Renal Division, Brigham and Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA

Purpose: Expanded criteria donors (ECD) are a source of kidneys that permit more patients to benefit from transplantation. Previous studies have compared ECD versus standard criteria donor (SCD) renal transplantation using triple-drug maintenance regimens. This is the first study to evaluate an early steroid withdrawal in SCD vs. ECD renal transplant recipients (RTR).

Methods: A retrospective study was conducted of adult deceased-donor RTR between May 2002 and December 2007. Only patients receiving rabbit antithymocyte globulin induction therapy and a maintenance regimen containing tacrolimus and mycophenolate were included in this analysis. The primary endpoint was the incidence of biopsy-proven acute rejection (BPAR), graft loss or death. Secondary endpoints included an analysis of renal function, time to first rejection episode, delayed graft function (DGF) and safety parameters.

Results: Demographics were comparable between the two groups, with the exception of recipient age (SCD = 49 ± 11.3 vs. ECD = 65 ± 10.5; p<0.0001).

	SCD (n=23)	ECD (n=29)	P-value
Primary endpoints at 12 months			
BPAR	17.4%	17.2%	1.000
Graft loss	4.3%	3.4%	1.000
Death	4.3%	3.4%	1.000

Conclusions: This analysis revealed that an early steroid withdrawal regimen in ECD RTR produces a similar efficacy profile when compared to an early steroid withdrawal regimen in SCD patients. All safety parameters were similar between the two groups.

215. Retrospective analysis of the efficacy of erythropoiesis-stimulating agents (ESAs) in the treatment of anemia following renal transplantation.

Nicole M. Schmidt, Pharm.D., Teresa Cavanaugh, Pharm.D., Amit Govil, M.D., Gautham Mogilishetty, M.D., Adele Rike Shields, Pharm.D., Nicholas Parrish, M.D.; The Health Alliance, Cincinnati, OH

Purpose: While the efficacy of ESAs has been demonstrated in the treatment of anemia in chronic kidney disease patients, studies of ESAs in renal transplant recipients are lacking and inconsistent. The specific aims of this study are to evaluate the efficacy of ESAs in the management of anemia after renal transplantation, describe the current practice of ESA use in renal transplant recipients, and evaluate the safety of ESAs in this patient population.

Methods: This was a single-center, retrospective cohort study conducted in patients aged 18 years and older who had received a renal transplant from January 1, 2005 through December 31, 2008. Patients were categorized based on hemoglobin values at seven days post-transplant (anemic vs. non-anemic) and further subdivided into those receiving ESAs and those not receiving ESAs.

Results: Of the 60 patients included, 17 (28.3%) were anemic and received ESAs, 19 (31.7%) were not anemic and received ESAs, and 24 (40%) were not anemic and did not receive ESAs. At 3 months post-transplant, hemoglobin values were highest in the non-anemic without ESA group (13.0 g/dL) versus the non-anemic ESA group (12.0 g/dL) and anemic group (12.2 g/dL) (p<0.010). A lower proportion of patients achieved a hemoglobin target of 12 g/dL at 3 months in the non-anemic ESA group compared to both the non-anemic without ESA group and anemic group (36.8% vs. 83.3% vs. 58.8%, p<0.008). Iron replacement was similar in both groups receiving ESAs, with less than half the patients in each group receiving iron. There was no difference in cardiovascular events regardless of ESA use.

Conclusion: Use of ESAs in renal transplant recipients post-transplant appears to have no effect on recovery of anemia regardless of baseline hemoglobin values.

Women's Health

216E. Genetic and environmental risk factors for postpartum depression.

Shareen Y. El-Ibiary, Pharm.D., BCPS[1], Steven Hamilton, MD, PhD[2], Carolyn Erdman, MS[2], Patricia Robertson, MD[2], Rebecca Abel, LCSW[2], *Patrick R. Finley, Pharm.D.*[2]; (1)Midwestern University, College of Pharmacy-Glendale, Glendale, CA; (2)University of California at San Francisco, San Francisco, CA

Purpose: To compare potential genetic and environmental risk factors for postpartum depression (PPD) between mothers with PPD and those exhibiting minimal depressive symptoms.

Methods: Mothers were screened for PPD during their well-baby visit 6 weeks after delivery. Subjects completed the Edinburgh Postnatal Depression Scale, and those with scores greater than 14 or less 7 were recruited for case and control groups, respectively. Qualified subjects returned within one week for assessment with questionnaires: Dyadic Adjustment Scale, MOS Social Support Survey, Life Threatening Events Survey, and QIDS-SR16 scale. A structured clinical interview confirmed major depression diagnosis. A blood sample was obtained to analyze 81 single nucleotide polymorphisms (SNPs) in 12 genes hypothesized to be PPD-related.

Results: Sixty-nine subjects were recruited, 21 did not complete the study leaving 48 participants enrolled (24 cases and 24 controls) for analysis. Preliminary data identified history of depression, perceived lack of psychosocial supports, and unplanned pregnancies as environmental risk factors significantly associated with PPD. Three SNPs in the serotonin 2A receptor (HTR2A) gene were associated, with the strongest association to rs6311, a functional promoter SNP (p=0.002, odds ratio 0.25, 95% CI 0.10–0.63), a finding robust to population stratification. EPDS scores in cases were nominally associated with a SNP in the progesterone receptor gene (p=0.008).

Conclusion: This analysis confirms history of depression and lack of psychosocial supports as risk factors for PPD. This small PPD dataset is the first to suggest that DNA variation in the HTR2A gene is associated with the diagnosis of PPD as well.

Presented at Presented at the 58th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG), San Francisco, CA May 17, 2010.

217E. Angiotensin-converting enzyme inhibitor, angiotensin-receptor blocker, and HMG-CoA reductase inhibitor use in women of childbearing potential.

Alison M. Walton, Pharm.D., BCPS, Karie A. Morrical-Kline,

Pharm.D., Tracey M. Guildenbecher, M.D.; St. Vincent Joshua Max Simon Primary Care Center, Indianapolis, IN

Purpose: Angiotensin-converting enzyme inhibitors (ACE-I), angiotensin-receptor blockers (ARB), and HMG-CoA reductase inhibitors (Statin) are utilized in hypertension, hyperlipidemia, and diabetes. These medications, not recommended during pregnancy, are known to cause birth defects. The purpose of this study was to quantify the number of women of childbearing potential prescribed ACE-I, ARB, or Statin and to determine the number of documented teratogenic risk discussions (Risk Documentation) before and after educational interventions.
Methods: The IRB-approved retrospective chart review included female patients ages 15 to 45 prescribed ACE-I, ARB, or Statin between January 1, 2007 and March 1, 2009. Exclusion criteria were tubal ligation and hysterectomy. A survey determined physician knowledge of teratogenic risks and prescribing practices for targeted medications. Educational interventions were implemented. Data will be reviewed and analyzed quarterly for one year.
Results: Baseline analysis included 200 patients. A majority of patients (176, 88%) were ages 31 to 45. A total of 129 (64.5%) patients were prescribed ACE-I, 29 (14.5%) ARB, and 88 (44.0%) Statin. Risk Documentation occurred for 40 (20%) patients and was more likely to occur with ACE-I or ARB (27.7%) compared to Statin (4.5%) ($p<0.001$) and patients age <40 (26.6%) versus >41 (2.6%) ($p<0.001$). Post-intervention analysis of 131 patients revealed Risk Documentation was 2.4 times greater than pre-intervention (OR 2.4; 95% CI: 1.5, 3.9; p=0.001). Risk Documentation continued more frequently for patients age <40 (41.7%) versus >41 (23.4%) (p=0.015), but became more consistent for patients prescribed ACE-I or ARB (40.7%) and Statin (38.1%) (p=0.484). No significant difference identified in survey responses pre- and post-intervention; however, physicians overestimated Risk Documentation.
Conclusion: Physician's baseline awareness of ACE-I, ARB, or Statin teratogenic risks and Risk Documentation was lacking. Post-intervention reveals improvement in Risk Documentation when targeted agents were prescribed to women of childbearing age; however, continual improvement is essential.
Presented at The Third International Conference for Individualized Pharmacotherapy in Pregnancy, Indianapolis, IN, June 7-8, 2010.

218. The impact of pharmacist counseling on patient knowledge of emergency contraception.
Denise Ragland, Pharm.D., Nalin Payakachat, Ph.D., Adam Pate, Pharm.D., Sara Harrod, Pharm.D. Candidate, 2011; University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR

Purpose: This study aimed to assess women's knowledge and awareness of emergency contraception (EC) and to evaluate the impact of pharmacist counseling on their knowledge and satisfaction.
Methods: A cross-sectional pre- and post-test study design was conducted with convenience sample of women receiving care at the University Women's Clinic from September 2009 to May 2010. A self-administered 12-question EC knowledge survey instrument was employed as a pre-test before a 10-minute education session provided by a pharmacist or a trained student pharmacist. This was followed by a post-test survey including 4 satisfaction questions in addition to the pre-test. The EC test questions were reviewed by College of Pharmacy faculty members for content validity. The possible highest score is 13. Sample size of 108 was calculated to achieve 80% power. Paired *t*-test statistics were used to determine the impact of the intervention.
Results: One-hundred and seventeen women participated in the study with average age of 25 years. The majority was currently pregnant (86%) and 74% were unintended pregnancies. Approximately 70% had a high school or some college education and earned less than $20,000 annual income. Thirty-five women (30%) reported no prior awareness of EC. Average knowledge scores of 5.4 (SD=4.1) for the pre-test and 10.7 (SD=1.4) for the post-test were reported. The post-test scores were statistically improved from the pre-test (p<0.0001). All participants highly-valued the counseling session with average satisfaction scores of 3.8 (out of 4, SD=0.3). Long-term impact is currently being assessed by follow-up phone surveys.
Conclusion: Pharmacists can positively impact patient knowledge of

EC during a 10-minute counseling session. Prior self-reported awareness of EC in this study population disclosed inaccurate understanding and misconceptions of EC. This demonstrates a clear opportunity for pharmacists to improve patient knowledge of EC. In addition, the patients were highly satisfied with the pharmacist counseling.

219. Evaluation of adherence, persistence, and switching patterns among women using six commonly prescribed hormonal contraceptives.
Amy W. Law, Pharm.D., M.S., Susan H. Foltz Boklage, M.S., Charles Kreilick, Jennifer Pocoski, Pharm.D., Richard. F. Lynen, M.D., M.B.A., Leo Plouffe Jr., M.D., CM; Bayer HealthCare Pharmaceuticals, Wayne, NJ

Purpose: Female contraception is widely used in the USA. Continued use is critical for contraceptive effectiveness, especially for methods that require daily intake. This study assessed adherence, persistence, and switching patterns of 6 commonly used hormonal contraceptives.
Methods: Women filling the same study contraceptive ≥2 times during the index period (1/1–12/31/2007) from Medstat MarketScan®, a commercial healthcare-claims database, were included in the analysis. Study contraceptives were medroxyprogesterone acetate (DMPA) 150mg injectable suspension, intravaginal etonogestrel 0.120 mg/ethinyl estradiol 0.015 mg/day (ENG/EE), oral contraceptives (OC): norethindrone acetate 1mg/ethinyl estradiol 20 µg (NETA/EE), norgestimate/ethinyl estradiol including generics (NGM 0.180 mg/EE 0.035 mg, NGM 0.180 mg/EE 0.025 mg Lo), and drosperinone 3mg/ethinyl estradiol 0.02 mg (DRSP/EE). Persistence, adherence, and switching rates were assessed during follow-up (ending 12/31/2008). Adherence was measured by medication possession ratio (MPR). Persistence was defined as total days drug was taken without gap(s) and switching as change from the index contraceptive to a different study/nonstudy contraceptive. Multivariate analyses adjusting for age, pill burden, Charlson Comorbidity Score, and insurance type were conducted.
Results: Cohort included 40,333 women. DRSP/EE was the predominantly used contraceptive (28% vs 20%, NGM/EE; 17% NGM/EE Lo; 14% NETA/EE and ENG/EE; 9%, DMPA). MPRs and annual mean persistency were similar among contraceptives. Switch rates were highest among women initially using OCs than non-OC: NETA/EE (13.2%), NGM/EE Lo (12%), NGM/EE (9.4%), DRSP/EE (8.0%) 4.6% (ENG/EE) and 4.1% (DMPA). Compared with DRSP/EE, women using NETA/EE, NGM/EE, or NGM/EE Lo were significantly more likely to switch to another contraceptive (OR=1.8/p<0.0001, 1.2/p=0.001, 1.6/p<0.0001, respectively). Age and number of chronic medications were significant predictors (OR=0.986 and 1.042, respectively, p≤0.0006) for switching.
Conclusions: DRSP/EE was the predominant index contraceptive. Fewer than 1 in 10 women initially using DSRP/EE switched to another contraceptive. Further exploration of factors influencing patient persistence, adherence, and switching patterns is warranted.

220. Obstetrical Practitioner Acceptability of Metformin for the Treatment of Gestational Diabetes Mellitus.
Portia N. Davis, Pharm.D.; Texas Southern University College of Pharmacy & Health Sciences, Houston, TX

Purpose: Gestational diabetes mellitus (GDM) is a common complication of pregnancy that has traditionally been managed with proper nutrition and insulin pharmacotherapy. There is a growing consideration of the need for to further evaluate oral antidiabetic agents, particularly metformin as an alternative treatment options for this condition.
Methods: The objective of this study is to determine practitioner acceptability of metformin as an alternative to insulin for the treatment of GDM by identifying current prescribing trends within Houston-area obstetrical practices by utilizing survey methodology. The survey contained items to assess practitioner prescribing practices for GDM patients, as well as their knowledge of the most current studies that evaluate the use of oral agents, particularly metformin. The survey was distributed to 250 obstetrical practitioners within the Texas Medical Center located in Houston, TX.

Results: Out of the 250 survey recipients, 57 responded yielding a response rate of 22.8%. Although 67% of responders did not currently prescribe metformin for GDM treatment, 61% of the same group indicate that they would consider prescribing metformin. Approximately 35% of participants that currently prescribe oral agents responded that they have observed favorable newborn and maternal outcomes at birth. Regarding the available literature on the topic, 47% of participants agree that there is sufficient data to affect their practice habits. Most participants (84%) were interested in participating in a clinical trial to further study this topic.

Conclusion: Current prescribing trends of the surveyed practitioners suggest that there is considerable interest in studying metformin as an alternative to insulin for GDM patients. Oral metformin is a logical option for women with this condition, and as more studies evaluating this drug for this indication become available, treatment recommendations may shift to more readily initiate metformin as primary GDM treatment.

CLINICAL PHARMACY FORUM

ADR/Drug Interactions

221. The Effects of Fluconazole Gargle on the Interactions of CNI and Hepatotoxicity in Kidney Transplant Recipients.
Heeyoung Ham, M.S.[1], Sukhyang Lee, Phram.D., Ph.D[1], Hyenoh La, Ph.D[2]; (1)Graduate School of Clinical Pharmacy, Sookmyung Women's University, Seoul, South Korea; (2)Department of Pharmacology, College of Medicine, The Catholic University of Korea, Seoul, South Korea

Purpose: Fluconazole to prevent fungal infection after kidney transplantation(KT) shows hepatotoxicity. To recover hepatotoxicity, fluconazole administration was stopped. However, because of the danger of infection and the tolerance, the administration method was changed such as tropical administration to the oral cavity and then spitting out(gargle). Accordingly, this study tried to identify the effects of the change of administration method on the actual interactions of calcinurin inhibitor(CNI), and if it makes positive effects on the recovery from hepatotoxicity.

Methods: The patients who had KT operation in the catholic university of Korea Seoul St. Mary's Hospital from February in 2008 to February in 2010 were investigated retrospectively. They were classified as three groups according to the administration methods of fluconazole. Then the hepatotoxic factors and interactions with CNIs were compared and analyzed between groups.

Results: Out of 132 subjects, 64 patients (48%) showed the hepatotoxicity. Regarding the level of the toxicity, there were 10 mild (44%), 4 moderate (17%), and 9 severe (39%)cases in the Stop Group (Group B, n=23). From the Gargle Group (Group C, n=41) there were 24 mild (59%), 8 moderate (20%), and 9 severe cases (22%). It took for Group C 11.5 ± 10.0 days and for Group B 14.3 ± 11.9 days (p=0.33) to recover from the hepatotoxicity. Additionally, as far as the interactions of the medicines are concerned, the dose of tacrolimus has been increased approximately 1.3 times from 8.2 ± 3.2 mg/D to 10.6 ± 4.4 mg/D (p<0.01) when comparing before and after the change of the fluconazole administration method on Group C.

Conclusion: When fluconazole is administered to the gargle, it brought the recovery of hepatotoxicity similar to stop of the administration. Additionally, it made blood concentration of tacrolimus decreased, so that tacrolimus doses were increased. Accordingly, when the fluconazole administration method is changed, the doses of tacrolimus should be adjusted in order to prevent the rejection because of the decrease of CNI concentration in the blood.

Allergy/Immunology

222. Standardization of intravenous desensitizations among hospital inpatients.
Amy C. Go, Pharm.D.[1], Lam Nguyen, Pharm.D.[1], Gerard Barber, R.Ph., M.P.H.[1], Christine Steckline, Pharm.D.[1], Stephen C. Dreskin, M.D., Ph.D.[2]; (1)University of Colorado Hospital, Aurora, CO; (2)University of Colorado Denver School of Medicine, Aurora, CO

Purpose: Desensitization, a process of administering offending medications to patients identified as allergic, starts with small doses progresses to therapeutic doses. Desensitizations can be employed to reverse the limitations posed by antimicrobial drug resistance in the patient with antibiotic allergies, but are complicated and time consuming for Allergy/Immunology physicians (AIMDs) to order, pharmacy to prepare and nursing to administer. Desensitizations are also prone to medication errors when not uniformly completed - posing potentially life-threatening reactions. To enhance patient safety; reduce confusion regarding administration and concentrations during preparation; decrease turnover time and possibly reduce length of stay (LOS) in an Intensive Care Unit, we standardized desensitizations and established a protocol to direct use, preparation and administration.

Methods: Commonly-used medications for desensitization at our institution were identified. Final therapeutic doses of each medication were determined, then smaller doses were established using 10-fold dilutions. Each medication required approximately 10–15 dilutions of smaller doses prior to therapeutic doses.

Results: Standardized desensitizations were established for nine antibiotics that were most commonly used: ampicillin, cefepime, ceftazidime, doripenem, imipenem, meropenem, nafcillin, penicillin and piperacillin/tazobactam. A protocol of the desensitization procedure was developed to encourage safe practices during preparation and administration.

Conclusion: After standardization, a restricted group of physicians may prescribe a desensitization in non-naïve patients following patient-specific recommendations from AIMDs. For desensitization-naïve patients and non-standardized desensitizations, only AIMDs may prescribe desensitization. The newly-established protocol eliminates confusion describing the proper order of administration, and provides detailed information management of adverse reactions, as well as how to proceed with desensitization depending upon the type of reaction. The template used for standardizing desensitization in this process will be utilized for future agents. Outcome measurements for ICU LOS, enhanced protocol compliance and patient tolerability are being readied for study submission.

Ambulatory Care

223. An Evaluation of Diabetes Related Measures of Control after 6 months of Clinical Pharmacy Specialist Intervention.
M. Shawn McFarland, Pharm.D., Rebecca Cripps, Pharm.D., Regina Cassidy, Pharm.D., Timothy Morgan, Pharm.D., Wendy Johnson, Pharm.D., Dharapuram Venugopal, M.D.; Veterans Affairs Tennessee Valley Healthcare System, Murfreesboro, TN

Purpose: This study determined if there was a statistically significant difference in baseline A1C, blood pressure (BP), and cholesterol levels (LDL, HDL, non-HDL, triglycerides, and total cholesterol) after 6 months of Clinical Pharmacy Specialist (CPS) intervention. Secondary objectives included the percentage of patients meeting American Diabetes Association (ADA) goals for A1C, BP, and LDL individually as well as meeting all ADA goals in combination after 6 months of CPS intervention. In addition, the percentage of patients meeting the Diabetes Quality Improvement Project (DQIP) performance measure goals was assessed. Performance measure goals were defined as A1c ≤9%, LDL ≤100 mg/dL, SBP <140 mmHg, and DBP <90 mmHg.

Methods: We retrospectively evaluated the electronic medical record of all new patients who were referred to a CPS between October 1st, 2007 to March 31st, 2009 with an A1C >7% and who were seen by the CPS ≥ 2 times. Wilcoxon rank sum test was used to compare continuous variables that were not normally distributed. A sample size of 60 patients allowed for a 90% power to detect a statistically significant change in A1C of 0.5% or greater.

Results: Of the 487 patients extracted, 197 patients met inclusion and exclusion criteria and were included in the final analysis. All 6 month follow-up results showed statistically significant differences from baseline. Eighty-one percent of patients did not meet performance measures goals at baseline. After 6 months of intervention, 79% of these patients meet all performance measure goals with 93% meeting A1C goal. At study end there were 6% of all patients who met all ADA goals with 43% of patients (n=83) at a goal A1c of <7%.

Conclusions: This study showed that CPS intervention resulted in statistically significant improvements in diabetes control. The evaluation of the ADA and performance measure goals did show an improvement.

224. Assessment of the monitoring and follow-up of patients prescribed darbepoetin in a chronic kidney disease clinic.
Megan M. Bergstrom, Pharm.D., Anthony M Ishak, Pharm.D., BCPS; Boston Medical Center, Boston, MA

Purpose: This medication use evaluation was completed to assess adherence to current recommendations for darbepoetin therapy in chronic kidney disease patients.
Methods: Medical records of 57 chronic kidney disease patients currently prescribed darbepoetin and seen in an outpatient clinic were reviewed. Patient vital signs, laboratory values, darbepoetin dosage, and dosing interval were reviewed.
Results: Darbepoetin had been initiated in 55/57 patients. Hemoglobin (hgb) was obtained monthly in 22 patients (40%) and iron studies were obtained every 3 months in 18 patients (33%). There were a total of 15 patients with a ferritin level <100 of which 5 patients were not on iron therapy. Ten patients received oral therapy and 1 patient received dual therapy with IV iron replacement. There were a total of 22 patients with a percent transferrin saturation (Tsat) <20% of which 9 were not on iron therapy. Thirteen patients received oral therapy, and 1 patient received dual therapy with IV iron replacement. Blood pressure (BP) was checked in 95% of administrations (199 darbepoetin injections administered). Darbepoetin was administered 12.5% of the time to patients with a systolic blood pressure >160 and 1.5% of the time to patients with a diastolic blood pressure >100. No hgb levels were greater than 13, however, 9 hgb levels were <9. Darbepoetin dose was properly adjusted in 18% of administrations, inappropriately adjusted in 30%, and unable to be assessed in 52% of administrations secondary to lack of hgb levels.
Conclusion: There is currently room to improve compliance to monitoring parameters in patients receiving darbepoetin in the chronic kidney disease clinic. Through the development of algorithms for darbepoetin and iron replacement and the implementation of a clinical pharmacist there is hope to increase adherence to current recommendations, optimize therapy, and potentially decrease costs associated with anemia management.

225. Cost effectiveness of antiarrhythmic medication monitoring by clinical pharmacists in an outpatient setting.
Melissa J. Snider, Pharm.D., BCPS, CLS, Cynthia Carnes, Pharm.D., Ph.D., Janel Grover, M.H.A., Rich Davis, Ph.D., Steven Kalbfleisch, M.D.; Ohio State University Medical Center, Columbus, OH

Purpose: We previously showed that pharmacist monitoring of outpatient antiarrhythmic therapy (AARx) with physician oversight improves patient care. This study is to evaluate the economic outcomes associated with a pharmacist managed antiarrhythmic clinic.
Methods: Patients were seen by a pharmacist for outpatient AARx monitoring. A subset of patients were included in a crossover analysis comparing the pharmacist clinic to physician care. A retrospective cost analysis assessed direct costs & reimbursement. Direct costs were defined for 3 appointment models: 1) Office visit, 2) Office visit with EKG & labs, or 3) Office visit with EKG, labs, PFT, & CXR. Primary endpoints were cost efficiency (contribution margins of pharmacy clinic) and cost effectiveness (comparison of pharmacy clinic versus physician care). Secondary endpoints were improvement of program efficiency and appropriate acute electrophysiology (EP) referral.
Results: In the clinic's first 2 years, 808 visits were included. Payer mix was Medicare (61.6%), Managed Care (33.2%), and other (5.2%). Contribution margins for appointment models 1, 2, and 3 were $0.34, $6.32, and $110.48 respectively. Cost efficiency was achieved as contribution margins were positive for all appointment models. The crossover analysis included 16 patients. Cost effectiveness was achieved as charges were reduced by 21% per visit compared to physician care (Panel B). In the clinic's second year, overall program efficiency was improved by releasing one EP physician clinic day per week. Acute EP referrals included 6 direct admissions and 2 immediate cardioversions.

Conclusion: Pharmacist monitoring of AARx is cost efficient, cost effective, improves overall program efficiency, and results in appropriate acute EP referrals.

226. Glycemic control and preventative care measures of indigent diabetes patients within a pharmacist-managed insulin titration program vs. standard care.
Marissa C. Salvo, Pharm.D.[1], Amie D. Brooks, Pharm.D., BCPS[2]; (1)University of Connecticut - School of Pharmacy, Storrs, CT; (2)St. Louis College of Pharmacy, St. Louis, MO

Purpose: Assess the impact of a pharmacist-managed insulin titration program compared to standard care on glycemic control and preventative care measures in an indigent population with diabetes.
Methods: This was a retrospective cohort study comparing pharmacist-managed insulin titration (n= 69) and standard care/control (n= 57). Control patients were matched by age and insulin regimen. The primary outcome was glycemic control, assessed by change in A1c from baseline to various time points and study end using student's *t*-test. Secondary outcomes included attainment of preventative care measures and change in weight and total daily insulin dose from baseline to study end.
Results: A total of 126 patients receiving care at a county-funded health center were included in the analysis (mean age 50 ± 10 years, 60.3% female, 70.6% non-Hispanic black, A1c $9.75\% \pm 2.27$). Enrollment in the insulin titration program reduced A1c at study end by 1.3 ($\pm$ 1.99) compared to 0.18 ($\pm$ 1.55) in the standard of care group (p=0.001). Significantly more patients in the intervention group completed all preventative care measures than the control group. From baseline to study end, there was an increase in total daily insulin dose by 35 units ($\pm$ 49.43) in the intervention group compared to 7.19 units ($\pm$ 29.51) in the control group (p<0.001). Patients in the insulin titration program also experienced significant weight gain (p=0.006).
Conclusion: Patients in the pharmacist-managed insulin titration program achieved significant reduction in A1c compared to standard of care. Conversely, they received greater total daily insulin doses and experienced weight gain. Significantly more subjects in the intervention group completed the ADA recommended preventative care measures.

227. Development, implementation, and outcomes of a pharmacist-led anemia screening service.
Autumn S. Tami, Pharm.D., Monica L. Skomo, Pharm.D.; Duquesne University, Pittsburgh, PA

Purpose: The value of pharmacist services has been well documented in the literature. As the role of pharmacists continues to expand, new areas of opportunity to serve public health needs should be identified. Iron deficiency anemia is considered a major public health problem due to the negative physical, functional, and economic outcomes associated with it. Our objective is to demonstrate the positive impact pharmacists can have in identifying, managing, and correcting anemia.
Methods: Hemoglobin screening is being offered as both a community outreach service and point-of-care service at Duquesne University's Wellness Clinic. Initial assessment includes collection of patient demographic information and completion of an anemia symptom questionnaire. Hemoglobin is tested via the Hgb Pro® using a small blood sample. Patients with low hemoglobin values and no prior history of anemia are asked to contact their physician for follow-up anemia testing. Patients with iron or vitamin deficiency anemia are offered pharmacist counseling regarding choice of oral supplement, side effect management, and the role of adherence in correcting vitamin and mineral deficiencies. All patients are offered a follow-up hemoglobin screen at three and six months.
Results: Reported outcomes include the prevalence of low hemoglobin levels in the study population, the percentage of patients identified as having "low" hemoglobin values according to CDC standards, and the mean change in hemoglobin among patients diagnosed with iron or vitamin deficiency anemia who receive follow-up counseling and pharmacist management of oral iron therapy. Hemoglobin values will also be characterized according to population demographics for the purpose of comparison to documented anemia prevalence.

Conclusion: In order to manage anemia, both prevention and treatment strategies need to be sought. Implementation of a pharmacist-led anemia screening program that strives to identify and manage anemia serves an important, established public health need.

228. Implementation of a diabetes group visit model in a community-based, family medicine residency program.
Dawn C. Fuke, Pharm.D.[1], Michael T. Dotter, Pharm.D.[2], Yelena Rozenfeld, M.P.H.[1], Heather B. Miller, Pharm.D.[3], Cynthia Talbot, M.D.[3]; (1)Providence Medical Group, Portland, OR; (2)Southern Arizona VA Health Care System, Tucson, AZ; (3)Providence Medical Group - Milwaukie, Milwaukie, OR
Purpose: Previous group visit studies have been found to decrease emergency department and specialist utilization, increase patient and provider satisfaction, increase adherence to diabetes guidelines, and potentially lower health care costs. This study was designed in two phases: 1) to determine feasibility of multidisciplinary group visits, and 2) to measure the effect of group visits on clinical outcomes and guideline adherence. Other secondary endpoints include patient activation and satisfaction.
Methods: Subjects with diabetes mellitus (DM) and recent hemoglobin A1c (A1C) greater than 6.9% were enrolled by physician referral, with a goal of 8–12 patients per group. A total of four group visits over three months occurred, with certified diabetes educator-led group discussions, medication review and adjustment by clinical pharmacists, and limited physical exam/assessment by the physician.
Results: Eight subjects were enrolled with 84% completing all four visits. The mean age was 55.6 years old, mean hemoglobin A1C was 8.7%, and 38% had blood pressure (BP) or low density lipoprotein (LDL) measurements at goal. Six of the eight subjects had collaborative management referrals to pharmacy. A total of 24 patient visits were completed and billed, with total revenue of $4393, which did not include potential revenue from diabetes educators. At the end of the study period, the mean A1C was 7.5%; 62.5% and 100% had BP or LDL at goal, respectively.
Conclusions: This pilot study determined that group visits for patients with DM are financially feasible and may lead to improved clinical parameters.

229. Reimbursement of a pharmacist-run, diabetes and cardio-vascular risk reduction telephonic program in a community-based, primary care medical group.
Dawn C. Fuke, Pharm.D., John M. Joffer, Pharm.D., Teresa M Maddalone Swift, Pharm.D., Nanette Bultemeier, Pharm.D., Dara L. Johnson, Pharm.D., Yelena Rozenfeld, M.P.H.; Providence Medical Group, Portland, OR

Purpose: The Providence Medical Group Clinical Pharmacy Specialists (CPS) have been collaboratively managing patients using a combination of office and telephonic visits since 1997. Through partnership with the affiliated health plan, a pilot phase was developed to evaluate reimbursement of telephonic management for diabetes and associated cardiovascular risk reduction.
Methods: Patients with uncontrolled diabetes mellitus (DM), as defined by their primary care physician, were referred to the CPS by a provider. The CPS also evaluated and managed blood pressure (BP) and/or low density lipoprotein (LDL) if these values were also not at goal. Initial evaluation occurred either in an office or telephonic visit, with follow-up visits scheduled with the CPS. Telephonic visits were billed to the affiliated insurance of those patients with a clinical pharmacy services benefit.
Results: Chart review was performed on a random sample of patients who were discharged from pharmacy services between August 2009 through May 2010 (n=106). The mean patient age was 58 years, and 39.6% had a clinical pharmacy services benefit. The mean baseline hemoglobin A1C (A1C) was 9.4%, blood pressure (BP) 126/72 mmHg, and low density lipoprotein (LDL) 85.5 mg/dL upon initiation of pharmacy services. At discharge, the mean decrease in values were A1C 1.5% (p<0.05), 2.2/0.6 mmHg (p=NS), and 1.5 mg/dL (p=NS). Of the patients with a clinical pharmacy services benefit, 303 billable telephonic visits were completed, resulting in over $20,000 in revenue.
Conclusions: Reimbursed pharmacist-run services demonstrated

clinically and statistically significant reductions in A1C in the sample population of patients. Complete results for all patients discharged between August 2009 through 2010 will be presented at the meeting.

230. Pneumococcal vaccination rates during an immunization-focused ambulatory care advanced pharmacy practice experience.
Michelle T. Martin, Pharm.D., Daphne E. Smith-Marsh, Pharm.D., CDE, Jessica B. Michaud, Pharm.D., BCPS, Vicki L. Groo, Pharm.D., Juliana Chan, Pharm.D.; University of Illinois at Chicago, Chicago, IL

Purpose: The Centers for Medicare and Medicaid Services (CMS) adopted goals to increase pneumococcal vaccination rates. Clinical pharmacists at the University of Illinois Medical Center (UIMC) developed an advanced pharmacy practice experience (APPE) rotation to enhance pharmacy involvement in pneumococcal immunization efforts and to offer student pharmacists an opportunity to gain experience administering vaccinations in busy clinics.
Methods: During the 2008–2009 academic year, six student pharmacists trained and certified in immunization participated in an elective 6-week APPE clerkship at the UIMC ambulatory clinics. Students reviewed patient charts for eligibility to receive the pneumococcal vaccine, approached eligible patients during clinic visits to offer the vaccine, administered the vaccine if the patient consented, and documented vaccine administration in the electronic medical record. Patients were eligible if they were 65 years or older or met the Centers for Disease Control and Prevention recommendations.
Results: Students approached 373 patients who were eligible to receive the pneumococcal vaccination after screening; 124 (33 %) had previously received the vaccination. Of the remaining 249 eligible patients, 147 (59%) were vaccinated during their clinic visits. Common reasons for refusal included: 59 patients (24%) that did not want or think they needed the vaccine, and 32 patients (13%) who wanted to speak with their primary care provider first or think more prior to receiving the vaccination.
Conclusion: Student pharmacists were effective in vaccinating many of the patients who were eligible for the pneumococcal vaccine and updating medical records to reflect immunization administration. The implementation of a pharmacy-based ambulatory care immunization program may help achieve CMS pneumococcal vaccination goals. Students gained experience, and clinicians had more time for clinical responsibilities when student pharmacists assisted with vaccinations.

Cardiovascular

231E. The impact of a comprehensive medication counselling and education on rehospitalization and mortality of heart failure patients at an the Knofo Anokye teaching hospital in Ghana.
Charles Anane, B.Sc., Pharm, M.Sc., Clinical, Pharmacy; Komfo Anokye Teaching Hospital, Kumasi, Ghana

Purpose: The purpose of this study was to assess the impact of a comprehensive management programme for heart failure patients referred to the cardiac clinic of Komfo Anokye Teaching Hospital (KATH). The study involved a systematic approach to medication therapy, patient education and counseling and its impact on rehospitalization and mortality of heart failure patients after discharge.
Methods: The study group consisted of 104 heart failure patients admitted at medical wards of KATH, with moderate to severe heart failure i.e. NYHA II, III and IV functional classes from 1st July to 30th December, 2007. Out of this number, 87 patients were discharged and referred to the specialist cardiac clinic for follow-up from 1st January to 30th June, 2008. These patients were taken through a comprehensive medication counseling and education by heart failure team comprising cardiologists, nurses and clinical pharmacists.
Results: The study also shown that 16.35% of the patients died whiles on admission before referral compared with 6.9% who died after rehospitalization representing a decrease of 9.45% in mortality. Functional class had improved significantly in all the 81 patients with 69% classified within NYHA function class 1 and 26% in function class II. Only 5% of the patients remained in functional class III as compared to 12.50% of the patients before referral. There were no patients after referral in the functional class IV as compared with 4.81% before referral.

Conclusion: The study has shown that an integrated and innovative approach to the management of heart failure patients based on well structured medication education and counseling can contribute to improved patients outcomes, including reduced morbidity and mortality rates, improved functional status and quality of life. The programme also enhanced compliance, reduced rates of rehospitalization and prolonged survival.

Published in Presented at the 10th Commonwealth Pharmacists Association Conference/Pharmaceutical Society of Ghana Annual Conference, Accra-Ghana, WA, August 5–9,2009

232. Blood pressure level attainment among patients with coronary artery disease.
Karen J. McConnell, Pharm.D., BCPS, Jessica L. Morris, Pharm.D., Thomas Delate, Ph.D., M.S., Alicia A. Cymbala, Pharm.D., BCPS, Roseanne Hornak, Pharm.D., BCPS, Amy B. Kauffman, Pharm.D., BCPS, Brandy McGinnis, Pharm.D., BCPS, Kari L. Olson, Pharm.D., BCPS; Kaiser Permanente Colorado Region, Aurora, CO

Purpose: Guidelines recommend a goal BP <130/80 mmHg for patients with CAD, although the feasibility of achieving this is questionable. This study aimed to determine the proportion of patients with CAD and elevated BP who attained a BP <130/80 mmHg. Factors independently associated with attaining this BP were identified.
Methods: This retrospective cohort study included patients with established CAD and a mean of two consecutive BP readings >140/90 mmHg in 2006 or 2007, most proximal to 12/31/07. The cohort was followed from 1/1/08 (baseline) through 6/30/09 (follow-up) to ascertain the proportion who attained specific BP levels and examine patient- and provider-related factors (e.g. demographics, co-morbidities, medication use, clinical aspects of BP measurements) associated with those levels. The follow-up BP level was the mean of the last two consecutive BP readings most proximal to 6/30/09.
Results: There were 1380 patients evaluated with 35% (n=482), 34% (n=469), and 31% (n=429) of patients attaining a BP <130/80 mmHg, 130/80 to 139/89 mmHg, and ≥140/90 mmHg, respectively, at follow-up. Factors associated with a decreased likelihood of attaining a BP <130/80 mmHg were higher baseline systolic (OR 0.97; 95% CI, 0.96–0.98) or diastolic (OR 0.99; 95% CI 0.97–0.99) BP. Factors associated with an increased likelihood of attaining a BP <130/80 mmHg were having a cardiac event during the study period (OR 2.04, 95% CI, 1.06–3.85) and more clinic visits (OR 1.02, 95% CI, 1.01–1.04). With each mmHg increase in systolic BP, there was a 4% increased likelihood of having an elevated BP addressed in clinic (OR 1.04, 95% CI, 1.03–1.05).
Conclusion: Approximately one-third of patients with CAD and elevated BP attained a BP <130/80 mmHg. Higher utilization of the heath care system (possibly due to a recurrent cardiac event) was associated with an increased likelihood of reaching this BP. Consistently addressing elevated BP during each clinic visit may lower BP levels.

233. Clinical efficacy comparison of bovine thrombin and compression method in femoral pseudoaneurysm of patients undergoing PCI (percutaneous coronary intervention) at Rajaie Heart Center.
Fariborz Farsad, Pharm.D., Hamidreza Pouraliakbar, M.D., Abbas Zavarehee, Ph.D., Hooman Bakhshande, Ph.D., Maryam Nadermohammadi, Pharm.D.; Rajaie Heart Center, Tehran, Iran

Purpose: Pseudoaneurysm has been an increasingly common complication of catheterization procedures during the past two decades with greatest incidence in femoral artery. Treatment of iatrogenic femoral artery pseudoaneurysms with thrombin injection has been reported as an efficacious and safe procedure. The major risk of this procedureis distal limb ischemia from thrombosis, resulting from thrombin escape. In this study we evaluated the efficacy and success rate of percutaneous ultrasonographically guided thrombin injection and compression method to treatment of pseudoaneurysm, and determine the effects of thrombin injection on systemic coagulation parameters.
Methods: 40 femoral pseudoaneurysms between 15–85 years old after

PCI (percutaneous coronary intervention) were randomized in two groups,one treated with compression method the other treated with US (ultra sound)-guided percutaneous thrombin injections.thrombin vials were reconstituted with normal salin 0.9% in hospital pharmacy under laminar air flow. Pseudoaneurysm size, neck length and width, thrombin dose, thrombosis time,outcome of therapy, and complications were documented prospectively. Duplex sonographic follow-up examinations were performed at 0 and 24 hours afte wards. partial thromboplastin time and Quick test (prothrombin time) in patients before and after intervention were monitored.
Results: Mean size of pseudoaneurysms was 3.8 cm x 2.7 cm.twenty thrombin injections were performed. Mean thrombin dose was 100 IU ± 700 IU in pseudoaneurysms. Primary success rate of thrombin injection was 94.5–96%(18 of 20 patients) which was significantly higher than compression method,74% (15 of 20 patients) (p<0.05). Secondary success rate was 100%. No thromboembolic, infectious, or allergic complications occurred except 1 from 20 patients.
Conclusion: US-guided percutaneous injection of thrombin is successful and safe in the management of femoral pseudoaneurysms. Changes in coagulatory factors indicates the possibility of thrombin passage into the arterial circulation.

234. Evaluation of 30-day Heart Failure Readmissions.
Vicki L. Groo, Pharm.D., Krista Williams, Pharm.D., Carolyn Dickens, APN, Thomas D. Stamos, M.D., Robert DiDomenico, Pharm.D.; University of Illinois at Chicago, Chicago, IL

Purpose: Readmissions within 30 days for heart failure (HF) was identified by CMS as common, costly, and often preventable. The first annual CMS 30-day HF readmission measures placed the University of Illinois Medical Center (UIMC) as worse than the US National Rate. We sought to identify risk factors for readmission and areas requiring improvement in care for HF at UIMC.
Methods: Retrospective cohort of patients > 18 years with discharge diagnosis of HF from 4/1/08 to 3/31/09. Cases had a 30-day readmission whereas controls had no readmissions in 6 months. Cases and controls were compared using unpaired-*t* test or χ^2 at the index admission.
Results: Cases included 51 patients age 63 ± 17 years, 24 females. Controls included 51 patients age 65 ± 14 years, 30 females. Cases were more likely to have mod-severely reduced EF (p=0.035), otherwise PMH was similar. There was no difference in the suspected cause of admission including non-adherence. Cases had a higher BNP on admit: 1302 ± 1161 vs. 852 ± 929 pg/ml (p=0.028). LOS was similar at 3.6 ± 3.2 vs 3.2 ± 3.0 days (p=ns). There was no difference in treatment during hospitalization (overall: IV diuretics 93%, IV NTG 5%, IV inotropes 10%) or in the use of ACE/ARB, beta-blockers, diuretics, NTG, hydralazine, spironolactone or digoxin at discharge. Patients' whose ACE/ARB, b-blocker, or diuretic dose was adjusted at discharge was the same between groups. Scheduled follow-up was earlier in cases (14 vs 21 days) p=0.015, however 33% of cases were readmitted prior to their follow-up appointment.
Conclusion: Cases were more likely to have a lower EF, higher admit BNP, and be readmitted prior to their follow-up appointment but had no difference in treatment compared to controls. More intense drug therapy and follow-up are potential areas for improvement in care.

Clinical Research

235. A public survey on receptivity to pharmacy-directed clinical research educational resources.
Jill Chappell, Pharm.D.[1], Zachary Hallinan, M.S.[2], Brian P. Schrock, M.S.[1], Diane Simmons, B.A.[2], Dorothy L. Smith, Pharm.D.[3]; (1)Eli Lilly and Company, Indianapolis, IN; (2)Center for Information and Study on Clinical Research Participation, Boston, MA; (3)Consumer Health Information Corp., McLean, VA

Purpose: Clinical research is fundamental to evaluate and understand medicines, yet public perception of clinical research has declined. Hypothesizing that pharmacists represent an untapped resource to educate and engage the public about clinical research, this study examined, via survey, patients' perspectives on receiving information about clinical research from their pharmacist.

Methods: 147,000 members of online social networks from 54 public/patient organizations received an e-questionnaire between 4/2 and 4/26/2010. Nineteen questions assessed respondent demographics and: (1) current health and clinical research information received by patients from pharmacists; (2) patient receptivity to clinical research information delivered by pharmacists; and (3) perceptions around the content and distribution method of this information. Chi-square tests were used to determine significant associations.
Results: 2650 respondents were from all U.S. states, aged 13-87 (median=51), primarily female, educated (72% completed college or higher), and used chain or grocery pharmacies (73%). 72% of respondents indicated they were very/somewhat interested in receiving clinical trial information from a pharmacist; <1% currently receive this information from their pharmacist. Few respondents (<2%) had ever asked for this information; 74% indicated interest in receiving information about clinical trials in nonstructured responses. Analyses indicated statistically significant differences in interest and need by demographic group; however, all pharmacy users desired information at rates greater than 77%, regardless of age, gender, education, pharmacy type, or geography. Primary areas of interest included finding a trial, safety of trials, and general information; printed information or email were preferred methods.
Conclusion: These results suggest that pharmacy users across demographics would be interested in receiving clinical trial information from their pharmacist. Education of patients about clinical research could provide an opportunity to strengthen pharmacist-patient relationships.

Community Pharmacy Practice

236. A searchable health data repository to enhance community-based pharmacy practice research.
Amy M. Franks, Pharm.D.; University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR

Background: Students and faculty from the UAMS College of Pharmacy frequently plan and conduct community health screenings. Historically, data were not tracked on a participant level to allow follow-up with participants or conduct of future research projects.
Purpose: To illustrate the utility of organized data collection from health screenings to enhance pharmacy-based research efforts in the community.
Methods: Participants in all UAMS College of Pharmacy-sponsored health screenings completed a brief form providing demographic, education, and health information. Participants were given the option to provide name and contact information for consideration as participants in future research, quality assurance, or education projects. Unique identifier numbers were assigned to each participant. A database was designed using Microsoft Office Access 2007.
Results: The uniform data collection procedures were implemented in January 2009. Data from 30 student-led health screenings held during the 2009 calendar year were entered in the database, resulting in participant-level data from 1058 adult screening participants. Five hundred sixty-two (53.1%) participants provided sufficient information for re-contact (name, mailing address, phone number). Two hundred eighty-six (27.0%) provided e-mail addresses for future correspondence. Participant-provided demographic and health risk behaviors (exercise, smoking status) were linked to data obtained from point-of-care health screening activities (blood pressure, glucose, lipid profiles, body mass index, percent body fat, and bone density T-scores). Female (66.2%) and minority (37.4%) participants are well-represented in the sample.
Conclusion: The newly developed research repository provides a rich resource to aid in identification of potential research subjects. Included data allows researchers to refine the potential research sample by considering health risk data and participant-reported health behaviors. This research repository will assist researchers in designing and investigating future community-tailored strategies to improve health.

Critical Care

237. Retrospective evaluation of the incidence of hypoglycemia and related outcomes with intensive insulin therapy in critically ill patients.
Maha Kadafour, Pharm.D., Patricia Parker, Pharm.D., Andrea Bechtold, Ph.D., Nancy Wu, M.S., Tina Palmieri, M.D.; University of California Davis, Sacramento, CA

Purpose: The aims of this study are to 1) assess and characterize the incidence of hypoglycemia with the current institutional insulin infusion protocol for ICU patients targeting a blood glucose of 70–120mg/dL , and 2) determine if a relationship exists between hypoglycemia and duration of mechanical ventilation, ICU length of stay and hospital length of stay.
Methods: A retrospective chart review was conducted on all ICU patients who were initiated on an insulin infusion between 08/01/2008 and 08/01/2009. Patient demographics, co-morbidities, diagnoses, blood glucose and point of care glucose readings, administration of dextrose, duration of mechanical ventilation, APACHE II score, and duration of ICU and hospital length of stay were documented.
Results: Of 741 patients initiated on an insulin infusion, 454 patients met inclusion and exclusion criteria. The overall rate of hypoglycemia was 49% and severe hypoglycemia was 9%. The average number of episodes and severity of hypoglycemia was variable depending on ICU service, but overall, patients experienced 3 episodes of hypoglycemia and 2 episodes of severe hypoglycemia. A relationship was found between hypoglycemia and prolonged duration of ventilation for Burn, Cardiac, Thoracic and Trauma Surgery patients. A relationship also exists between prolonged hypoglycemia and ICU and hospital length of stay for Cardiac and Trauma Surgery patients. There was no relationship between 30-day mortality and hypoglycemia.
Conclusion: The current ICU insulin infusion protocol is associated with high rates of hypoglycemia and severe hypoglycemia necessitating a revision of the current protocol to have a less aggressive target range to reduce the incidence of hypoglycemia and potential for morbidity and mortality.

Drug Information

238. Problem-oriented medicines information services on a pharmacist-operated centre at a University Hospital.
Ana C. Ribeiro Rama, Ph.D.[1], Cristina M. Silva, Pharm.D.[2], José A. Feio, Pharm.D.[3]; (1)Pharmacy Department, Coimbra University Hospitals and Center for Pharmaceutical Studies, Faculty Pharmacy, Coimbra University, Coimbra, Portugal; (2)Faculty of Pharmacy, Porto University, Porto, Portugal; (3)Hospitais da Universidade de Coimbra, Coimbra, Portugal

Purpose: To assess the scope of services performed by a national medicines information centre for all types of healthcare professionals.
Methods: To assess activity of the centre, during the 7 years evaluation period, 2000–2006, we will review information on what, how and why service was performed, through the evaluation of inputs, processes and outputs. Data collection for outputs analysis was carried out on 6414 requests. Descriptive statistics (Microsoft Excel) was used to analyze much of the data. Quality assurance was carried out through a survey sent to 500 users.
Results: Conception and development will be described regarding scope, affiliation and funding. Inputs evaluation involves the main goal of the service, personnel, availability, information resources and education activities. The processes implicated in the answer to information requests according to developed guidelines are described. A created hierarchic system to classify clinical question will be presented. Outputs analysis based on classification system covers: time spent in different activities (51% answering requests); Total number of request/year; ways of contact used (45.4% telephone); type of question (40.6% disease/medication-oriented; 21.2% patient-oriented); Type of subject (51.4% pharmacotherapy); medication-oriented requests were related in 14% to central nervous system medications, 12% antineoplastic agents. Characterization of users shows that 75.6% were from the public sector and 24.6% private sector with ppharmacists and physicians the most frequent users.

Education and training to pharmacy students, pharmacy residents and hospital pharmacist's postgraduate courses were also performed. Quality assurance survey regarding utility, quality and satisfaction returned 65.6% answers with calculated scores qualifying serve as very satisfied and excellent.

Conclusion: The activities developed are mainly related to answering requests patient, disease and medication-oriented, from pharmacists and physicians. Classification system is a good base to evaluate performance. Survey shows that service is performed with quality, is useful and users are satisfied.

Education/Training

239. A combined pharmacy practice residency / Master of Public Health (MPH) postgraduate program.

Amy M. Franks, Pharm.D.[1], Leslie A. Mooney, Pharm.D.[1], Katharine E. Stewart, Ph.D., M.P.H.[2], Cindy D. Stowe, Pharm.D.[1], Lisa C. Hutchison, Pharm.D., M.P.H.[1], Paul O. Gubbins, Pharm.D.[1], Stephanie F. Gardner, Pharm.D., Ed.D.[1]; (1)University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR; (2)University of Arkansas for Medical Sciences Fay W. Boozman College of Public Health, Little Rock, AR

Purpose: Integration of public health principles in pharmacy practice is evident, yet few pharmacy practitioners have advanced knowledge of public health concepts. We describe the development and implementation of a combined Pharmacy Practice Residency/Master of Public Health (MPH) program as a new model in postgraduate pharmacy education.
Methods: Faculty from the Colleges of Pharmacy (COP) and Public Health (COPH) designed a unique 2-year structured postgraduate program to allow simultaneous completion of a pharmacy practice residency and M.P.H. degree. M.P.H. curriculum includes core, elective, and capstone courses (18, 18, and 6 credit-hours, respectively). Six specialty tracks accommodate the resident's public health concentration (biostatistics, epidemiology, environmental/occupational health, health education/health behavior, and health policy/management). At least 10 month-long clinical rotations in interdisciplinary team settings are scheduled during the 2-year period. Residents may select clinical experiences to complement M.P.H. coursework, thus interweaving clinical experiences with public health focus. Work/life balance is considered during scheduling of the combined program experiences. A Residency Advisory Committee assists the resident in meeting program goals.
Results: The program launched in May 2009 with enrollment of its first resident. As a full-time employee, the resident receives a 70% tuition discount in COPH; the remainder of the tuition is included in the program's benefits package. The resident's program plan has been tailored to her focus in academia and chronic disease control/prevention. Elective coursework focuses on biostatistical methods and health behavior, while clinical experiences focus on cardiology and ambulatory care. After 1 year, the resident has completed 7 clinical rotations and 24 M.P.H. credit-hours (average 8 hours/term). The resident's successful completion of the program is planned for summer 2011.
Conclusion: The combined Pharmacy Practice Residency/M.P.H. Program represents a novel educational experience well-suited for motivated pharmacy graduates with desire to integrate public health principles into clinical pharmacy practice.

240. Characterizing the ACCP Education and Training PRN membership in 2010.

Nancy L. Shapiro, Pharm.D., BCPS[1], Heather P. Whitley, Pharm.D., BCPS, CDE[2], Michael J. Peeters, Pharm.D., ME.d., BCPS[3], Sekhar Mamidi, Pharm.D.[4], Samatha Karr, Pharm.D., BCPS[5], Tina H. Denetclaw, Pharm.D., BCPS[6]; (1)University of Illinois at Chicago, Chicago, IL; (2)Auburn University, Harrison School of Pharmacy, Tuscaloosa, AL; (3)University of Toledo College of Pharmacy, Toledo, OH; (4)Ohio Northern University Raabe College of Pharmacy, Ada, OH; (5)Midwestern University College of Pharmacy, Glendale, AZ; (6)University of California at San Francisco School of Pharmacy, San Francisco, CA

Purpose: The Education and Training (EDTR) Practice & Research Network (PRN) was recognized by ACCP in 2002 with 52 members. The first demographic membership survey, completed in 2003, helped to initially inform and shape the direction of the PRN. Since that time, the PRN's membership has grown substantially to 328 members in May 2010. As a result, the 2003 member survey results may not continue to hold validity within the current membership constituency. The purpose of this survey is to characterize the current membership of the EDTR PRN.
Methods: A membership committee within the EDTR PRN constructed a 30-question survey and posted it onto Survey Monkey. The link was sent to all EDTR PRN members within the listserv. Members will have the month of June 2010 to complete the survey.
Results: To date, the EDTR PRN membership is comprised of 14 PharmD students, 4 residents, 2 fellows, with the remainder of members out of training. As well (and different for 2003), 28 members are ACCP Fellows, and 7 are members on the ACCP Board of Regents. The survey is currently being administered, and the results will be available for the ACCP 2010 Annual Meeting in Austin, TX.
Conclusion: The survey results will be compared with the initial survey results from 2003. This information will guide the direction of the PRN in the coming years.

241E. Cost savings of clinical interventions made by Pharm.D. students at a community teaching hospital.

Pamela M. Moye, Pharm.D., BCPS, *Lisa M. Lundquist, Pharm.D., BCPS*, Phillip S. Owen, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

Purpose: To determine cost savings by pharmacy students' clinical interventions at a community teaching hospital.
Methods: Clinical interventions of fourth year pharmacy students completing advanced pharmacy practice experiences (APPE) in ambulatory care, internal medicine, and critical care at a community teaching hospital were compiled. All intervention data from May 2008–October 2008 were recorded on a data collection form and were classified by intervention type. Intervention types included: allergy clarification, order clarification, medication initiation/discontinuation, dose evaluation, laboratory evaluation, antibiotic recommendation and IV to PO. The data were entered into Quantifi®, a computer software program to record clinical intervention data. A dollar value was associated with each intervention to record a total of estimated cost impact.
Results: A total of 449 clinical interventions were attempted; 371 (79%) were accepted. Overall, cost savings for the accepted intervention for the 6-month period was $57,955 ($34,272 ambulatory care, $14,794 internal medicine, $8,889 critical care). The major types of attempted clinical interventions with corresponding cost savings and acceptance rates (AR) include: medication initiation/discontinuation (n=153, $18,207; AR= 78%) laboratory evaluation (n=110, $14,382; AR=85%), clarification of orders (n=63, $9,639; AR=100%), dose evaluation (n=80, $9,639; AR= 79%), and antibiotic recommendations (n=33, $5,136; AR= 73%).
Conclusion: Pharmacy students on faculty-precepted APPE have the potential to impact cost savings for a health system through clinical interventions in ambulatory care, internal medicine, and critical care. The type of interventions with the highest acceptance rates and cost savings opportunities were laboratory evaluation, clarification of orders, dose evaluation, and medication initiation/discontinuation.
Presented at American Association of Colleges of Pharmacy Annual Meeting, Seattle, WA, July 12, 2010.

242. Impact of pharmacist-provided nursing education on medication history accuracy.

Erin M. O'Toole, Pharm.D., Susan M. Fosnight, R.Ph., Kathleen F. Cubera, R.Ph., Maria J. Giannakos, Pharm.D., Dorcas J. Letting, Pharm.D.; Summa Health System - Akron City Hospital, Akron, OH

Purpose: Identify the barriers of obtaining accurate medication histories and subsequently test the efficacy of a pharmacist-driven educational program to overcome the modifiable barriers.
Methods: This is a three phase, prospective observational study. In the initial phase, the pharmacist obtained a medication history from the patient and compared it to the nurse-obtained list. All discrepancies

were categorized and tabulated. This information was used in the interventional phase to develop a nursing education program focusing on the modifiable barriers. Once education was completed, identical methods to the initial phase were implemented in the final phase. The results from the initial phase were compared to those from the final phase. The primary outcome of the study was to evaluate the change in total discrepancies after nursing education was delivered.
Results: In the initial phase, 46 patients were included and 205 discrepancies were identified. After the education program, 44 patients were included and 150 discrepancies were identified. The difference in total number of discrepancies per patient decreased by 10.6% (mean discrepancies per patient = 4.46 vs. 3.41, p=0.096).
Conclusion: Accurate medication reconciliation is not possible without an accurate medication history. This targeted education program was able to decrease the discrepancies in medication histories by more than one discrepancy per patient. Although not statistically significant, this may translate into clinical significance by avoidance of adverse medication events resulting from inaccurate medication reconciliation. Pharmacist-provided education is effective in decreasing the number of discrepancies on medication histories.

243. An educational intervention to increase college aged adults' awareness of COPD and COPD risk-associated behaviors.
Michael J. Gonyeau, B.S., Pharm.D., BCPS[1], Beverly Belisle, B.S.[2]; (1)Northeastern University School of Pharmacy, Boston, MA; (2)Northeastern Univeristy School of Pharmacy, Boston, MA

Purpose: Chronic Obstructive Pulmonary Disease (COPD) is the 4th leading cause of death and prevalence and mortality rates are increasing. 18-20% of adults ≥40 who smoke or have smoked will acquire COPD. Health strategies have changed from early disease detection/intervention to risk reduction and disease prevention. Our objectives were to target college-aged adults to determine effects of an educational intervention on COPD awareness and education, changes in COPD risk-associated behaviors, as well as preferences of different educational strategies/media.
Methods: Pre- and post-educational intervention surveys were distributed. The pre-survey assessed participants' baseline knowledge of COPD and current smoking behavior. The educational intervention consisted of a COPD presentation (risk factors, signs/symptoms, associated costs, death rates) and a live demonstration of how a COPD patient breathes, followed by dissemination of written materials. Each participant was invited to join a Facebook group for COPD awareness containing the same information presented as well as useful COPD links and photographs/videos. The post-survey was administered two weeks later to determine any change in COPD knowledge, smoking habits and which educational method was most helpful.
Results: 100 students (64% female) completed pre- and post-surveys (mean age 21.4 ± 1.8 years). Increases in COPD information including symptoms (pre = 4% post = 24%; p<0.01), mortality rates (pre = 44% post = 82%; p<0.001) and smoking as number one risk factor (pre = 90%, post = 100%; p=NS) were observed. Most students (66%) stated that the COPD demonstration/live presentation were the most educational, followed by written material (16%) and Facebook (8%). Students who smoked socially decreased from 14% to 12% (p=NS), and an additional 4 students stated quitting smoking on the post survey.
Conclusions: Targeting college-aged students with a COPD awareness educational intervention improves knowledge of the disease symptoms as well as risk factors and avoidance behavior strategies.

244E. A 12-week integrated ambulatory care and internal medicine APPE.
Michael J. Gonyeau, B.S., Pharm.D., BCPS[1], Maureen McQueeney, Pharm.D.[2]; (1)Northeastern University School of Pharmacy, Boston, MA; (2)Northeastern Univeristy School of Pharmacy, Boston, MA

Purpose: Reports from AACP and ACCP state that to ensure quality experiences, educators are encouraged to actively involve students in patient-centered care, support preceptor development and focus education on development of skills, attitudes and values. Our objectives were to describe and discuss the development of an integrated APPE model, identify barriers to successful implementation

and value added to students, preceptors and institutions, and to assess student attitudes regarding the integrated APPE.
Methods: A 6-week ambulatory care and 6-week internal medicine APPE were integrated into a longitudinal 12-week APPE comprised of a fluid structure where students were required to transition from inpatient to outpatient services within the same day and sign-out responsibilities to one another in such transitions similar to medical and nursing models. Students were given greater exposure to the continuum of care experienced by patients by providing pharmacy services to patients beginning while in the hospital and continuing with outpatient care at follow-up appointments for patients utilizing the hospital internal medicine clinic. Typical student responsibilities included medication reconciliation, provision of drug information, therapeutic drug monitoring and discharge counseling. Potential benefits over traditional APPE models include: decreased orientation time for students and preceptors, greater breadth of disease state exposure, increased interactions and stronger relationship development with patients, other healthcare providers and APPE preceptors and increased interaction and communication with other pharmacy students.
Results: Twelve students will have completed the integrated APPE and post-APPE survey results evaluating students' attitudes and perceived benefits of learning with this model, as well as comments regarding perceived strengths and weaknesses will be presented.
Conclusion: This study hopes to demonstrate the benefits of a 12-week integrated APPE model on students' learning and attitudes. It will serve as model for others considering this approach.
Presented at AACP Annual Meeting, Seattle WA, July 2010

245. Nontraditional Post Graduate Year 2 (PGY-2) Pharmacy Residency in Critical Care at a Large Urban Teaching Hospital.
Tracey J. Lasak, Pharm.D., Edward G. Szandzik, B.S.Pharm., M.B.A., Mark E. Mylnarek, B.S.Pharm., Michael A. Peters, B.S.Pharm.; Henry Ford Hospital, Detroit, MI

Purpose: The creation, structure and implementation of a nontraditional PGY-2 pharmacy residency in critical care at a large urban teaching hospital.
Methods: An accredited nontraditional PGY-2 critical care pharmacy residency at Henry Ford Hospital, an 800 bed urban teaching hospital in Detroit, Michigan, was developed for additional training of clinical staff pharmacists who have a PGY-1 residency and are employed by Henry Ford Hospital. This program was modeled after the existing PGY-1 nontraditional program at Henry Ford Hospital that is also accredited by the American Society of Health-Systems Pharmacists. The program consists of an orientation, 11 four week rotations including 2 medical ICU rotations, 2 surgical ICU rotations, 1 neurosurgical rotation, 1 cardiovascular rotation, 1 emergency department rotation, 1 infectious disease stewardship rotation, 1 solid organ transplant rotation and 2 elective months. Candidate requirements include a certificate of completion from an accredited PGY-1 residency, employment by the hospital before applying for this position and a desire to enhance their clinical skills. Funding for the residency is provided through the pharmacy department as the pharmacist resident is a staff member and required to work as a staff pharmacist 8 months of the year. Challenges faced during the program included scheduling, keeping a pool of applicants on staff that meet the program requirements, and coordination of the resident's rotations and activities with the staffing model to keep within the department budget.
Conclusion: The non traditional PGY-2 pharmacy residency in critical care was modeled after an existing PGY-1 program at a large urban teaching hospital, to provide an opportunity for clinical pharmacist to continue their education, enhance their clinical skills and become a specialist in critical care.

246. Effects of an integrated internal medicine and ambulatory care APPE on clinical interventions.
Michael J. Gonyeau, B.S., Pharm.D., BCPS[1], Maureen McQueeney, Pharm.D., BCPS, CDE[2]; (1)Northeastern University School of Pharmacy, Boston, MA; (2)Northeastern Univeristy School of Pharmacy, Boston, MA

Purpose: Most APPEs occur from 4–6 weeks, allowing a narrow window for students to feel comfortable and confident in their clinical responsibilities before moving on. This affects their ability to accurately and completely document clinical interventions. Our objectives were to evaluate the effects of an integrated 12-week APPE model on the documentation of clinical interventions in both an internal medicine (IM) and ambulatory care (AC) setting and to quantify value added to students, preceptors and institutions of this model.

Methods: A 6-week AC and IM APPE were integrated into a longitudinal 12-week APPE comprised of a fluid structure where students transitioned from inpatient to outpatient services within the same day and completed sign-out responsibilities similar to medical and nursing models. This increased student exposure patients transitioning from inpatient to outpatient care. Clinical intervention documentation was required via a web-based system and data from the integrated APPE was compared to previous students from each preceptor from stand-alone AC and IM rotations at the same hospital. Specific comparisons included: number/type of interventions, common drugs and disease states, clinical and economic impact, and acceptance rates.

Results: Twelve integrated APPE students documented 1984 interventions vs. 873 interventions from 12 students completing separate APPEs with the same preceptors (p<0.001). Intervention categories remained consistent with a significant increase in medication histories performed (11.5% to 18.3%). The percent of student-initiated interventions without direct preceptor aid also increased (67.6% to 75.9%), which may indicate an increased level of confidence of students on the integrated APPE. The student documented intervention level of significance also increased in the integrated model.

Conclusion: An integrated APPE decreases orientation time for students and preceptors, increases interactions and promotes stronger relationship development with patients, other healthcare providers and APPE preceptors and increases clinical intervention documentation.

247. Utilization of recorded therapeutic lectures in a school of pharmacy.
Paul Juang, Pharm.D., Alexandria Wilson, Pharm.D.; St. Louis College of Pharmacy, St. Louis, MO

Purpose: Recent studies have indicated that use of technology, such as recorded multimedia lectures, has been effective in supplementing student comprehension in large lecture courses in the higher learning setting. The purpose of this study was to examine the student expectations and utilization of recorded multimedia lectures designed to supplement a large lecture-style therapeutics course in a school of pharmacy as well as its effects on the course.

Methods: This single center, case-controlled observational study was conducted through the administration of a pre- and post-course survey administered to students enrolled in a 5th year pharmacy therapeutics course. Outcomes examined included the student utilization, rationale for viewing, expectations and perceived effect on class attendance with recorded course lectures. Chi-square test was used to analyze the data.

Results: One hundred and ninety-one students were surveyed with 145 and 101 responses to the pre- and post-survey, respectively. Students frequently viewed the recorded lectures to take notes on material or keep up with material that the lecturers mentioned during lecture. In examining student behavior in the course, more students utilized recorded lectures in place of attending live lectures (P<0.01) and less students utilized recorded lectures in addition to attending live lectures (P<0.01). Student usage was greatest within a week of the lecture as well as within 24 hours of the exam. Even though students stated that they seldom or occasionally used recorded lectures in place of attending live lectures, overall, students indicated that the recorded lectures greatly decreased or decreased the number of students attending live lectures. Student expectations on the availability of recorded lectures did not change.

Conclusion: Use of recorded therapeutic lectures have been successful in supplementing student reviewing of materials that were covered during the live lecture but played a large part in decreasing student attendance during the live lectures.

248. Implementation of medication therapy management in the post computerized physician order entry era.
Anita P. Rahman, Pharm.D., Kristin S. Alvarez, Pharm.D., Alissa Lockwood, Pharm.D., Carrie Berge, Pharm.D.; Parkland Hospital, Dallas, TX

Purpose: The objective of this quality improvement project was to implement a medication therapy management (MTM) service in a public health system following the transition to computerized physician order entry (CPOE).

Methods: The pharmacy department surveyed senior administration in regards to broadening clinical pharmacy services and specific areas were identified. During phase I, all inpatient pharmacists were invited to participate in the MTM project and interested individuals were interviewed. Based on areas of strength and personal preference, the management team assigned selected pharmacists to predetermined teams. MTM pharmacists were provided 2 weeks of training with a Clinical Pharmacy Specialist and emphasis was placed on therapeutic guidelines. Bi-weekly meetings were conducted with the pharmacy staff and administration to discuss process improvement. For analysis of phase I, physicians and inpatient pharmacists were surveyed.

Results: Eight-six percent of physicians surveyed agree that MTM services improve patient management, 77% state that clinical pharmacists promote evidence-based prescribing, and 83% believe that MTM services have a positive impact on medication management and disease outcomes. Based on written responses, pharmacists indicate an increase in job satisfaction.

Conclusions: Physicians and pharmacists believe MTM services are a vital component in providing quality patient care in the post-CPOE era. Furthermore, the increase in job satisfaction with implementation of this service is despite the fact that the project did not provide monetary incentives to those who participated. The goal of phase II is to assess patient outcomes including patient satisfaction, decreased length of stay, medication compliance, lower re-admission rates, decreased adverse events, and cost avoidance to the patient and to the institution. Future directions for the project include expanding services and staff development.

249. Development of a novel medical home: an interprofessional teaching clinic in an assisted living facility.
Karen Gunning, Pharm.D., BCPS, FCCP[1], Susan Saffel-Shrier, M.S., R.D.[2], Wilhelm Lehmann, M.D., M.P.H.[2], Nadia Miniclier, M.S., PA-C[2], Timothy Farrell, M.D.[2]; (1)University of Utah Departments of Pharmacotherapy & Family and Preventive Medicine, Salt Lake City, UT; (2)University of Utah Department of Family & Preventive Medicine, Salt Lake City, UT

Purpose: To describe the development of a novel medical home in an assisted living facility; demonstrate the integration of pharmacy students with physician assistant (PA) students and family medicine (FM) residents in the provision of care, and document the qualitative responses of pharmacy students after participating in the experience.

Methods: While pharmacists have been extensively involved in the provision of medications, and to some extent consulting for patients in assisted living facilities, the provision of direct care in coordination with primary care providers has not been well documented. Along with FM residents and PA students, fourth year pharmacy students on an advanced pharmacy practice experience (APPE) in family medicine participated in patient assessment, care plan development and discussion in 4–5 clinic days at an assisted living facility over a 6-week clerkship.

Results: The interprofessional assisted living clinic has been operational since January 2008, with 23 pharmacy students participating. Student opinions regarding the experience were elicited, and the following themes emerged: students valued the experience working with PA students and FM residents; felt valued in their role as the medication expert of the team, and felt a connection to the patients, as many of them saw the same patient for 4 or 5 visits, establishing continuity in the face of changing resident and PA learners at the clinic.

Conclusion: An interprofessional clinic experience in an assisted living center has been successful in its goal of providing important lessons in interprofessional communication for pharmacy student

learners. Future goals include quantifying the effect of pharmacist influence on medication safety and appropriateness in this novel setting and evaluating the influence of experience with patients in this setting on future career plans for pharmacy students.

250. Send in the clowns! Humor and humanism in medicine.
Carolyn C. Brackett, Pharm.D; The Ohio State University College of Pharmacy, Columbus, OH

Purpose: To expand our capacity to make genuine, compassionate, healing contact with patients, and in so doing, enhance our efficacy as healthcare providers.
Methods: Students from The Ohio State University Colleges of Pharmacy and Medicine travel as clowns to hospitals, community service health events, nursing homes, and special-education facilities. Both from experience with patients and from instructional sessions, how to interact with compassion, humor, spontaneity, and celebration with patients, families, and co-workers. The teaching model mirrors Dr. Patch Adams' approach to clowning, which emphasizes humanism and tenderness in care. Workshops and reflective exercises give students basic tools that can be used in groups and at bedsides to facilitate humanistic interactions with patients and protect caregivers from burnout.
Results: Patients and students alike enjoy the program thoroughly! Students learn to approach patients as fellow humans rather than from the restricted position of a professional role. They report feeling much more relaxed and happy when working with patients during their clinical rotations, and feeling empowered to assume humanistic care of others.
Conclusion: Teaching the rudiments of humor and compassion through clowning enhances students' ability to give effective care.

Emergency Medicine

251. Impact of Emergency Pharmacist and Emergency Nursing Pneumonia Protocol.
Darrel W. Hughes, Pharm.D., BCPS[1], Kimberlea King, B.S.N., R.N.[2], Denise De La Rosa, B.S.N., R.N., CEN, CCRN[2]; (1)University Health System/University of Texas Health Science Center San Antonio, San Antonio, TX; (2)University Health System, San Antonio, TX

Purpose: To assess the impact of a pneumonia protocol (PNA-P), designed by an Emergency Pharmacist and Emergency Center Nursing Leadership, on time to administration of anti-infectives, a Center for Medicare & Medicaid Services (CMS) Core Measure.
Methods: Quality records of pneumonia patients presenting to the Emergency Center at University Hospital, San Antonio, TX between September 1, 2009 and May 31, 2010 were reviewed. Patients' age, registration time, signs and symptoms of pneumonia, pneumonia type, time of anti-infective order, and time to administration of anti-infectives were documented.
Results: Two hundred seventy two patients presented with pneumonia during the 9-month study period. Community acquired pneumonia (CAP) and health-care associated pneumonia (HCAP) accounted for 85.2% and 14.8% of pneumonias respectively. Triage nurses successfully initiated the PNA-P in 85.2% of patients who met PNA-P criteria. Among patients with CAP, 89% of patients received anti-infectives within 6 hours of registration compared to 78% during the congruent period of 2008–2009. A greater proportion of PNA-P patients received anti-infectives within 6 hours of registration vs. non-PNA-P patients (91% vs. 67%, p<0.0005). The median time from registration to administration of anti-infectives was 246 minutes (IQR 167–346) overall, and 244 minutes (IQR 167–311) vs. 278 minutes (IQR 165–746) for CAP PNA-P patients vs. non-PNA-P patients respectively (p=0.11). Combination 3rd generation cephalosporin plus a macrolide accounted for 85% of CAP treatment followed by respiratory fluoroquinolone (10%) and macrolide monotherapy (5%).
Conclusions: Implementation of the PNA-P increased the proportion of pneumonia patients who received anti-infectives within 6 hours of registration compared to the congruent 2008–2009 time period. Activation of a PNA-P in the Emergency Center increases the likelihood that patients with CAP receive the first dose of anti-infectives within six hours of registration, a CMS core measure.

Family Medicine

252. Effect of pharmacist interventions on the management of diabetes mellitus, hypertension, and hyperlipidemia in a family medicine clinic.
Erin Lockard, Pharm.D.[1], *James D. Hoehns, Pharm.D.*[2]; (1)Northeast Iowa Family Practice Center, Waterloo, IA; (2)University of Iowa College of Pharmacy/Northeast Iowa Family Practice Center, Waterloo, IA

Purpose: The objective of our study was to evaluate the effect of pharmacist involvement in improving patient adherence to current national guidelines for the treatment of diabetes, hypertension, and hyperlipidemia.
Methods: Patients included in this quality improvement project were those identified in the Wellmark Pharmacy Collaboration on Quality Pilot Program with a diagnosis of diabetes, hypertension, and/or hyperlipidemia. Patient interviews were performed by pharmacists both in person and via telephone. The primary outcome was the frequency of patients achieving therapeutic goals for diabetes, hypertension, and hyperlipidemia, among patients who actively received pharmacist recommendations. Secondary outcomes included the types and acceptance of pharmacist recommendations, and generic medication usage. The duration of the evaluation period was 7 months.
Results: A total of 218 pharmacist reviews were performed for 192 patients and resulted in 99 patient care recommendations. The frequency of therapeutic goal attainment at baseline and study end among patients who received pharmacist recommendations was as follows: diabetes, HgbA1c ≤7%, 32.1% and 46.4%; diabetes, LDL <100mg/dL, 62.1% and 75.9%(p<0.001), hypertension, BP at goal, 66.7 and 69.8%; and hyperlipidemia, LDL at goal, 65.6% and 74.2% (p<0.001). In-person reviews resulted in the highest number of pharmacist recommendations as well as the highest acceptance rate from both patients and physicians. Twelve patients accepted a recommendation to switch from a brand medication to a generic medication and were still taking the generic medication at the end of the evaluation period. The anticipated total drug acquisition cost savings for these 12 patients was equal to $15,672 per year.
Conclusion: Several benefits were observed from pharmacist recommendations. These included a total yearly cost savings of over $15,000 due to increased generic drug usage, significant improvement in patients attaining their LDL goal, and improvement in diabetic patients achieving goal HbA1c.

Gastroenterology

253. Eicosapentaenoic acid and docosahexaenoic acid synergistically attenuate bile acid-induced hepatocellular apoptosis.
Emma M. Tillman, Pharm.D., Richard A. Helms, Pharm.D., Dennis D. Black, M.D.; University of Tennessee Health Science Center, Memphis, TN

Purpose: Parenteral nutrition (PN)-associated liver disease (PNALD) is a common complication occurring in children receiving long-term PN. Clinical studies in infants with PNALD have demonstrated improvement and even reversal of PNALD with omega-3 polyunsaturated fatty acid supplementation containing both eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Preclinical evidences suggest that one possible mechanism is attenuation of apoptosis induced by high levels of retained hydrophobic bile acids. The aim of this study was to determine whether there is a difference in attenuation of hepatocellular apoptosis induced by the hydrophobic bile acid, chenodeoxycholic acid (CDCA), with treatment with EPA and DHA separately or in combination.
Methods: Cultured HepG2 cells were treated with 200 μM CDCA in the presence and absence of 10 μM EPA, 10 μM DHA, or 5 μM EPA + 5 μM DHA. Controls included cells incubated with vehicle alone (EtOH). Apoptosis was evaluated after 4, 8, 12, 18, 24 hours using the Apo-ONE® Homogeneous Caspase-3/7 Assay.
Results: Treatment with 200 μM CDCA resulted in peak caspase activity at 12 hours. Treatment with EPA alone and DHA alone resulted in 22% and 9% caspase-3/7 attenuation, respectively. Caspase-3/7 activity was attenuated by 52% when treated with a combination of EPA and DHA (*p*=0.0034).

Conclusion: The combination of EPA and DHA resulted in a synergistic attenuation of bile acid-induced hepatocellular apoptosis as compared to treatment with EPA and DHA separately. These data support the therapeutic use of fish oil containing both EPA and DHA for prevention and treatment of PNALD. More studies are needed to further evaluate the appropriate dose and the most effective ratio of EPA to DHA and to translate these results from *in vitro* to *in vivo*.

254. Outcomes of a pharmacist-driven protocol for albumin use in patients with liver cirrhosis.
Kayta Kobayashi, Pharm.D., BCPS[1], Alissa Raines, Pharm.D., BCPS[2], Joey Wilkinson, Pharm.D.[2], Travis B. Dick, Pharm.D., BCPS[2], Gordon Harmston, M.D.[3]; (1)University of Southern Nevada, College of Pharmacy, South Jordan, UT; (2)Intermountain Medical Center, Murray, UT; (3)Mountain West Gastroenterology, Salt Lake City, UT

Purpose: Evaluate the impact of a pharmacist-driven albumin-use protocol on appropriate prescribing of intravenous human albumin for adult patients with liver cirrhosis.
Methods: A protocol for albumin use in patients hospitalized with liver cirrhosis was approved by the hepatology service on September 25, 2008. Protocol indications included large volume paracentesis (LVPA), spontaneous bacterial peritonitis (SBP), and hepatorenal syndrome type 1 (HRS). A retrospective cohort study design was utilized to assess the impact of the protocol. Electronic medical records were queried for patients with liver cirrhosis and patients administered 25% intravenous albumin during the pre- and post-protocol assessment periods. Albumin use for each patient was reviewed for appropriate indication and dose.
Results: Pre-protocol, 69 patients with liver cirrhosis were administered intravenous 25% albumin between March 16, 2008 to September 25, 2008. In this 6.3-month period, albumin was prescribed 134 times, of which 25 prescriptions (18.7%) were for appropriate indications. Post-protocol, 42 patients with liver cirrhosis were administered albumin between September 26, 2008 and March 15, 2009. During the 5.7-month post-protocol assessment period, albumin was prescribed 98 times, of which 31 prescriptions (31.6%) were for protocol-approved indications. The protocol significantly improved the number of appropriate prescriptions for LVPA, SBP, and HRS (p=0.023). Also, the amount of albumin administered for other indications decreased 51.3% from 18,000 grams during the pre-protocol period to 7,850 grams during the post-protocol period.
Conclusion: The albumin-use protocol reduced inappropriate prescribing of albumin for complications of liver cirrhosis and reduced the total amount of albumin given to patients with liver cirrhosis. Extrapolating the success of the protocol in its first 5.7 months, the protocol is expected to save $137,000 per year in AWP cost for intravenous albumin.

Health Services Research

255E. Use of an interactive online information service to improve patient care in the field of anticoagulation and antithrombotic therapy.
Henry I. Bussey Jr., B.S., Pharm.D.[1], Marie Walker, B.B.A.[2]; (1)University of Texas HSC and Genesis Clinical Research, San Antonio, TX; (2)Clotcare.com, San Antonio, TX

Purpose: To assess the value and impact of ClotCare which is a non-profit, charitable organization that provides an online information service (ClotCare.org) to address awareness, prevention, and treatment of blood clot related conditions. Popularity of the site is reflected by a doubling in hits every two years (more than 500,000 in March, 2010); but the value and impact of the information provided had not been assessed.
Methods: Visitors and listserve subscribers were asked to complete an online questionnaire. Because of rapid growth, many visitors are new to the site; therefore, responses from frequent (monthly) users were evaluated separately.
Results: 826 individuals completed the survey, 87% were from the U.S. with others from the United Kingdom, Canada, Australia, the Philippines, India, Malaysia, Mexico, Italy, Argentina, Ireland, Estonia, Uganda, Spain, Singapore, Jamaica, Israel, Slovenia, Macedonia, Germany, and Scotland. 55% were list serve subscribers, 58% were healthcare professionals and 30.6% were patients. Nearly 80% of patients and health care professionals could identify a specific change in practice that they had implemented as the result of information provided by ClotCare 40% who were frequent users indicated: 94% ranked ClotCare among the top 5 sources for information related to blood clotting conditions, 95% agreed or strongly agreed that "ClotCare has increased my knowledge of issues relating to blood clots." 98% agreed or strongly agreed that "Information provided by ClotCare is valuable." 97% agreed or strongly agreed that "I can trust information provided by ClotCare." 98% agreed or strongly agreed that "ClotCare provides a valuable service."
Conclusion: ClotCare is a rapidly growing service that is valued by its users, and especially those who use it most, to increase their awareness and understanding of information about prevention, diagnosis, and treatment of blood clotting conditions. Further, these individuals take action to improve care as a result of information obtained from ClotCare.org.
Presented at The University of Texas Red McCombs School of Business Inaugural Symposium on Information Technology Innovation in Health Care Delivery, Austin, TX, April 29, 2010

Hematology/Anticoagulation

256. Argatroban Usage Patterns in US Hospitals: Results from the Management of Heparin-induced thrombocytopenia in US hospitals (the HIT-ME study).
Alan S. Multz, M.D.; Nassau University Medical Center, East Meadow, NY

Purpose: The Study assessed utilization of argatroban (GlaxoSmithKline; Research Triangle Park, NC) as a surrogate for IV DTIs used in the management of heparin-induced thrombocytopenia (HIT). Argatroban was chosen because it is the IV direct thrombin inhibitor (DTI) with the broadest use in the setting of HIT.
Methods: The Study sample comprised of 26 US hospitals with the highest argatroban usage in 2008. Each institution provided data for at least 10 recent patients treated with argatroban. All data were blinded for analysis.
Results: Argatroban was used in either isolated HIT or history of HIT without confirmatory serology 69% of the time and in patients with HIT with thrombosis syndrome (HITTS) 23% of the time. On average, patients used 5–7 vials of argatroban. The amount of argatroban used did not differ significantly between patients with HITTS, isolated HIT or history of HIT.

Patient Data (n = 391)			
Heparin antibody test performed, n (%)		Yes	No
		280 (71.6%)	111 (28.4%)
Test results, n (%)	Positive	Negative	n/a
	172 (61.4%)	108 (38.6%)	
Reason argatroban was given, n (%)			
Known allergy	58 (33.7%)	3 (2.8%)	40 (36.0%)
HIT without thrombus	74 (43.0%)	51 (47.2%)	42 (37.8%)
HIT with thrombus	32 (18.6%)	42 (38.9%)	14 (12.6%)
Don't know	8 (4.7%)	12 (11.1%)	15 (13.5%)
Argatroban use			
Vials used (mean)	7.12	5.33	6.97
Days on argatroban (mean)	6.95	5.71	5.01
Days in hospital (mean)	23.4	19.1	15.56

Conclusion: In US hospitals, argatroban is mostly used in isolated HIT and in patients with a history of HIT. HITTS was seen in less than a quarter of patients treated with argatroban. Over 28% of patients treated with argatroban did not have confirmatory serology reported during their hospital admission.

Infectious Diseases

257E. Evaluation of a revised treatment algorithm for community-associated methicillin-resistant *Staphylococcus aureus* skin infections.

Marisel Segarra-Newnham, Pharm.D., MPH, FCCP, BCPS; Veterans Affairs Medical Center, West Palm Beach, FL
Background: A treatment algorithm for community-associated methicillin resistant *Staphylococcus aureus* (CA-MRSA) skin infections was revised in 2007 after changes in epidemiology from the original 2004 protocol were documented. The main changes were an emphasis in the need for incision and drainage (I&D) of lesions and to properly treat recurrences.
Purpose: Retrospectively review of patients with CA-MRSA skin infections presenting to the emergency department (ED) in the 18 months after treatment algorithm revision.
Methods: All patients with first episode of CA-MRSA skin infections presenting to the ED from November 2007 to April 2009 were reviewed. Patients who did not meet the CDC criteria of CA-MRSA were excluded. Data collected included demographics, chief complaint, culture results, antibiotic therapy, nasal swab result for admitted patients and outcomes.
Results: Electronic records for 74 patients (4 women) were reviewed. Average age was 54 years. All patients had a culture done and 45 patients (61%) had I&D performed during the initial ED visit. Only 9 patients received a beta-lactam on the first visit to the ED (12%) compared to almost 30% before algorithm revision. Eight patients were changed to anti-MRSA agents after cultures results were available; one patient, who received I&D, responded to beta-lactam therapy. Fourteen patients needed hospital admission (19%) and 12 of 13 (92%) with nasal swabs had a positive MRSA screen upon admission. Nineteen patients had at least one recurrent episode (27%) a median of 2 months after the initial one, compared to 39% a median of 3 months for the patients evaluated prior to the algorithm revision. Eighteen of these 19 patients (95%) received appropriate treatment upon recurrence.
Conclusion: A revised treatment algorithm for CA-MRSA skin infections continues to facilitate timely and proper treatment of patients with CA-MRSA, including recurrences, at our medical center. Presented at Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta, GA. March 18-22, 2010.

258. A retrospective medication use evaluation of daptomycin in a medical center in Taiwan.
Yi-Chieh Chen, B.S.[1], Chin-Hua Kuan, B.S.[1], Yen-Ying Lee, M.S., Pharm.D.[1], Hsiang-Yin Chen, M.S., Pharm.D.[1], Shao-Ling Li, B.S.[2], Yu-Ning Aw, B.S.[2], Sy-Chyi Ho, B.S.[2]; (1)Department of Pharmacy, Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan; (2)School of Pharmacy, Taipei Medical University, Taipei, Taiwan

Purpose: Daptomycin was approved for the treatment of complicated skin and skin structure infections (cSSSI) caused by gram-positive bacteria in 2003 and also right-sided infective endocarditis (IE) caused by Staphylococcus aureus in 2006. In Taiwan, daptomycin was approved in the market since 2006. Due to the increasing use of daptomycin, we conducted a retrospective medication use evaluation (MUE), to evaluate the use of daptomycin in Taipei Medical University-Wan Fang Hospital.
Methods: Inpatients between February 5, 2009 and March 22, 2010 who received at least one dose of daptomycin were included. Medical records were reviewed and data was organized in predesigned MUE form. Initiation of daptomycin as first-line or second line therapy, treatment dosing, duration, indications and renal dosing adjustment rate were studied.
Results: Fourty-one patients with 42 cases were included. Daptomycin was mostly indicated for bacteremia (46%), followed by cSSSI (17%) and IE (17%). Two cases (4.8%) were cured and 26 cases (62%) showed improvement by daptomycin treatment. Surprisingly, 19 cases (45%) were prescribed as first-line therapy. The duration of treatment was all appropriate and the average prescribing dosage was 8.1mg/kg for bacteremia, 7.9 mg/kg for IE, 7.1mg/kg for cSSSI. Among 22 cases needed renal dosing adjustment, 13 cases (59%) were adjusted appropriately. There were only 4 cases (9.5%) monitored Creatine Kinase (CK) level during the treatment.
Conclusions: Daptomycin is effective against the gram-positive infection. However, it would be preferably reserved as second-line agent when standard treatments have failed. The average dosage used was higher than the recommended dosage by the FDA. Renal dosing

adjustment and CK level monitoring are strongly suggested. The results derived from this study may be used for the development of strategies for optimizing daptomycin usage in our hospital.

259. Preliminary evaluation of a service-based inpatient antimicrobial stewardship program at an academic medical center: surgical service implementation.
Rachel DiVincenzo, Pharm.D.[1], *Eric W. Mueller, Pharm.D.[2]*, Michelle Wiest, Pharm.D., BCPS, FASHP[2], Joseph S. Solomkin, M.D.[3]; (1)College of Pharmacy, University of Cincinnati, Cincinnati, OH; (2)Department of Pharmacy Services, University Hospital and Division of Pharmacy Practice, University of Cincinnati, Cincinnati, OH; (3)University of Cincinnati, College of Medicine, Cincinnati, OH

Purpose: Antimicrobial stewardship programs improve patient outcomes, limit antibiotic resistance, and decrease antibiotic costs. However, institutional cost constraints may preclude development of a dedicated stewardship service. We report the results of the surgical service-specific, definitive therapy-focused implementation phase for an antimicrobial stewardship program (ASP) using service-based clinical pharmacists to enforce program guidelines.
Methods: 72–96 hours after initiation, clinical pharmacists (n=5) prospectively reviewed ASP-targeted antibiotics for adult surgical patients (10 services) admitted to a 400-bed academic, tertiary care hospital between Sept 2009 and Feb 2010. ASP adherence was defined according to evidence-based, definitive therapy guidelines developed by the interdisciplinary ASP committee. If non-adherent, pharmacists were to recommend changes according to the ASP guidelines. If the recommendation was not accepted, an on-call ASP infectious disease physician was consulted for final decision.
Results: 119 patients with 179 antibiotic encounters were evaluated. ASP non-adherence was 59%, varied between specialties, and was most prevalent with piperacillin/tazobactam (74%), cefepime (70%), and vancomycin (55%). Pharmacists made recommendations in 63/111 (57%) non-adherent encounters with 61 (96.8%) accepted. De-escalation (36.5%) or discontinuation (60.3%) made up all of the recommendations. Non-adherent antibiotic duration was shorter for pharmacist-recommended encounters compared to those not addressed (3.2 ± 1.7 days vs. 5.3 ± 3.6 days; P<0.001). Reasons for not addressing non-adherent encounters included work shift logistics (65%), ID consult (19%), and culture-negative empiric therapy (8%). ASP physicians were consulted in two (1.8%) non-adherent encounters; both had continuation of non-adherent antibiotic therapy. Overall, non-adherent encounters represented over $14,000 during the evaluation period.
Conclusion: ASP-guided, service-specific pharmacist recommendations can decrease targeted antibiotic duration; however, workflow challenges need to be overcome to increase the frequency of intervention. The next phases of the ASP should include intervention at the time of prescribing; broader service coverage; and continued education.

Informatics

260. Implementation of pharmacy consult orders via computerized provider order entry utilizing an electronic medical record in an academic teaching hospital.
Kristin S. Alvarez, Pharm.D., Anita P. Rahman, Pharm.D., Carol Chamberlain, Pharm.D., Travis Cooper, Pharm.D., Alissa Lockwood, Pharm.D., Carrie Berge, Pharm.D.; Parkland Hospital, Dallas, TX

Purpose: This process improvement project aimed to use a pharmacy consult order by way of computerized provider order entry (CPOE) to streamline and formalize workflow for clinical activities that pharmacists perform, as well as collect information on services that are provider-initiated.
Methods: A pharmacy consult order was built into the existing CPOE system with the following consult types: admission medication history, adverse drug event documentation, allergy documentation/counseling, antimicrobial stewardship, discharge medication counseling and reconciliation, heart failure project, home IV antibiotics, pain medication management, and other. Information was collected from November 2009 to February 2010 post order creation

on consult volume and type, completion, appropriateness, participating pharmacist, and which services are requesting consults. When an electronic note is written in the patient's medical record documenting the pharmacist's recommendations and/or actions the consult is considered complete.

Results: A total of 255 consult orders were received and the most common consult types were discharge medication reconciliation, heart failure project, and other. Over 92% of consults were completed and 86% were deemed appropriate consults. The majority of the consults were performed by clinical pharmacy specialists (42%) or service-based pharmacists (28%). The hospitalist group ordered 47% of the consults using CPOE.

Conclusion: Creation of a pharmacy consult order in a CPOE system not only gives information on the types of services that providers are requesting, but can provide an environment in which a pharmacist can work off of a queue for clinical requests. Documentation of clinical services and data collection also provides information needed to uncover areas for improvement.

Managed Care

261. Pharmacist-driven prescription medication savings for employees of a self-insured employer.
Jeanette L. Altavela, Pharm.D., BCPS, Thomas A. Sorrento, R.Ph., CGP, Cori A. Wyman, Pharm.D., CDE, Michael T. Van Ornum, R.Ph., R.N., BCPS; Greater Rochester Independent Practice Association, Rochester, NY

Purpose: To determine if a single email about potential prescription cost savings sent to employees of a large (10,000) self insured employer in 2010 would increase the number of employees that self-referred for clinical pharmacist services and increase the percent of recommendations accepted compared to 2009.

Methods: The clinical pharmacists employed by a physician organization created a one page document that listed the names of 55 costly prescription medications, the associated opportunity to lower the cost of these treatments and contact information. This document was emailed one time to employees through their company email or employees without company email were provided a paper document by their supervisors. Clinical pharmacists were available Monday through Friday 8 am–5 pm to answer phone calls from interested employees to facilitate changes to less expensive medications alternatives. The number of calls received were counted during the first week after the email.

Results: In the first week, there were 32 phone calls from employees to clinical pharmacists, 12 of which occurred in the first hour. Within 17 days of the email, 30 of the employees who called were identified as candidates for more cost effective therapy. This resulted in 41 recommendations. Preliminary results indicate that 18 of the recommendations were completed (44%) producing a potential annual savings of over $8000 with about 40% of the savings to employees and 60% of the savings to the employer. Further analysis will be provided at the time of the poster presentation.

Conclusion: Compared to 2009, preliminary results show a 300% increase in self-referrals for cost savings opportunities and a 10% increase in completed recommendations in 2010.

262. Evaluation of a dynamic therapeutic conversion initiative from felodipine to amlodipine.
Karim Prasla, Pharm.D., M.S.[1], Yoona A. Kim, Pharm.D.[2], Paul J. Godley, Pharm.D.[1]; (1)Scott & White Health Plan, Temple, TX; (2)University of Texas at Austin, Austin, TX

Purpose: The study evaluated the impact of a dynamic conversion program from felodipine to amlodipine, two comparably efficacious calcium channel blockers, on medication adherence, clinical effectiveness, and costs.

Methods: With physician approval, patients on felodipine were converted to equipotent doses of amlodipine at point-of-sale in pharmacies. Patients 18 years and older converted to amlodipine between October 1, 2008 and December 31, 2008 were evaluated for inclusion. Patients were included if they had at least two outpatient blood pressure (BP) readings and minimum of two claims for both felodipine and amlodipine during the pre- and post-index periods, respectively; first fill date of amlodipine was considered the index date. The pre- and post-periods were 365 days before and after the index date, respectively. Pharmacy claims and electronic medical records were utilized to evaluate medication adherence based on medication possession ratio (MPR) and BP control. Paired t-test was used to analyze MPR and BP.

Results: 152 patients were evaluated for medication adherence; 72% (n=110) patients had at least two outpatient BP measurements during pre- and post-periods. The study population was predominantly female (n=72) and white (n=123); average age was 72.0 ± 11.6. MPR for felodipine and amlodipine were 0.91 and 0.89 (*P*=0.164), respectively. Average systolic BP was reduced from 139.3 ± 12.5 mm Hg to 137.4 ± 12.8 mm Hg following the conversion (*P*=0.172). Average diastolic BP went from 72.0 ± 8.4 mm Hg to 70.5 ± 7.8 mm Hg (*P*=0.029). Of the 152 patients, 3.3% (n=5) patients switched back to felodipine. The savings from the program was $61,000 per 100 patients.

Conclusion: The dynamic conversion program was successful at limiting therapy disruption, as less than 5% of the patient switched back to felodipine. Also, in addition to maintaining medication adherence and achieving significant savings, patients demonstrated stable BP control after the conversion.

Medication Safety

263. Identifying gaps in documentation of anticoagulation counseling.
Catherine D. Lewis, Pharm.D., CACP, BCPS[1], Chadana Barnum-Parker, R.Ph., Pharm.D. Candidate[2], Kristen Engel, Pharm.D.[2], Jenna Huggins, Pharm.D., BCPS[2], Lynn Eschenbacher, Pharm.D., M.B.A.[2]; (1)Campbell University/ WakeMed Health and Hospitals, Raleigh, NC; (2)WakeMed Health and Hospitals, Raleigh, NC

Purpose: This study evaluated documentation of discharge education in patients receiving anticoagulants as part of the Joint Commission patient safety goal. Primary measures included specific anticoagulation education and any type of education documentation. Secondary measures were new warfarin patients and patients discharged on warfarin plus enoxaparin with education documented.

Methods: Patients were identified by anticoagulation monitoring forms. Each month from January 2009 through April 2010, a random sample of 50 patients was reviewed for documentation of discharge education in the electronic charting system. Data collected included documentation of warfarin education, any type of discharge education, whether the patient was new or established on anticoagulation at admission, patients discharged on warfarin plus enoxaparin, and the level of care to which the patient was discharged.

Results: During the study period, 45% (range 30–56%) of charts reviewed had documentation of anticoagulation education on discharge. Patients with any type of education documented were 62% (range 44–92%). New warfarin patients with education documented were 71% (range 50–89%). Patients discharged on warfarin plus enoxaparin with education documented were 59% (range 14–100%). It was also found that 18% (range 3–33%) of patients discharged to another level of care had documentation of education.

Conclusion: Documentation and provision of anticoagulation education on discharge is not at the 90% goal. The gap between patients with anticoagulation education and those with documentation of any type of education may represent missing data. Emphasis should be placed on the importance of documenting anticoagulation education separately in order to accurately represent the number of patients taught. Another gap may occur when patients are discharged to another level of care. There is currently no specific instruction regarding education for these patients as compared to those being discharged home. Strategies are being implemented to standardize these processes based on the gaps identified.

264. A Multi-disciplinary Approach to Inpatient Management of Prostacyclin Therapy for Pulmonary Arterial Hypertension Patients.
Laura A. Duvall, Pharm.D., BCPS; The Ohio State University Medical Center, Columbus, OH

Purpose: To compare medication-related events before and after implementation of policies and educational tools developed between 2006 and 2008 in order to improve safety and overall care of patients admitted to the Progressive Care Unit (PCU) on continuous infusion prostacyclin therapy (CIPT).

Methods: Medication-related event reports for 42 patients in 2005 and for 75 patients in 2009 were reviewed. Institution specific event severity level, and a pharmacy rating based on the National Coordinating Council for Medication Error Reporting & Prevention (NCC MERP) medication error index, was documented.

Results: In 2005, there were 21 PCU admissions for patients on CIPT. In 2009, there were 58 PCU admissions for patients on CIPT. There were 7 of 42 (17%) medication-related event reports filed in 2005, and 2 of 75 (3%) medication-related event reports filed in 2009 related to CIPT (p=0.01). Based on The Ohio State University Medical Center (OSUMC) scoring system, an event severity score ≥ 3 was assigned to 3 of 7 (43%) of the CIPT events in 2005, compared to 0 of 2 (0%) of the CIPT events in 2009 (p=0.5). An event severity score of 3 is defined as an error occurred resulting in a change in vital signs and/or labs were drawn, plus increased monitoring was required. A pharmacy rating ≥ D was assigned to 4 of 7 (57%) of the CIPT events in 2005, compared to 0 of 2 (0%) of the CIPT events in 2009 (p=0.444). A pharmacy rating of D is defined as an error occurred, reached the patient, required monitoring or intervention to preclude harm.

Conclusions: Our comparative data shows that collaborative initiatives have significantly decreased the number of medication-related event reports for patients on CIPT. The common goal that all team members share to provide the best patient care has lead to these successful outcomes.

265. Initial dosing and monitoring of argatroban: impact of computerized clinical decision support.
Ashley L. Quintili, Pharm.D., BCPS, Bob Lobo, Pharm.D., BCPS, Josh Peterson, M.D., M.P.H.; Vanderbilt University Medical Center, Nashville, TN

Purpose: To evaluate the impact of computerized clinical decision support on the appropriateness of argatroban dosing and monitoring in patients with heparin-induced thrombocytopenia.

Methods: This was a retrospective before and after study that reviewed medical records of patients who received argatroban therapy for at least 24 hours between January 1, 2009 and August 1, 2009 or August 25, 2009 and January 30, 2010. Argatroban clinical decision support was implemented within the CPOE system on August 25, 2009. Doses were deemed appropriate when initial rates were less than or equal to those recommended by the American College of Chest Physicians.

Results: A total of 55 patients were included for analysis; 32 in the pre-implementation group and 23 in the post-implementation group. Adherence to guideline recommended dosing increased from 63% to 100% with the implementation of clinical decision support (p<0.01).Hematology consults as required by the institution improved post-implementation (47% vs 100%, p<0.01). Percent of aPTTs within the therapeutic range during the first 24 hours increased from 24% to 33%, with a concomitant decrease in supratherapeutic aPTTs from 54% to 30%. As a secondary outcome, supratherapeutic aPTTs were reviewed for the entire course of therapy. Fewer supratherapeutic aPTTs (aPTT >80sec, aPTT>100sec, and aPTT>200sec) were measured in the post-implementation group. Peak aPPT in the first 24 hours also decreased from 100 to 84 seconds with clinical decision support implementation. Two bleeding events were noted, one life-threatening, both in the pre-implementation group.

Conclusions: Argatroban clinical decision support improved appropriateness of initial argatroban dosing.

266. Compliance to Immunosuppressives in Renal Transplantation - Case of Tacrolimus and Sirolimus.
Clara M. Sequeira, Pharm.D.[1], *Ana C. Ribeiro Rama, Ph.D.*[2], José A. Feio, Pharm.D.[3], Alfredo Mota, Ph.D.[4], Carlos A. Fontes Ribeiro, Ph.D.[5]; (1)Coimbra`s University Hospital, Coimbra, Portugal; (2)Pharmacy Department, Coimbra University Hospitals and Center for Pharmaceutical Studies, Faculty Pharmacy, Coimbra University, Coimbra, Portugal; (3)Hospitais da Universidade de Coimbra, Coimbra, Portugal; (4)Department of Urology and Renal Transplantation, Coimbra University Hospitals, Coimbra, Portugal; (5)Faculty of Medicine, Coimbra University, Coimbra, Portugal

Purpose: Compare two renal transplant patients' groups – Tacrolimus (FK) and Sirolimus (SRL) - regarding: a) Compliance using Electronic Monitoring (EM); b) Clinical events potentially due to noncompliance to immunosuppressives; c) Self-perceived quality of life (QoL).

Methods: Observational/prospective study (FK: 125 20 days; SRL: 140 32 days, N.S.) of 49 patients (FK: 18; SRL: 31). MEMS (AARDEX) monitors used for compliance evaluation. Compliance-operational-definitions according to method/investigators criteria. Compliance rate (CR) expressed by median (Percentile$_{25}$-Percentile$_{75}$). Adherents/Non-adherents categorization using 80.0% CR cut-off level. Clinical events identification using patients' interview and medical prescriptions/notes review. Self-perceived QoL assessed at final visit by self-administered QoL questionnaire ESRD-SCL, with authors' permission. Statistical analysis (SPSS-11.5): Student's-t or Mann-Whitney-U tests and Chi-squared or Fisher's-exact tests. Statistical significance threshold p<0.05 (N.S. = Not statistically significant).

Results: Groups' baseline characteristics essentially similar [mostly males (FK:72.2%; SRL:61.3%); comparable age (mean: 47 years old); 77.8%(FK)/93.5%(SRL) with cadaveric donor grafts; mean time since transplantation (months): 22(FK)/24(SRL); baseline immuno-suppression predominantly triple, mostly FK/SRL+Mofetil Mycophenolate+Prednisone]. Comparable compliance results: CR according-to-dose : FK - 98.8% (92.4%–100.1%); SRL - 99.3% (97.7%–100.7%); CR according-to-doses-interval : FK - 88.9% (75.0%–96.5%); SRL - 89.7% (83.9%–97.6%); CR according-to-days : FK - 91.7% (82.0%–97.0%); SRL - 95.0% (88.6%–99.2%); Non-adherents: FK - 33.3%; SRL - 16.1%. Groups were comparable regarding clinical events, except for experienced adverse effects (FK - 33.3%; SRL 71.0%, p=0.010). Self-perceived QoL scores were comparable in the two groups [global score: 1.012 0.683 (FK)/1.029 0.499 (SRL)].

Conclusion: Compliance to study drugs, clinical events (the majority) and self-perceived QoL were comparable in the two groups, in other words, they weren't related specifically to any of the two immuno-suppressives. We found high CRs (probably explained by study design or mostly by patients' perceptions) and a total of 22.4% non-adherents (in accordance to other authors' findings in this population).

Nephrology

267. Pharmacist Performed Educational Intervention in Dialysis Patients with Hyperphosphatemia.
Betty Ha, Pharm.D, Renee Weng, Pharm.D., Madeleine Pahl, M.D., Ashish Kalthia, M.D.; UC-Irvine, Orange, CA

Purpose: This study focuses on determining if pharmacist-performed educational intervention of oral phosphate binders in renal dialysis patients with hyperphosphatemia is effective in improving patient adherence and therefore reduces phosphate levels. Secondly, the role socioeconomic factors play in medication adherence is evaluated.

Methods: A prospective study of 35 hemodialysis patients (13 in the study group and 22 in the control group) between December 1, 2009 and February 28, 2010 was conducted. Individualized pharmacist education (including pill counts, medication diary logs and counseling) was performed on a monthly basis. Effectiveness of the intervention was assessed by comparing the phosphate levels of the study group to a control group. Demographic data was also compared to assess what effect socioeconomic status has on adherence to therapy.

Results: At baseline the mean phosphate level in the control group was 7.07 mg/dL compared to 6.72 mg/dL in the study group (P=0.78). After 3 months of intervention, mean phosphate levels were 6.61 mg/dL and 6.57 mg/dL, respectively (P=0.55). Nine of thirteen (69%) study group patients were adherent to drug therapy. All adherent patients completed high school compared to only 50% of the non-adherent patients completing high school. All non-adherent patients were in the lower median income bracket compared to the adherent patients.

Conclusions: Patients in the study group showed a tendency toward lower phosphate levels when compared to the control group. Socioeconomic factors such as education and median income did play a role in adherence. Although the majority of study patients were adherent to therapy, even adherent patients did not have a reduction of phosphate levels to NKF KDOQI recommended target ranges.

Neurology

268. Clinical pharmacy roles on the brain attack team: focus on timely administration of tissue Plasminogen Activator (tPA).
Frank Diaz, Pharm.D.[1], Kevin O. Rynn, Pharm.D., FCCP, DABAT[2], James S. McKinney, M.D.[3]; (1)Rutgers University, Piscataway, NJ; (2)Rutgers University Ernest Mario School of Pharmacy, Piscataway, NJ; Robert Wood Johnson University Hospital Emergency Department, New Brunswick, NJ; (3)Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ

Purpose: Pharmacy interventions have improved outcomes in various settings. Timing of tPA administration in ischemic stroke is crucial to positive patient outcomes. A Brain Attack Team was initiated at our institution, including bedside pharmacy intervention during peak hours. We set out to evaluate the impact of pharmacist involvement on the stroke service in the management of ischemic stroke.
Methods: Medical records of 106 patients treated with tPA between 01/01/06 and 11/24/09 were reviewed. Evaluation of patient care was assessed when pharmacists responded to the bedside (peak) vs. no initial bedside response (off-peak). tPA admixture/delivery and door to tPA administration time were primary outcomes assessed. Secondary timing outcomes included CT scan completion, lab completion, and decision to use tPA. Bleeding and mortality during hospitalization were also assessed.
Results: Patients were divided into two groups based on presentation time, peak (n=63) vs. off-peak (n=43). Mean tPA admixture/delivery times for peak vs. off-peak hours were 13.05 vs.16.40 minutes respectively. Door to tPA administration time during peak vs. off-peak were 74.02 vs. 85.45 minutes. Laboratory turnaround time was 46.10 vs. 51.68 minutes and CT scan turnaround time was 26.60 vs. 25.60 minutes respectively. In all patients intracranial hemorrhage within 1st 7 days was seen in 6 patients (5.6%). Nine patients (8.5%) expired.
Conclusions: Medication turnaround time was decreased when a pharmacist was actively involved at the bedside of ischemic stroke patients. Overall time to administration was also decreased with direct pharmacist involvement. Bleeding and mortality were similar to rates seen with other trials of treating stroke with tPA.

Nutrition

269. Comparison of the incidence of parenteral nutrition-associated liver disease in infants with congenital heart disease and infants with necrotizing enterocolitis.
Emma M. Tillman, Pharm.D., Johanna L. Norman, Pharm.D. Candidate, Richard A. Helms, Pharm.D.; University of Tennessee Health Science Center, Memphis, TN

Purpose: Infants with congenital heart disease (CHD) or necrotizing enterocolitis (NEC) often require parenteral nutrition (PN) during critical illness. PN is associated with complications such as PN-associated liver disease (PNALD). Clinical observations suggest a non-functional gastrointestinal (GI) tract may be more predictive of PNALD than PN duration. The aim was to evaluate the incidence of PNALD in infants with CHD who have an intact GI tract compared to patients with NEC.
Methods: This retrospective study included infants with CHD or NEC requiring PN support for greater than 30 days. Demographic, laboratory, and PN data were collected.
Results: Sixteen patients with CHD and 93 patients with NEC were identified. From the NEC patients, two cohorts of 16 patients were identified based on duration of PN and bowel length. Group 1 included 16 patients with less than 10 cm of small bowel resected, and group 2 included 16 patients with greater than 20 cm of small bowel resected. There were three cases of PNALD in the CHD group, and 15

and 14 cases in the NEC groups, respectively. The incidence of PNALD was greater in patients with NEC than in patients with CHD (*p*<0.01); no difference was observed between the two groups of NEC patients. There was no difference in PN duration between the CHD group 68 ± 41 days (mean ± SD) and NEC group 1, 70 ± 36 days; however, duration of PN was greater in NEC group 2, 123 ± 55 days (*p*<0.01).
Conclusion: Patients with CHD receiving PN are less likely to develop PNALD than patients with NEC receiving PN for a similar duration. The length of small bowel and duration of PN may not be reliable predictors for risk of PNALD. These data suggest that the GI tract plays an integral role in the etiology of PNALD.

Pediatrics

270. Factors influencing a drug's role in elevating serum bilirubin levels of very low birth weight neonates.
Zon-Min Lee, M.S.[1], Ping-Yu Lee, M.S.[1], Chi-wen Chiang, Ph.D.[2], Shin-Tarng Deng, Ph.D.[3]; (1)Department of Pharmacy, Chang Gung Memorial Hospital, Kaohsiung, Taiwan; (2)Department of Pharmacy, Pingtung Hospital, Department of Health, Executive Yuan, Pingtung, Taiwan; (3)Department of Pharmacy, Chang Gung Memorial Hospital, Linkou, Taiwan

Purpose: Neonatal hyperbilirubinemia can be physiological or pathological, drug-induced hyperbilirubinemia may also occur. Cotrimoxazole and ceftriaxone are known to be contraindicated in neonates less than two months old for fear of potential kernicterus due to their high protein-binding ability. However, drugs like furosemide, which has high protein-binding ability (91-99%), on the contrary, is commonly used in neonates.
Methods: In total, 46 neonates with BW <1500g who used parenteral nutrition in the NICU of Chang Gung Memorial Hospital, Kaohsiung branch (Taiwan), were included in this study starting from January 1, 2009 to March 31, 2010. Twenty-nine neonates used furosemide, the other 17 neonates didn't.
Results: Average rising bilirubin levels/day on the ascending slope for furosemide users and non-users are 1.43 mg/dl and 1.75 mg/dl, and average falling bilirubin levels/day on the descending slope are 1.54 mg/dl and 1.81 mg/dl, p=0.09 and 0.12 respectively, suggesting no significant rises of serum bilirubin levels were detected after furosemide had been administered in comparison with those of the non-user group.
Conclusion: In addition to protein-binding, daily dosage or mole of a drug may also play an important role in the net effect of replacing serum bilirubin which eventually causes hyperbilirubinemia or even kernicterus in VLBW neonates. Further studies are needed to form a formula for predicting hyperbilirubinemia potential of a drug.

271. Clinical pharmacy development of an interprofessional pediatric intestinal rehabilitation program.
Catherine M. Crill, Pharm.D., Michael L. Christensen, Pharm.D., Emily B. Hak, Pharm.D., Jasmine K. Sahni, Pharm.D., Chasity M. Shelton, Pharm.D., Emma M. Tillman, Pharm.D., Richard A. Helms, Pharm.D.; The University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN

Purpose: A pharmacy-directed parenteral nutrition (PN) service comprised of clinical pharmacy faculty, residents and students manages an average of 40 patients daily (average PN length 30 days) at our 225-bed pediatric institution. Approximately one-third of patients receive long-term PN due to short bowel syndrome (SBS), which is associated with significant morbidity and mortality, including recurrent catheter-related infections and the development and progression of PN associated liver disease (PNALD). In order to improve care of this high-risk population, our clinical pharmacy group initiated and organized the development of an interprofessional intestinal rehabilitation program.
Methods: Over 30 individuals representing pharmacy, gastroenterology, neonatology, surgery, nutrition, nursing, developmental pediatrics, infection control, and rehabilitation services were convened in November 2007 to standardize and optimize management of SBS patients through an evidence-based, integrated and interprofessional

approach to patient care. Subgroups, each chaired by a pharmacist, evaluated and developed patient care plans for intestinal rehabilitation and risk factors for liver disease and other complications in SBS. Five major directives have been implemented thus far: 1) an ethanol lock protocol to decrease catheter-related infections and hospitalizations, 2) postoperative enteral feeding guidelines to promote enteral feeding initiation and success, 3) standardization of PN delivery in liver disease, 4) a clinical research agenda to evaluate early markers and investigational therapies for PNALD, and 5) an outpatient clinic (staffed by a gastroenterologist and pharmacist) to manage specialized nutrition support needs in our home PN patients. In addition, an inaugural visiting professor was hosted, a monthly conference to discuss program progress and patients has been initiated, and recruitment is underway for a care coordinator.

Results: Preliminary data regarding interventions and outcomes are forthcoming.

Conclusion: This program has garnered the recognition and support of hospital administration and is being used as an example of interprofessional collaboration to improve outcomes in complicated populations.

Pharmacoeconomics/Outcomes

272. Pharmacoeconomic analysis of short course vs. standard dose Rabbit Anti-thymocyte Globulin induction therapy in Cadaveric Renal Transplant Recipients.

Kwaku Marfo, Pharm.D., Enver Akalin, M.D., Danielle Garcia, Pharm.D., Saira Khalique, Pharm.D., Amy Lu, M.D.; Montefiore Medical Center, Bronx, NY

Purpose: Rabbit anti-thymocyte globulin (RATG) has demonstrated significant efficacy as an induction agent in renal transplantation. Due to RATG's prolonged inhibition of T-lymphocytes (half-life ~ 6 days after a single dose) and significant toxicity, tailoring RATG administration may reduce complication rates and treatment costs without compromising immunosuppressive benefits. The primary endpoint of this study is to assess whether similar immunosuppressive benefits were achieved in renal transplant patients who received a short course of RATG (shRATG) induction versus those who received a standard course of RATG (scRATG). As a secondary endpoint, cost-savings from the two groups will be analyzed.

Methods: Consecutive cadaveric renal transplant recipients in 2008 who received RATG as an induction agent were analyzed on 15 donor and recipient variables including rate of biopsy proven acute rejection, serum creatinine levels, incidence of complications and drug costs. Patients with panel reactive antigen > 20% and/or donor specific antibodies prior to transplant were excluded.

Results: There were no significant differences between the two groups in baseline demographic characteristics. At 6 months, biopsy confirmed acute rejection episodes (17.8 vs. 12.5%) and serum creatinine (1.65 vs. 1.84 mg/dL) were similar in the shRATG and scRATG groups, respectively (P=NS). There was a trend to higher incidence of delayed graft function and RATG-related side effects and complications in the cohort that received scRATG. The cohort of patients who received shRATG received a total mean dose of 4.6 mg/kg compared to 7.3 mg/kg in the cohort who received scRATG. This reduction in dosage was associated with a mean cost difference of $2,548/patient.

Conclusion: shRATG has the advantage of reduction in the dose and cost of RATG induction therapy in cadaveric renal transplant recipients without compromising immunosuppressive effects. Additional cost-savings of $106,528 could have been realized if all patients received induction treatment with shRATG.

273. Utilization pattern of intravenous iron products at an academic medical center.

Elissa V. Klinger, M.S.[1], Yu-Chen Yeh, M.S.[1], Adam DeVore, M.D.[2], William Churchill, M.S.[3], Maryann Vienneau, B.S.H.A.[4], *Steven Gabardi, Pharm.D.*[5]; (1)Center for Drug Policy, Partners Healthcare, Needham, MA; (2)Department of Medicine, Brigham & Women's Hospital, Boston, MA; (3)Department of Pharmacy, Brigham & Women's Hospital, Boston, MA; (4)High Performance Medicine Team 5, Partners Community Healthcare, Inc., Needham, MA; (5)Department of Pharmacy & Renal Divison, Brigham & Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA

Purpose: Ferumoxytol, a recently approved intravenous (IV) iron product for patients with chronic kidney disease (CKD), requires less frequent dosing and shorter duration of administration compared to existing IV iron agents but is 2- to 4-fold more expensive. We sought to evaluate the utilization pattern of iron dextran (ID), iron gluconate (IG), and iron sucrose (IS) to determine place of ferumoxytol at our hospital.

Methods: Patients receiving IV iron between January and June 2009 were identified in the billing database. The number of patients receiving IS and ID was small, thus all patients who received either were included; a random sample of IG patients was selected. Demographic information, indication for IV iron, administration setting, dose, and duration of infusion were obtained via medical record review. Patient- and administration-level analyses were performed.

Results: In total, 108 patients (IG=89, IS=13, ID=6) with 244 IV iron administrations were included. IG was used in a broad range of indications including CKD (54.0%), anemia not specified (13.5%), and gastrointestinal bleeding (10.1%). Indications for IS were similar to IG while gynecologic bleeding was the leading reason to use ID. Only 2.8% of patients received IV iron for anemia in cancer; all received IG. Most IG and IS treatment was administered in the inpatient setting (IG 83%, IS 59%); ID was given entirely in the outpatient setting. All IG administrations were given in 125 mg doses over 1-hour infusions; 100 mg and 200 mg of IS were administered over 5 minutes and 1 hour, respectively; ID was given over 3 to 6 hours.

Conclusions: IG is most commonly administered at our institution, with over 50% used in CKD patients. While ferumoxytol may be of value for select outpatients, the majority of IV iron treatment is given in the inpatient setting where ferumoxytol would be an expensive option with limited benefit.

274. A low- molecular weight heparin conversion at 11 community hospitals in Connecticut and Massachusetts.

Allison V. Tauman, Pharm.D., M.P.H.; VHA, Southport, CT

Purpose: In November 2008, 11 VHA member hospitals in Connecticut and Massachusetts formed a collaborative and hired a clinical consultant to identify and implement pharmacy programs that focus on changing utilization practices and standardizing drug formularies. The objective of this study was to test whether a shared clinical resource could successfully implement an enoxaparin interchange program across 11 diverse hospitals.

Methods: All peer-reviewed publications and example therapeutic interchange policies, guidelines, and protocols were collected. A customized implementation work plan was developed for each individual institution. During October 2008–May 2010, cost savings were compared using an unpaired t-test for the continuous variable, monthly dollars of dalteparin, enoxaparin, fondaparinux, and heparin per patient-day.

Results: All 11 hospitals committed to implementation of the interchange. Implementation dates varied by each institution (range: April 1, 2009–September 22, 2009). Three of the 11 hospitals (27%) adopted a complete interchange to dalteparin and fondaparinux, 1 of the 11 hospitals (9%) adopted an interchange to dalteparin and fondaparinux and kept enoxaparin on formulary for acute coronary syndrome, and 7 of the 11 hospitals (64%) adopted a partial interchange from enoxaparin to fondaparinux for some indications and did not utilize dalteparin. Monthly dollars per patient-day post-implementation were significantly lower (range: -28 to -49%, p=0.0461) in the 3 hospitals that adopted a complete interchange to dalteparin and fondaparinux compared to the monthly dollars per patient-day in the 7 hospitals that adopted a partial interchange (range: +19% to -13%). The single hospital that kept enoxaparin on their formulary for acute coronary syndrome was not included in the analysis because they did not implement a new interchange during the study period.

Conclusion: Adoption of a low-molecular-weight heparin interchange protocol can be accomplished across a diverse group of hospitals in

the Northeast. Cost-savings are greatest for those hospitals that eliminated enoxaparin from their formulary.

Psychiatry

275. Bridging the transition from hospital to home: Implementation of a medication discharge program.
Jamie Montgomery, R.Ph., Jessica Harms, Pharm.D., Edie Whipple, R.Ph., Kristen Sakely, R.Ph., Tanya Fabian, Pharm.D., Ph.D., BCPP; Western Psychiatric Institute and Clinic, Pittsburgh, PA

Purpose: Hospital discharge can be a vulnerable time for any patient, but may be particularly challenging for patients with a mental illness. Our ever-changing health care system presents many barriers to medication access which can negatively impact treatment adherence. A successful inpatient stay can be quickly reversed if patients are unable to continue their medication regimen after discharge.
Methods: Integrating pharmacy services into the discharge planning process improved patient care and enhanced communication between inpatient and outpatient settings. This standardized program allowed discharge prescriptions to be processed through our outpatient pharmacy, allowing the pharmacist to quickly resolve insurance and medication issues while the patient remains in the hospital and treatment team and medical records are readily accessible. In addition to leaving with medications in hand, patients were counseled by a pharmacist prior to discharge.
Results: During the one-year pilot, 74 patients were discharged with a total of 464 discharge prescriptions. Notably, 35% of prescriptions processed required pharmacist intervention. A greater proportion of patients who participated in the medication discharge program attended their first scheduled outpatient appointment (42% vs 11%) than those who received written prescriptions. In addition, readmission rates to Western Psychiatric Institute and Clinic within 60 days were 12% lower in those receiving medications versus written prescriptions.
Conclusion: This innovative practice facilitated a critical transition in care by providing patients with the information and medication needed to be successful in their recovery. This collaborative, multidisciplinary program embraces the team approach to patient care and improves clinical outcomes. While this program was implemented primarily to improve patient care, revenue generated by the program was used to create a new Transitional Care Pharmacist position. Furthermore, the business opportunity presented has resulted in expansion of the program to additional units.

276. Development of a Pharmacist-Managed Medication Therapy Management Services (MTMS) in a Mental Health Clinic.
Kimberly Tallian, Pharm.D., BCPP[1], Jan D. Hirsch, Ph.D.[2], Cathy A. Chang, B.S., Pharm.D. Candidate[2], Mindl Messinger, Pharm.D. Candidate[2], Todd Gilmer, Ph.D.[3], Grace M. Kuo, Pharm.D., M.P.H.[2], Pauline Chan, R.Ph.., M.B.A., BCPP[4], Charles E. Daniels, Ph.D.[2], Kelly C. Lee, Pharm.D., BCPP[2]; (1)University of California, San Diego Medical Center, San Diego, CA; (2)University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla, CA; (3)UCSD Department of Family and Preventive Medicine UCSD School of Medicine, San Diego, CA; (4)Senior Pharmaceutical Consultant Pharmacy Benefits Division Department of Health Care Services, Sacramento, CA

Purpose: Except for a few reports of MTMS models for depression, descriptions of pharmacist-managed MTMS in mental health are lacking. In this report, we describe the implementation of MTMS at an outpatient mental health-clinic at the University of California, San Diego (UCSD) with related challenges and opportunities.
Methods: Stakeholders implementing the MTMS included 1) the UCSD School of Pharmacy, 2) UCSD Outpatient Clinic; 3) San Diego County Mental Health Services and 4) the California Mental Health Care Management Program (CalMEND). Two board-certified psychiatric pharmacists participated in MTMS direct patient-care activities.
Results: Since initiation of the MTMS in June 2009, over fifty mental health patients, served under a contract between UCSD OP Clinic and San Diego County Adult and Older Adult Mental Health Services,

have been managed by the two psychiatric pharmacists. The pharmacists completed credentialing processes and received UCSD Provider Identification (PID), National Provider Identification (NPI) and a US Drug Enforcement Agency (DEA) registration. The pharmacists provided care, under a collaborative practice protocol with psychiatrists, to patients referred by residents and attending physicians. Pharmacists billed for medication minutes the same way as rendered by psychiatrists. Pharmacists' practice opportunities included psychiatric evaluation, medication management, laboratory and adverse effects monitoring, medication adherence assessment, lifestyle, counseling, therapy referral and clinical practice integration. Challenges of initiating the MTMS included delay in patient referrals, space allocation, acceptance of pharmacists' role at the clinic and changing needs of the clinic and County due to diminished state funds.
Conclusion: Since implementation of the MTMS, there has been an increased enthusiasm regarding the role of psychiatric pharmacists in the management of patients with serious mental illness. The pharmacist caseload is continuing to grow and there may be opportunities for expanding the role of pharmacists to integrating primary and mental health care in this population.

277. Evaluation of metabolic effects and monitoring frequency with quetiapine.
Marra J. Burr, B.S., Pharm.D., Tami Argo, Pharm.D., Jason Egge, Pharm.D., Shella Johnson, Pharm.D.; Iowa City Veterans Affairs Medical Center, Iowa City, IA

Background: Quetiapine-a second generation antipsychotic (SGA)-at low doses (<300mg/day) is commonly used within the Iowa City Veterans Affairs Medical Center (ICVAMC). Quetiapine metabolic effects may develop independent of dose, but data are inconsistent. ICVAMC recommends patient's metabolic parameters be monitored at baseline and three months, but practitioner vigilance may vary by SGA dose.
Purpose: Our primary objective was to investigate the effect of quetiapine initiation on body mass index. Secondary objectives examined other metabolic parameters and monitoring compliance.
Methods: Electronic medical record review was completed for 611 patients initiated on quetiapine. Metabolic parameters were recorded at baseline and after 90–365 days of treatment. Patients were excluded if initiated on quetiapine outside the ICVAMC (n=172), had less than three months of continuous use (n=306), current daily dose prescribed for less than one month prior to monitoring date (n=5), monitoring not completed within one year of initiation (n=14) or dose was unknown (n=1). Diagnosis and treatments for co-morbid conditions (e.g. diabetes, hyperlipidemia, and hypertension) were noted.
Results: We enrolled 113 subjects, 91.2% male, average age 58.1 ± 12.6 years. Average follow-up quetiapine dose was 143.4 ± 147.3 mg/day, resulting in a BMI increase of 0.50 (p=0.016). Weight monitoring occurred on average at 150.2 ± 52.0 days post-initiation. Insomnia was listed as an indication for use for 71.7% of patients.
Conclusion: Patients with metabolic monitoring showed a statistically significant increase in BMI at the first follow-up after the initiation of quetiapine. Of clinical relevance is the infrequency of baseline weight monitoring and the frequency of off-label use.

Transplant/Immunology

278. Tolerability of de novo maintenance immunosuppressive therapy with sirolimus versus mycophenolic acid in combination with tacrolimus and prednisone in renal transplant recipients – 12 months results.
Kwaku Marfo, Pharm.D., Julie Chen, Pharm.D., Amy Lu, M.D., Javier Chapochnick, M.D.; Montefiore Medical Center, Bronx, NY

Purpose: Sirolimus is widely used in combination with other immunosuppressive agents to prevent graft rejection. However, the optimal time to initiate SRL therapy is still unclear due to potential side effects such as deficient wound healing, proteinuria and thrombosis. The purpose of this prospective inception cohort study is to evaluate tolerability of tacrolimus/prednisone (FK/PRED) in combination with *de novo* sirolimus (SRL) versus mycophenolic acid (MPA) in renal transplant recipients.

Methods: We analyzed medical records of 90 patients who underwent kidney transplantation at two different time points: a cohort of 45 patients who were transplanted between January 1 and June 30, 2007 and received SRL/FK/PRED and a cohort of 45 patients who were transplanted between January 1 and June 30, 2008 and received MPA/FK/PRED. The two groups were compared for rate of drug discontinuation, incidence of acute rejection, side effects (wound healing, lymphocele formation, infections, pneumonitis, thrombosis, dyslipidemia and hyperglycemia) and renal function (serum creatinine and proteinuria).
Results: Baseline demographics were similar between groups. At the end of 1 year, biopsy-confirmed acute rejection episodes (13.5% vs. 15.5%; p=0.655) and mean serum creatinine (1.9 ± 0.45 vs. 1.4 ± 0.62 mg/dL; p=0.017) were similar SRL vs. MPA group, respectively. There was a trend to higher blood levels of triglycerides (195 ± 100.3 vs. 163 ± 85.8 mg/dL) and cholesterol (269 ± 457.5 vs. 175 ± 29.8 mg/dL) in the SRL-group compared to baseline. SRL-group had a drug discontinuation rate of 37.8% compared to 13% in the MPA-group (P<0.001).
Conclusion: Both groups performed similarly, showing similar rates in acute rejections. However, compared to the MPA-group there was a significant higher drug discontinuation rate in the SRL-group. The major reason for sirolimus drug discontinuation was higher incidence of lipid abnormalities during the first three months of therapy.

Women's Health

279E. Improving adherence to oral bisphosphonates through focused telephonic pharmacist intervention.
Amy Steinkellner, Pharm.D., Laurie Greenberg, M.D., Sandra Eldridge, Pharm.D., Lisa Lenzi, Pharm.D., Shannon Denison, M.A.; Medco Health Solutions, Inc., Tampa, FL

Purpose: This Quality Improvement (QI) project focused on understanding baseline performance levels and improving adherence to oral bisphosphonates in patients with a history indicating non-adherence. Our goal was to test the hypothesis that adherence could be improved via telephonic counseling by Medco Women's Health Specialist Pharmacists.
Methods: This retrospective analysis was based on de-identified patient data extracted from a national database managed by Medco Health Solutions, Inc. Our analysis focused on female patients with complete pharmacy claims information from 1/1/2008 to 12/8/2009 and who were dispensed at least 2 prescriptions from the Medco Pharmacy. Patients were identified as non-adherent based upon a medication possession ratio of less than 80% and being late to fill for the most recent claim. These patients were considered to have a gap in care. Two intervention strategies were deployed: 1) proactive telephonic outreach by a pharmacist and, 2) the offer of counseling when a patient called for other reasons. Pharmacist counseling covered the importance of osteoporosis drug therapy as well as barriers to adherence. We measured number of patients counseled and number of gaps closed. Gap closure was defined by evidence of a subsequent claim for the osteoporosis medication in question within 30 days of counseling.
Results: Of the baseline target population, 76.3% were shown to be adherent. We spoke with a total of 5280 patients, and as a result of pharmacist counseling, we were able to close 2850 adherence gaps in care.
Conclusion: The use of pharmacy claims data is an effective way to identify patients who may require assistance. Telephonic counseling by Specialist Pharmacists resulted in improved adherence to oral bisphosphonates in women who were identified as non-adherent. Patients were found to be receptive to counseling by pharmacists with additional Women's Health training.
Published in Our poster is based on an abstract published in Journal of Clinical Densitometry: Assessment of Skeletal Health, vol. 13, no. 1, 126, 2010 and a poster presented at Clinical Osteoporosis 2010: An ISCD-NOF Symposium, San Antonio, TX, March 10–13, 2010.

RESIDENTS AND FELLOWS RESEARCH IN PROGRESS

Cardiovascular

280. Evaluation of Peripheral Arterial Tonometry in Coronary Artery Disease Patients and Healthy Volunteers.
Bryant A. Tran, Pharm.D., M.S.[1], Kyle J. Ellis, Pharm.D.[1], Almasa Bass, Pharm.D.[1], Melissa Caughey, R.V.T.[2], Katherine N. Theken, Pharm.D.[1], Robert N. Schuck, Pharm.D.[1], George A. Stouffer, M.D.[2], Alan L. Hinderliter, M.D.[2], Craig R. Lee, Pharm.D., Ph.D.[1]; (1)Division of Pharmacotherapy & Experimental Therapeutics, Eshelman School of Pharmacy, UNC at Chapel Hill, Chapel Hill, NC; (2)Division of Cardiology, School of Medicine, UNC at Chapel Hill, Chapel Hill, NC

Purpose: Peripheral arterial tonometry (PAT) is a noninvasive and automated method to assess endothelial function, and can be completed by pharmacists in an ambulatory setting. However, it is not known if PAT can distinguish patients with coronary artery disease (CAD) from healthy volunteers (HVTs).
Methods: Using a cross-sectional design, thirty-nine non-smoking CAD patients (≤65 years old) with ≥50% stenosis in ≥1 major epicardial artery were studied 60 ± 29 (mean ± SD) days following their cardiac catheterization, after fasting overnight and withholding morning medications. Thirty-three HVTs without CAD risk factors (e.g., hypertension, diabetes, cholesterol >240 mg/dL, hs-CRP >3 mg/L, BMI >30 kg/m², smoking) were enrolled. Baseline digital pulse volume amplitude (PVA) was measured using the EndoPAT2000 device (Itamar Medical). Reactive hyperemia was induced by forearm cuff occlusion for 5 minutes, and the change in PVA relative to baseline (PAT-ratio) was calculated. Baseline PVA and PAT-ratio were log-transformed and associations with disease status were evaluated by regression.
Results: CAD patients were significantly older (56 ± 7 versus 51 ± 8; P=0.008) and more likely to be male (69% versus 45%; P=0.042) compared to HVTs, respectively. Racial differences were not observed (13% versus 18% African-Americans; P=0.529). PAT-ratio was lower in CAD patients compared to HVTs [median (25–75%): 1.5 (1.16–2.33) versus 2.01 (1.32–2.56), respectively; P=0.089]; however, this difference was not statistically significant and was attenuated after adjusting for age, gender and race (P=0.206). CAD patients had significantly higher baseline PVA compared to HVTs [771.3 (466.2–1159.3) versus 356.3 (169.6–724.5), respectively; P=0.001], that remained statistically significant after adjusting for age, gender, and race (P=0.010).
Conclusion: PAT measures of endothelial function differ between CAD patients and HVTs. The largest differences were observed with baseline PVA, not PAT-ratio, suggesting this may provide greater utility as a phenotypic measure of endothelial function. Additional studies remain necessary to define the clinical utility of PAT testing.

281. Effect of dronedarone on the defibrillation threshold of cardioverter defibrillators in atrial arrhythmia patients.
Jamie M. Ecklund, Pharm.D.[1], Tammy Chung, Pharm.D.[1], Brian Le, M.D.[2]; (1)Texas Health Presbyterian Hospital Dallas, Dallas, TX; (2)Cardiology and Interventional Vascular Associates, Texas Health Presbyterian Hospital Dallas, Dallas, TX

Purpose: This study will evaluate the effect of dronedarone on the defibrillation threshold (DFT) of automatic implantable cardioverter defibrillators (AICD) in patients with atrial flutter or atrial fibrillation. Other antiarrhythmic agents, particularly amiodarone, have been demonstrated to increase DFT, which poses a risk for AICD failure, sustained ventricular tachyarrhythmia, and death. Due to these clinical implications, it is necessary to determine if dronedarone therapy is associated with similar effects on DFT.
Methods: Patients will be identified via retrospective electronic chart review. Criteria for inclusion are adults with paroxysmal or persistent atrial fibrillation or flutter, AICD placement, and initiation of dronedarone therapy by an electrophysiologist. Patient must have a recorded baseline DFT measured any time before dronedarone initiation, as well as one subsequent DFT after initiation. Patients will

be excluded if they received amiodarone therapy within three months prior to dronedarone initiation. Statistical analysis will include the two-tailed comparison of DFT before and after dronedarone initiation via Wilcoxon Signed-Rank test.

Results: This study is currently ongoing, and final data collection and analysis are highly likely to be completed before presentation. Of the four patients whom have met criteria for study inclusion, the mean baseline DFT was 20.5 Joules. After three days mean duration of dronedarone therapy, the mean follow-up DFT was 17.75 Joules (-12.38%). One of the four patients experienced an increase in DFT from 21 to 23 Joules (+9.5%). The follow-up DFT of every patient remained at least 10 Joules below the maximum output of the ICD device.

Conclusions: Preliminary analysis suggests that dronedarone therapy may not be associated with an acute increase in the DFT of AICD devices in atrial arrhythmia patients. Final conclusions will be drawn upon study completion.

282. Rationale for Proton Pump Inhibitors Use in Clopidogrel Treated Patients.
Ola O. Oyetayo, Pharm.D.[1], Steven Bailey, M.D.[2], Christopher R. Frei, Pharm.D., M.S.[1], Laurajo Ryan, Pharm.D., M.S.[1], Robert L. Talbert, Pharm.D.[1]; (1)The Univeristy of Texas at Austin and The Univeristy of Texas Health Science Center at San Antonio, San Antonio, TX; (2)The Univeristy of Texas Health Science Center at San Antonio, San Antonio, TX

Purpose: In patients receiving clopidogrel in combination with aspirin or at high risk of a GI bleed, the prophylactic use of proton pump inhibitors (PPIs) is recommended. We investigated the rationale for proton pump inhibitor (PPI) use in patients receiving clopidogrel in a large academic medical center.

Methods: We conducted a retrospective chart review of patients in the University Hospital System, (San Antonio, TX), who received clopidogrel between January 1, 2007 and April 30, 2009. Patients were included after discharge for acute coronary syndromes, stroke/TIA, revascularization (coronary, cerebral or peripheral arteries) or stable angina (aspirin allergy).

Results: We identified 572 patients who received clopidogrel for a qualifying event. The median follow-up time was 332 days. Patients received clopidogrel therapy for coronary artery revascularization (66%) followed by cerebral/peripheral artery revascularization (15%), stroke/TIA (14%), ACS-medical (5%) or aspirin allergy (0.5%) respectively. Overall, 79% of patients also received aspirin. PPI therapy was initiated in 201 patients (35%). Patients receiving PPI had higher rates of prior PPI use (67% vs. 1%, p<0.0001) and during hospitalization use (73% vs. 27%, p<0.0001). Esomeprazole (56%) was the most frequently used PPI followed by pantoprazole (35%). The most common indication for PPI use was GERD (48%) followed by patients receiving PPI for no clear indication (43%). Only 4% of patients received PPI for documented GI prophylaxis. PPIs were often continued from prior use (21%), or initiated at discharge (10%) or follow-up (4%).

Conclusion: In this single center study, there was low utilization of PPIs for GI prophylaxis. There is a need to re-evaluate the rationale for PPI use given the large proportion of patients receiving it for no clear indication.

283. *N*-acetylcysteine opposes the effects of tumor necrosis factor-alpha on ventricular function and improves cardiac remodeling following acute myocardial infarction through inhibition of neutral sphingomyelinase activity.
Abdulkhaliq J. Alsalman, M.S., Stefano Toldo, Ph.D., Eleonora Mezzaroma, Ph.D., Neeru Goyal, B.S., Amber Smith, B.S., Gihun Kim, B.S., Jason Quarles, B.S., Che Chang, B.S., Antonio Abbate, M.D., Ph.D., Benjamin W. Van Tassell, PharmD, BCPS; Virginia Commonwealth University, Richmond, VA

Purpose: Tumor necrosis factor-a (TNFa) is an inflammatory cytokine that plays an essential role in the pathophysiology of acute myocardial infarction (AMI) and heart failure. The neutral sphingomyelinase (NSMase) pathway has been implicated as a contributor to pathologic TNFa signaling in the heart. As glutathione

has been reported to inhibit NSMase, we evaluated the use of *N*-acetylcysteine (NAC) to oppose TNFa signaling and ameliorate cardiac remodeling after AMI.

Methods: Healthy mice were injected with a single dose of TNFa (5 μg/kg IP) or control saline followed by transthoracic echocardiography (N≥6 per group). The same protocol was repeated following pre-treatment with saline, NAC120 (120 mg/kg IP), or NAC500 (500 mg/kg IP). In the ischemic model, AMI was induced by surgical ligation of the left coronary artery followed by treatment with saline or NAC500 (daily for 7 days).

Results: TNFa decreased LV fractional shortening (LVES) from baseline by 21%. Pre-treatment with NAC120 partially blocked this effect (-5.8% vs -21%, p<0.001), whereas pre-treatment with NAC500 completely abolished the TNFa effect (-0.04% vs 21%, p<0.001). Consistent with these findings, NSMase activity increased by 4 times from baseline with TNFa (5.3 vs 22.4 nmol/h/mg) and returned to a baseline level following NAC500 (4.99 nmol/h/mg), but without achieving statistical significance between groups. In the AMI model, NAC500 significantly improved LVFS (17.4% vs 14.2%, p=0.03) and decreased LV end diastolic diameter (4.5 vs 5.0 mm, p<0.001) compared to saline group. Consistent with these findings, NSMase activity increased 2 times in AMI mice versus baseline (12.3 vs. 5.3 nmol/h/mg) and returned to below baseline levels with daily NAC treatment (1.8 nmol/h/mg), but without achieving statistical significance between groups.

Conclusion: NAC treatment is sufficient to block the effect of TNFa on cardiac function. Daily treatment with NAC significantly improves cardiac remodeling and function following AMI. The benefits of NAC may be mediated through NSMase inhibition.

284. Evaluation of prescribing patterns of direct thrombin inhibitors, argatroban and lepirudin.
Heather A. Personett, Pharm.D., Narith N Ou, Pharm.D., Magali P Disdier-Moulder, Pharm.D.; Mayo Clinic, Rochester, MN

Purpose: To define current prescribing habits of direct thrombin inhibitors (DTI), argatroban and lepirudin, at Mayo Clinic, a 1,950-bed tertiary care center. With a focus on initial dosing, monitoring, and transition to warfarin, the primary objective was to employ results as a bridge to order set development and approximate cost differences associated with these medications.

Methods: Retrospective descriptive study of 50 argatroban and 25 lepirudin patients from June 2008 to November 2009. Patients <18 years old, those receiving a DTI for <24 hours or both agents during the same admission were excluded. Laboratory data, dosage regimens, monitoring strategies and cost implications were analyzed.

Results: Of the sixty-two percent of argatroban patients who had an indication for initial dose adjustment based on current guidelines and the product package insert (PI), only 16% were dosed appropriately. Lepirudin was used largely in patients with normal renal function, with 56% of prescribers following PI dosing and 28% utilizing new clinical guideline recommendations. Discordance existed between the number of aPTT tests and dose changes prior to reaching therapeutic goal. Twenty-eight percent of patients never achieved goal. The percentage of patients with appropriate recovery of platelets prior to warfarin initiation was 42% and 58% for argatroban and lepirudin patients, respectively. Three warfarin patients lacked a follow-up INR after discontinuation of the DTI. The opportunity for cost savings with lepirudin was approximately $392 a day.

Conclusions: Data suggests areas of improvement for effective utilization of DTI include initial dosing and titration strategies. Platelet recovery prior to initiating warfarin was inconsistent. At Mayo Clinic, the potential for cost savings exists by preferentially using lepirudin in appropriate patients. Targeting these interventions with the use of an order set may enhance safe, effective and economical utilization of argatroban and lepirudin.

285. Ascorbic acid utilization for atrial-fibrillation prophylaxis post coronary-artery-bypass graft and valve replacement surgeries: an interim analysis of a prospective, randomized study.
Regan M. Healy, Pharm.D., Devere Day, Pharm.D., Chuck Van Gorder, Pharm.D.; Intermountain Medical Center, Murray, UT., Bountiful, UT

Purpose: Postoperative atrial fibrillation (AF) occurs in approximately 30% of patients undergoing coronary-artery-bypass graft (CABG) and heart-valve replacement (HVR) surgeries. Identifying oxidative stress as a potential contributing factor to this incidence of electrophysiological disruption introduces a possible role for ascorbic acid, a powerful antioxidant and free-radical scavenger.
Methods: One-hundred and fifty CABG and/or HVR surgical patients are actively being randomized to a control group receiving standard-of-practice (b-adrenergic blockers) or a group receiving standard-of-practice with the addition of ascorbic acid perioperatively. Objectives are to compare the incidence of AF, length of hospital stay, and total hospital cost among groups. Inclusion criteria consists of patients greater than 18 years old able to provide informed consent. Exclusion criteria are patients with persistent or recent AF, or patients who have taken a class I or III antiarrhythmic agent within a predefined period.
Results: The interim analysis includes sixty total patients, with 42% having experienced atrial fibrillation. No difference was found in AF incidence or length of hospital stay. Median total hospital cost was found to be greater in the control group (p=0.0428). In a subanalysis including CABG surgery patients, 7 out of 11 (64%) in the control group versus 5 out of 19 (26%) in the ascorbic acid group experienced AF. However, this difference was found to be non-statistically significant (p=0.063).
Conclusion: Interim data demonstrate that supplementation of ascorbic acid for patients undergoing CABG and/or HVR surgeries leads to no difference in incidence of AF postoperatively. The applied intervention may reduce postoperative AF in patients undergoing CABG surgeries alone.

Clinical Administration

286. Evaluating the clinical and economic impact of an electronic real-time patient surveillance system in a community hospital.
Manal Rassam, Pharm.D.; Saint Barnabas Medical Center, Belleville

Purpose: Interventions have been electronically documented with in the Saint Barnabas Health Care System for the past five years utilizing a web-based documentation software program called Quantifi™. Surveillance of potential interventions have been identified through the manual review of the laboratory, pharmacy profile and admission information. This process has been time-consuming and inefficient at identifying potential clinical interventions. An electronic solution that interfaces each of these systems allowing rules to be applied to them was identified as a need for our system. Further, recent studies have shown that an electronic real-time web-based patient surveillance system, improves the medication review process. The Saint Barnabas Health Care System purchased a electronic web-based surveillance system, Sentri-7™ in 2008 and was implemented in May of 2009. To evaluate the clinical and economic impact of an electronic real-time patient surveillance system in a community hospital
Methods: Quantifi™, the electronic pharmacy intervention repository was queried to determine the number of different types interventions within five specific domains: adverse drug reactions (ADRs), IV to oral, anticoagulation, antibiotic stewardship, and renal dosing. We evaluated these domains three months prior and three months post implementation of Sentri-7™
Results: The number of medications survieled daily have increased for all five domains. Intravenous to oral medications has increased from five to seven, four to eight in the renal dose, two to eight for anticoagulation and three to nine for antibiotic stewardship. The documentation of adverse drug reactions rose by 50% post Sentri-7™ implementation. A report generated from Quantifi™, demonstrated the total dollars saved has increased to $78,503 post conversion verses $35,450 prior to implementation of the Sentri-7™.
Conclusion: A real time surveillance system may increase the number of different clinical pharmacy interventions thus resulting in an increase in dollars saved.

Community Pharmacy Practice

287. Re-engineering the discharge prescription delivery service at Intermountain Medical Center.

Derrick C. Shepherd, Pharm.D.; Intermountain Healthcare, Murray, UT

Intro: Approximately 21% to 27% of patients do not fill their discharge prescription medication orders in a timely manner. The failure to fill discharge prescriptions may result in suboptimal clinical outcomes.
Purpose: Increase healthcare professionals' and patients' awareness of, use of, and satisfaction with the discharge prescription delivery service (Hospitality Program) at Intermountain Medical Center.
Methods: Three patient care units were selected for inclusion in the study based on geographic location (acute cardiovascular unit, post partum unit, and orthopedics unit). A computer based training module (CBTM) was developed for nurses and pharmacists at Intermountain Medical Center (IMC) that details the Hospitality Program. All nurses and pharmacists from the selected units were assigned to complete the CBTM. After completing the CBTM and following the data-collection period, the nurses and pharmacists were surveyed to determine their knowledge of the Hospitality Program. Patients who did and did not use the Hospitality Program were randomly selected for interview by a clinical pharmacist at discharge and 7 days following discharge. Mean turn-around-time was monitored for all patients who used the Hospitality Program from selected units.
Results: Patients who use the Hospitality Program report an improvement in their understanding of discharge medications 83.3% (25/30) of the time. Overall, the Hospitality Program improves patient hospital experience 77% (23/30) of the time. Healthcare professionals' Hospitality Program knowledge had a modest improvement following completion of the CBTM. Implementation of medication-delivery volunteers failed to improve unit-based median turn-around-time. Increased awareness of the Hospitality Program failed to produce increases in volume.
Conclusion: Facilitated patient-pharmacist interactions leads to improved understanding of medication regimens. The Hospitality Program seemed to improve patients' hospital stay overall. A major barrier to Hospitality Program success is the prolonged turn-around-time. Healthcare professionals' recommendation to use the Hospitality Program would increase if turn-around-times were decreased.

Critical Care

288. An evaluation of scheduled versus symptom-driven alcohol withdrawal therapy in the intensive care unit.
Amber L. Elliott, Pharm.D.[1], Krystal K. Haase, Pharm.D.[1], Shawna King, Pharm.D.[1], Harvey M. Richey III, M.S., D.O., M.B.A., FCCP[2]; (1)Texas Tech Health Sciences Center School of Pharmacy, Amarillo, TX; (2)Texas Tech Health Sciences Center School of Medicine, Amarillo, TX

Purpose: Alcohol withdrawal syndrome (AWS) is a common complication of ICU admission. However, limited data exist regarding the best strategy for management of AWS in ICU patients. This is a pilot study to compare AWS management strategies in the ICU and determine their relation to patient outcomes.
Methods: We conducted a retrospective cohort study of 44 patients admitted to the ICU for >24 hours with AWS identified by ICD-9-CM codes and verified through physician documentation. We compared length of stay (LOS), length of ICU stay (LOICUS), and frequency of complications for patients treated with scheduled versus symptom-driven therapy. We used Mann-Whitney U to compare factors in relation to LOS and LOICUS. χ^2 analysis was used to compare frequency of complications.
Results: Patients were predominantly male (84%) and nearly half were admitted with a primary diagnosis of alcohol intoxication or withdrawal. Patients receiving scheduled (74%) versus symptom-driven (26%) gabaminergic therapy on hospital day 1 had median LOS of 6 versus 11.5 days and LOICUS of 3 versus 4 days, respectively (p>0.05). Complications were common, including aspiration pneumonitis (16%), intubation (16%), and falls (13%); 68% of patients required use of restraints. Complications were associated with increased LOS (4.5 versus 9 days, p=0.021). Regression models are being developed to determine independent risk factors for prolonged LOS in these patients.

Conclusion: Current strategies for management of AWS in the ICU include both scheduled and symptom driven modalities. In our study, patients with scheduled therapy had a trend toward lower LOS. The relationship between patient outcomes and treatment approach requires evaluation in a larger prospective sample. Several areas for quality improvement were identified within our institution, including early identification of patients at risk for AWS, prevention of complications, and improved documentation of sedation scores.

Education/Training

289. Attitude and knowledge changes in health profession students towards pharmacy: before and after completion of an Interprofessional Education Fellowship.
Melissa L. Thompson, Pharm.D.[1], Andrea D. Boan, M.S., Ph.D., Candidate[2], Amy V. Blue, Ph.D.[2]; (1)University of Kentucky HealthCare, Lexington, KY; (2)Medical University of South Carolina, Charleston, SC

Purpose: This study will determine health profession students' baseline interprofessional knowledge and attitudes towards interprofessional healthcare teams. It will also assess any change in these variables after the completion of the Interprofessional Education Fellowship at the Medical University of South Carolina. The requirements for completion of the Fellowship are participation in and reflection upon specific collaborative learning experiences and activities at MUSC.
Methods: Interprofessional knowledge will be measured using a pre/post 6-point Lickert scale survey to assess how confident the student feels in his/her knowledge of the other health care professions. This tool has been piloted in a sample of health profession students who are not participating in the Fellowship. Any change in attitudes or feelings towards working in interprofessional healthcare teams will be measured by the pre and post completion of the Attitudes Toward Health Care Teams (ATHCT) scale. This scale has been previously validated and used in other health professions education studies. Students' responses to the instrument pre and post Fellowship experience will be linked to assess changes over the period of the Fellowship.
Results: Data collection is currently taking place while students are completing the Fellowship, a minimum of three semesters. Pilot data from five health profession students in different disciplines with various exposures to interprofessional activities are available. The results from the survey of interprofessional knowledge varied among the respondents, with greater confidence in knowledge of health professions seen in the students who had previously participated in interprofessional activities. Feedback from these respondents was incorporated into the final survey tool which is currently being used in data collection.
Conclusion: Pilot data available show that student involvement in interprofessional activities within the professional curriculum influences perceptions of knowledge of the different health professions. Data collection is anticipated to be complete in the fall of 2011 to allow time for students to complete the Fellowship.

Gastroenterology

290. Evaluation of octreotide prescribing patterns at a tertiary care center.
Erin N. Frazee, Pharm.D., Jenna K. Lovely, Pharm.D., John G. O'Meara, Pharm.D.; Mayo Clinic, Rochester, MN

Purpose: To characterize inpatient octreotide utilization specifically as it pertains to prescribing service, indications, and utilization of the long-acting release formulation, in order to recommend opportunities for cost savings without compromising patient care.
Methods: This study was a retrospective descriptive analysis of 53 inpatients at Mayo Clinic, a 1950-bed tertiary care center, between September 2009 and November 2009. Included patients received ≥1 dose of octreotide for a therapeutic indication. Patients were identified using the Pharmaceutical Care Hospital Rule-Based System. Demographic data, prescribing service, indication, and dosing strategy were collected from the electronic medical record for analysis.

Results: Octreotide was the eighteenth highest drug dollar expense in 2008, with 18% of costs attributable to the inpatient setting. Of inpatient costs 67% were due to the use of the long-acting release (LAR) formulation, a non-reimbursable indication. The median duration of octreotide therapy was 3 days (range 1 to 45 days), with 11% of patients receiving therapy for ≥10 days. The most common services to prescribe octreotide were gastroenterology (25%), critical care (17%) and general surgery (15%). Patients received octreotide for 12 different indications, primarily variceal bleeding (38%), carcinoid syndrome (19%), and non-variceal gastrointestinal bleeding (6%). Three patients (6%) received the LAR formulation of octreotide during their inpatient stay. Pharmacist recommendations on dosing, duration, indication, and discontinuation were accepted 85% of the time.
Conclusions: This analysis led to recommendations which were adopted at Mayo Clinic in Rochester, Minnesota and shared with other Mayo Clinic sites. Restriction of the LAR formulation to the outpatient setting with immediate release formulation substitution for short-term inpatient stays has the potential to substantially reduce inpatient costs. Opportunities for targeted education include emphasizing discontinuation of octreotide when used for non-variceal gastrointestinal bleeding and reassessment of appropriateness for all indications when used in excess of five days duration.

291. Retrospective analysis of alvimopan in open abdominal colorectal surgical procedures.
A. Rebecca Bickley, Pharm.D.[1], Gregory S. King, Pharm.D.[1], Marintha R. Short, Pharm.D.[1], Douglas T. Steinke, Ph.D.[2], John T. Dvorak, M.D.[3], Charles L. Papp, M.D.[3], Bruce M. Belin, M.D.[3], Kevin L. Poe, Pharm.D.[1]; (1)Saint Joseph Hospital, Lexington, KY; (2)University of Kentucky College of Pharmacy, Lexington, KY; (3)Colorectal Surgical Associates, Lexington, KY

Purpose: Following abdominal surgery involving the large or small bowel, postoperative ileus (POI) is one of the most common complications in patient recovery. Alvimopan is a peripherally acting μ-opioid receptor antagonist (PAM-OR) indicated to accelerate the time to upper and lower gastrointestinal (GI) recovery following partial large or small bowel resection surgery with primary anastomosis. The objective of this study was to compare the postoperative length of stay (LOS) in patients who received alvimopan plus alternative postoperative care versus alternative postoperative care alone following open abdominal colorectal surgical procedures.
Methods: This was a single-centered non-interventional retrospective cohort study. Patients with documented open abdominal colorectal surgery since August 2008 who received at least one dose of alvimopan preoperatively and one dose postoperatively were screened for study inclusion and matched with a historical control group of patients according to surgical procedure type and colorectal surgeon. The primary endpoint of this study was to compare the postoperative LOS of patients who received alvimopan plus alternative postoperative care versus alternative postoperative care alone. Descriptive statistics, Student t-test, and Wilcox rank sum test were utilized where appropriate.
Results: Postoperative mean LOS was 5.0 ± 2.5 days for alvimopan plus alternative postoperative care (n = 29) and 6.3 ± 4.7 days for alternative postoperative care alone (n = 29) [P-value = 0.156]. Postoperative median LOS was 5.0 (Range: 2–13) and 5.0 (Range: 2–20), for alvimopan plus alternative postoperative care and alternative postoperative care alone, respectively [P-value = 0.189].
Conclusion: Alvimopan demonstrated a decrease in postoperative LOS in patients treated with alvimopan plus alternative postoperative care versus alternative postoperative care alone in open abdominal colorectal surgical procedures. These findings suggest that alvimopan may play a role in various types of hospital settings.

HIV/AIDS

292. Post-exposure prophylaxis regimens for occupational exposures to HIV.
Lori A. Hensic, Pharm.D., Betty J. Dong, Pharm.D.; University of California, San Francisco, San Francisco, CA

Purpose: The Centers for Disease Control (CDC) recommends specific antiretroviral agents (ARVs) for HIV Post-Exposure Prophylaxis (PEP). CDC PEP guidelines were last updated in 2005, thus do not address the role of newer ARVs for PEP. Alternative, non-guideline PEP regimens may be necessary if there is concern that the source patient harbors a drug resistant virus. PEP experts presently recommend both preferred and non-guideline PEP regimens as clinically warranted. The purpose of this study is to describe non-guideline PEP regimens recommended by PEP experts, and analyze predictors for such recommendations.

Methods: PEP recommendations provided by the National HIV/AIDS Clinicians' Consultation Center Post-Exposure Prophylaxis Hotline (NCCC PEPline) between 1/1/2009–12/31/2009 for occupational percutaneous exposures to HIV-infected source patients were reviewed. Consultations were provided by physicians or clinical pharmacists. Predictor variables were evaluated using univariate analysis with χ^2 tests.

Results: A total of 465 exposures yielded 638 recommended PEP regimen options. Of recommended options, 13.8% (88/638) were non-guideline regimens and included darunavir (42%), raltegravir (36%), atazanavir (22%), or maraviroc (7%) containing PEP regimens. Significant predictors for recommending non-guideline PEP regimens included the following source patient variables: currently on ARVs, specific ARVs in source patient regimen known, prior ARV exposure, known ARV resistance, and clinical status (p<0.05). Variables related to the type of exposure, exposed patient and NCCC clinician profession were not statistically significant.

Conclusion: NCCC PEPline recommendations for non-guideline PEP regimens are primarily associated with source patient characteristics, including a history of ARV resistance. Thus, detailed information about the HIV-infected source patient is crucial in determining the most appropriate PEP regimen. Updated CDC PEP guidelines are needed to incorporate the use of a wider range of available and clinically appropriate antiretroviral agents.

Infectious Diseases

293. Daptomycin Dose-Effect Relationship against Vancomycin-Resistant Enterococcal Bacteremia.
Truc C. Tran, Pharm.D.[1], Hannah R. Palmer, Pharm.D., BCPS[1], Jaye S. Weston, M.S., R.Ph.[1], Elizabeth B. Hirsch, Pharm.D.[2], Dhara N. Shah, Pharm.D.[2], Jessica M. Cottreau, Pharm.D.[2], Vincent Tam, Pharm.D.[2], Kevin W. Garey, Pharm.D., M.S.[2]; (1)St. Luke's Episcopal Hospital, Houston, TX; (2)University of Houston-College of Pharmacy, Houston, TX

Purpose: Daptomycin exhibits in vitro bactericidal activity against clinically significant Gram-positive bacteria, particularly vancomycin-resistant Enterocococci (VRE). Pharmacodynamic evaluations suggest that the area under the concentration-time curve/minimum inhibitory concentration (AUC/MIC) is the marker to favorable microbiologic outcomes. The primary goal of this study is to examine the relationship between daptomycin AUC/MIC with recurrence and mortality in patients with VRE bacteremia.

Method: Cohort study of hospitalized patients with VRE bacteremia given daptomycin. Patients were excluded if they received continuous renal replacement therapy or polymicrobial bacteremia. AUC/MICs were calculated based on population pharmacokinetics, MICs were determined by Etest. Attributable mortality and VRE recurrence was assessed stratified by AUC/MIC ratio (<>400 µg/ml/h).

Results: Fifty-six patients (52% male; 41% Caucasian) aged 58 ± 14 years were included. Average AUC/MIC was 3,616 ± 19,294 µg/mL/h (range 69–145,214). Twelve of 56 (21%) patients had daptomycin AUC/MIC < 400. Mortality trended higher in patients with AUC/MIC<400 (5 of 12 (42%)) compared to patients with an AUC/MIC ratio >400 (11 of 44 (25%)) (p=0.29). VRE recurrence was higher in patients with an AUC/MIC ratio <400 (3 of 12 (25%)) compared to patients with a AUC/MIC ratio >400 (5 of 44 (11%)) (p=0.34).

Conclusion: A large range of daptomycin AUC/MIC ratios were achieved in this patient population. Although not statistically significant, a daptomycin AUC/MIC ratio greater than 400 showed trends to decreased mortality and recurrence rates. Ongoing data

collection to create a larger database will help to validate these findings.

294. Likelihood of inadequate antimicrobial treatment for catheter-related and primary bacteremia.
Megan Davis, Pharm.D., BCPS[1], Richard H. Drew, Pharm.D., M.S., BCPS[2], Deverick Anderson, M.D., M.P.H.[1], Michelle Sharpe, Pharm.D.[1]; (1)Duke University Medical Center, Durham, NC; (2)Duke University Medical Center and Campbell University College of Pharmacy and Health Sciences, Durham, NC

Purpose: To determine the utility of Likelihood of Inadequate Therapy (LIT), a calculated parameter based on both pathogen frequency and in vitro susceptibility, for determination of appropriate empiric unit-specific antimicrobial therapy for catheter-related and primary bloodstream infections (BSIs).

Methods: This single-center, retrospective study included adult patients hospitalized July 1, 2007–June 30, 2009 in either medical or surgical intensive care units (ICU) with a BSI. Patients with secondary bacteremia (defined as positive cultures at a distant site yielding the same pathogen and resistance less than or equal to 7 days prior to the BSI date) were excluded. Data collected included patient demographics, date of admission and BSI, location, pathogen and antimicrobial susceptibilities. Pathogen frequency and drug resistance rates for each ICU were used to calculate the organism-specific, cumulative, and syndrome-specific probability of inadequate antimicrobial treatment as described by the LIT (Infect Control Hosp Epidemiol 2009;30:672)

Results: Two hundred and eighteen pathogens were isolated from 205 unique patients during the study period. Of the isolates, 47.2% were gram-positive bacteria, 31.2% were gram-negative, and 16% were fungi. The medical ICU antimicrobial rank based on BSI LIT (best to worst) was gentamicin > carbapenems > tobramycin > piperacillin-tazobactam > ciprofloxacin > 3rd and 4th generation cephalosporins. For the surgical ICU, it was tobramycin > carbapenems > piperacillin-tazobactam > gentamicin > ciprofloxacin > 3rd and 4th generation cephalosporins.

Conclusions: Despite high overall susceptibility and usage, determination of LIT revealed piperacillin-tazobactam inferior to other empiric therapies for BSI. In addition to antibiograms, determination of LIT may reveal differences in the rank order of appropriate empiric antibiotics, illustrating the need for unit-specific surveillance of microbiological data.

Managed Care

295. Prevalence of meeting the A1c, blood pressure, and cholesterol (ABC) goal in veterans with diabetes mellitus at the Iowa City Veterans Affairs (ICVA) Medical Center.
Scott M. Vouri, Pharm.D., Robert Shaw, Pharm.D., M.P.H., Nancee Waterbury, Pharm.D., Jason Egge, Pharm.D., BCPS, M.S., Bruce Alexander, Pharm.D., BCPP; Iowa City VAMC, Iowa City, IA

Background: Poorly controlled diabetes mellitus increases microvascular and macrovascular disease risk. The American Diabetes Association (ADA) recommends treatment goals for hemoglobin A1c (<7.0%), blood pressure (<130/80 mmHg), and LDL-cholesterol (<100mg/dl) to prevent complications. Collectively, these goals are referred to as the "ABCs" of diabetes and achieving all the three goals is considered meeting the ABC goal of diabetes. In the National Health and Nutrition Examination Survey (NHANES) 1999–2000, only 7.8% of patients with diabetes achieved this goal. Two other studies, Look AHEAD and CBEP study, also assessed the ABC goal which was achieved in 10.1%, 22% of patients, respectively.

Purpose: Determine prevalence of veterans meeting their ABC goal. Our secondary analysis determined who met individual goals and identified predictors for achieving the ABC goal.

Methods: We identified 7359 patients who received hyperglycemic medications. Most recent A1c, blood pressure, and LDL-cholesterol were collected from 1/1/2008 through 9/29/2009.

Results: Of the 6770 (97.6% male) patients meeting inclusion criteria, 17.9% achieved the ABC goal. Individually A1c, blood pressure, and LDL-cholesterol goals were met in 54.6%, 42.6%, and 66.6% patients,

respectively. Multivariate analysis revealed the following positive predictors to achieve the ABC goal: older age, BMI <30, HMG-COA reductase inhibitor, influenza vaccination, and macrovascular disease. Negative predictors included: use of insulin, use of sulfonylureas, or enrolled in Diabetes Telehealth clinic.

Conclusion: Our study results show continued improvement in meeting the ADA's established ABC goal. Also, five positive predictors were identified which correlate with achieving the ABC goal of diabetes.

Pediatrics

296. Dry blood spot analyses: a significant advance in pediatric clinical trials.
Casey Baker, Pharm.D.[1], Claudia Meek, Ph.D.[2], Richard D. Leff, Pharm.D.[2]; (1)Children's Hospital of the King's Daughter, Norfolk, VA; (2)Texas Tech University Health Sciences Center, Dallas, TX

Purpose: Clinical trials in infants and children are often limited by frequency and volume of blood sampling. Dry blood spot analyses promise to decrease required blood volume and simplify sample storage. A method for analyses of serum ibuprofen content using dry blood spots is being validated for use in support of intravenous ibuprofen pharmacokinetic and efficacy trials in pediatric management of moderate to severe pain.
Methods: A LC-MS/MS method for analyses using liquid:liquid extraction has been developed and qualified to support initial pharmacokinetic investigations in children. Whole blood obtained from subjects in the pharmacokinetic study will be used to compare analytical methods; a total of 100 samples will be used for comparison. Using dry blood spots, a dry blood spot extraction and preparation technique will be developed. Serum ibuprofen concentrations determined from dry blood spot extraction will be compared to concentrations determined from liquid:liquid extraction. Significant differences between the two methods will be determined using Student's t-test; the predetermined level of significance is a = 0.05. A difference of >10% between concentrations determined using the two methods will be determined to be clinically significant.
Results: Dry blood spot extraction require less than 0.050 mL of whole blood. In comparison, the liquid:liquid extraction method requires ~0.400 mL. The ibuprofen analyte is separated using a Varian Diphenyl 5m (50 x 0.2 mm) column, 0.1% Formic Acid in Water:0.1% Formic Acid in Methanol (0.2 mL/min) mobile phase, and m/z = 207 → 161. The lower and upper limits of quantitation are 50 ng/mL and 90 ug/mL, respectively (RSD <15%).
Conclusion: We speculate that there will be no statistical or clinically significant difference between ibuprofen concentrations determined using either analytical (extraction) method. Use of dry blood spot analyses promise to significantly reduce loss of blood volume from clinical investigations in infants and children.

Pulmonary

297. Respiratory outcomes associated with inhibition of the renin-angiotensin-aldosterone system among patients with chronic obstructive pulmonary disease.
Cory E. Fominaya, Pharm.D., Jack Brown, M.S., Pharm.D., Fred Doloresco, M.S., Pharm.D., Scott V. Monte, Pharm.D.; SUNY: University at Buffalo, Buffalo, NY

Purpose: The goal of this study was to determine pulmonary and cardiovascular outcomes of patients with chronic obstructive pulmonary disease (COPD) and hypertension (HTN) treated with renin-angiotensin-aldosterone system inhibitors (RAAS) compared to those who were not treated with RAAS inhibitors.
Methods: Using managed care and pharmacy claims, patients were retrospectively identified and were eligible for inclusion if they were <65 y/o and had an ICD-9 code associated with both COPD and HTN. A comprehensive medication record was obtained for each patient. Exposure to RAAS inhibitors such as angiotensin converting enzyme inhibitors (ACE) or angiotensin receptor blockers (ARB) was examined in years of exposure. Patients were excluded if they had

been admitted to the hospital within 90 days of study entry with a primary diagnosis of respiratory exacerbation defined by (DRG 079–081, 085–102, 475, 565–566), or if they had a diagnosis of malignancy, diabetes, emphysema, or asthma. Kaplan-Meier analysis was performed for patients receiving ACE/ARB therapy compared to those who never received therapy for the composite outcome of hospitalization (DRG 87, 88), oral steroid use, and pneumonia.
Results: Of the 3731 patients identified as having COPD and HTN, 623 met the criteria for evaluation. Kaplan-Meier analysis found that the cohort receiving an ACE/ARB had a higher event rate within the first two years compared to those not exposed.The number of events in the at-risk population not exposed to ACE/ARB therapy was 79/271. The number of events in the at-risk population exposed to ACE/ARD therapy from <1 year, 1–2 years, 2–3 years, 3–4 years, and greater than 5-years was 149/352 (p=0.018), 106/207 (p=0.001), 63/102 (p<0.001), 41/65 (p=0.008), and 25/42 (p=0.067), respectively.
Conclusion: Overall, patients receiving ACE/ARB therapy tended to have increased respiratory exacerbations. Further research is necessary to determine the risk-benefit profile of ACE/ARB therapy among COPD patients.

Transplant/Immunology

298. To load or not to load: comparison of a mycophenolic acid oral load vs. standard dosing.
Jamie Joseph, Pharm.D.[1], James Thielke, Pharm.D.[2], Patricia West-Thielke, Pharm.D.[3]; (1)University of Illinois at Chicago, Morton Grove, IL; (2)University of Illinois Medical Center at Chicago (UIMCC), Chicago, IL; (3)University of Illinois at Chicago, Chicago, IL

Purpose: MPA is available as MMF and EC-MPA. Aim: To compare outcomes among patients who received the EC-MPA oral load versus the MMF oral load versus std MMF dosing; under both thymoglobulin and daclizumab induction. To compare the PK of the 2 loading strategies.
Methods: Ninety renal transplant recipients were retrospectively reviewed for rejection (empirically-treated and biopsy-proven), infection, patient and graft survival, and tolerability. Under thymoglobulin induction, 20 pts received EC-MPA oral load, 20 pts received MMF oral load, and 20 pts received std MMF dosing. Under daclizumab induction, 15 patients received MMF oral load and 15 patients received std MMF dosing. Five pts in the MMF oral load group will undergo a PK study to compare with EC-MPA oral load PK data.
Results: Baseline characteristics were similar except the MMF oral load group (daclizumab) was older (52.2 vs. 40.7, p=0.03). At 6 months, there was no significant difference in patient or graft survival. Notably, there was 100% tolerability of the oral loads. Incidence of all rejections (thymoglobulin) were 25% in MMF std dose group, 50% in EC-MPA oral load group, and 30% in MMF oral load group (p=NS). Incidence of all rejections (daclizumab) were 20% in both MMF std dose and MMF oral load groups (p=NS). Rates of infection (thymoglobulin) were 20% in the MMF std dose group and 10% in both oral load groups (p=NS). Rates of infection (daclizumab) were 13% in MMF std dose group and 7% in MMF oral load group (p=NS).
Conclusion: MPA oral load does not reduce rejection however a larger sample is required to detect a significant reduction. There was no significant difference in patient or graft survival at 6 months. The oral load does not increase infection and is well-tolerated. PK comparison between the EC-MPA and MMF oral loads is underway.

299. Conversion of Prograf® to generic tacrolimus (Sandoz) in stable renal transplant recipients.
Barrett R. Crowther, Pharm.D.[1], Heather Dobie, Pharm.D.[1], Rebecca Brady, Pharm.D., BCPS[1], Reed C. Hall, Pharm.D., BCPS[1], Cody L. Allison, Pharm.D., BCPS[1], Kay Green, R.Ph., BCPS[2], Pamela R. Maxwell, Pharm.D., BCPS[1]; (1)University Transplant Center, The University of Texas Health Science Center at San Antonio, San Antonio, TX; (2)University Health System, San Antonio, TX

Purpose: To assess the short-term efficacy, safety, and need for dosage changes of a milligram-per-milligram conversion from brand

(Prograf®, Astellas) to generic tacrolimus (Sandoz) in stable renal transplant recipients.

Methods: This is a prospective, single-center, observational trial including adult renal transplant recipients at least 3 months post-transplant who are voluntarily converting from stable doses of Prograf® to a milligram-per-milligram equivalent dose of generic tacrolimus by Sandoz. Mean tacrolimus trough concentrations and serum creatinine are being analyzed at baseline, after approximately one week, and after approximately 30 days. Study investigators are monitoring patients for adverse events via questionnaire, tacrolimus dose changes, hospitalizations, and allograft rejection after approximately 30 days post conversion. To detect a 2 ng/mL difference from baseline, 18 patients are required to provide 80% power.

Results: To date, three stable renal transplant recipients have been converted from Prograf® to generic tacrolimus, with a target of 18 patients to be enrolled by October 2010. Two males and one female have enrolled with an average age of 58.3 ± 2.5 years. The mean difference in serum tacrolimus trough concentration from study baseline with brand compared to generic after one week is 0.367 ± 0.115 ng/mL. Comparatively, the mean change of tacrolimus trough levels between most recent level measured prior to enrollment and baseline is 1.300 ± 0.954 ng/mL. One patient required a tacrolimus dose increase after one week of generic tacrolimus due to sub-therapeutic trough concentration at the start of the study. Minimal serum creatinine variability has been observed. No patient has experienced serious adverse effects, required hospitalization, or experienced graft rejection during the study.

Conclusions: Preliminary study results demonstrate the inherent variability of brand tacrolimus may be similar to or exceed the variability of switching from brand to generic in stable renal transplant recipients.

STUDENT SUBMISSIONS

Ambulatory Care

300. Evaluation of initial clinical outcomes from a newly established medication therapy management initiative.
Kathleen A. Matthews, Pharm.D. candidate[1], Heather B. Congdon, Pharm.D.[1], Michael Akers, Pharm.D. candidate[1], Hoai An Truong, Pharm.D.[1], Faramarz Zarfeshan, R.Ph.[2]; (1)University of Maryland School of Pharmacy, Baltimore, MD; (2)ALFA Specialty Pharmacy, Silver Spring, MD

Purpose: To assess selected clinical outcomes from the first year of clinical pharmacy services (CPS) at Mercy Health Clinic (Gaithersburg, MD), a Health Resources and Services Administration (HRSA) Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) safety net clinic

Methods: The population of focus was identified as uncontrolled diabetic patients referred by clinic physicians and staff. Pharmacists conducted a medication therapy review (MTR) and provided diabetes education as appropriate. A summary of pharmacists' findings and recommendations were provided to the physician as part of the patient chart prior to the physician-patient encounter. A chart review was conducted for patients who received CPS between October 1, 2009 and July 1, 2010. Data collection will continue until September 30, 2010. Selected clinical outcomes included glycosylated hemoglobin (A1c), blood pressure (BP), and calculated low-density lipoprotein (LDL). The most recent laboratory data collected prior to the patient's first CPS encounter served as the baseline (pre-CPS) measure. The most recent laboratory data collected since patient began receiving CPS served as post-CPS measure.

Results: Forty-nine patients received services. Twenty-four patients had pre- and post-A1c data available. Mean A1c decreased from 9.3 ± 2.0% at baseline to 8.1 ± 1.5% at follow-up. Twenty-eight patients had pre- and post-BP data available. Mean systolic BP decreased from 133 ± 20 mmHg at baseline to 130 ± 20 mmHg at follow-up. Mean diastolic BP decreased from 81 ± 9 mmHg at baseline to 75 ± 12 mmHg at follow-up. Twelve patients had pre- and post-LDL data available. Mean LDL decreased from 124 ± 34 mg/dL at baseline to 106 ± 42 mg/dL at follow-up. Final data analysis will be completed on October 1, 2010.

Conclusions: CPS provided by pharmacists in a collaborative, safety net clinic setting resulted in positive clinical outcomes for potentially high-risk, high-cost, complex patients.

Cardiovascular

301. Effect of Severe Hypervolemia on Anticoagulation in Patients Taking Warfarin.
Tiffany N. Sanders, Pharm.D. Candidate, Toni L. Ripley, Pharm.D.; University of Oklahoma College of Pharmacy, Oklahoma City, OK

Purpose: Bleeding complications from anticoagulation with warfarin therapy can be catastrophic. Hypervolemia due to heart failure (HF) may be one of the factors associated with excessive anticoagulation, though a recent prospective study showed there was no association with *mild hypervolemia* from HF. However, the effects of severe hypervolemia due to HF on anticoagulation are still unclear. These are results from a retrospective chart review characterizing the association between severe hypervolemia due to HF and International Normalized Ratio (INR) elevations in patients taking warfarin.

Methods: This is a retrospective chart review of patients admitted to the University of Oklahoma Medical Center with a primary diagnosis of HF between 1/1/2009–5/1/2010. Records were reviewed and included in the analysis if the patient is: ≥ 18 years old, taking warfarin for ≥ 3 months, and admitted for hypervolemia due to HF requiring intravenous diuretics. Patients are excluded if they received treatment with an intravenous inotrope (not including digoxin) or for an acute coronary syndrome.

Results: Three hundred thirty-two HF admissions were identified. Forty-eight admissions included patients taking warfarin. Eight events were excluded due to not taking warfarin for ≥ 3 months (n=3), not being treated with an intravenous diuretic (n=1), receiving an intravenous inotrope during admission (n=1), or not having an INR available prior to the event (n=3), leaving 40 events to be included in the final analysis. The average INR prior to admission was 2.38 ± 1.097; the average INR on admission was 2.75 ± 1.60 (p=0.15). The mean INR change was 0.43 ± 1.38.

Conclusions: These results suggest severe hypervolemia does not cause elevation of the INR. Although this analysis is limited by its retrospective design, it provides hypothesis-generating data that advances understanding of the relationship between HF and anticoagulation. These results need to be confirmed by prospective analysis.

302. The incidence of bleeding with enoxaparin bridging.
Johanna L. Norman, Pharm.D.,Candidate[1], Maria Pham, Pharm.D.[2], Kelly C. Rogers, Pharm.D.[1], Shannon W. Finks, Pharm.D.[1]; (1)University of Tennessee College of Pharmacy, Memphis, TN; (2)Veterans Affairs Medical Center Memphis, Memphis, TN

Purpose: Although sometimes necessary to maintain therapeutic anticoagulation, enoxaparin bridging may cause significant hemorrhagic complications. Observation at our institution suggested the incidence of bleeding associated with bridging therapy was high.

Methods: We performed a retrospective review of medical records of patients who received concomitant enoxaparin and warfarin from the Memphis Veterans Affairs Medical Center between July 1, 2007 and June 30, 2009. Demographics, indication, duration of therapy, dosing, concomitant medications, laboratory data, transfusions, and rehospitalizations within 30 days of cessation of bridging therapy were evaluated. Bleeding events were classified according to both TIMI and GUSTO criteria.

Results: A total of 238 patients were bridged for a mean of 12.5 (± 8.2) days. The mean age and creatinine clearance were 64.6 years (± 10.9) and 70.5 mL/min (± 25.1), respectively. Enoxaparin was dosed appropriately in 231(97%) patients. Bleeding events were identified in 52 (22%) patients with 36 (15%) meeting TIMI (17 major, 8 minor, 11 minimal) and 43 (18%) meeting GUSTO (1 severe, 6 moderate, 36 mild) criteria for bleeding. Two patients who bled received higher doses than recommended for renal function. Patients who experienced bleeding had reduced creatinine clearance (59.99 ± 22.49 vs. 73.46 ± 25.04, *p*<0.05) and were more likely to take concomitant medications (69% vs. 53%, *p*<0.05) known to increase bleeding risk or interact

with warfarin. Nineteen (8%) required hospitalization, and 13 (5%) received transfusions. No deaths were attributed to bleeding.

Conclusion: Even when dosed appropriately, the frequency of hemorrhagic complications from enoxaparin bridging is considerable. Careful assessment of the risks and benefits of bridging, including screening for diminished renal function and interacting medications, is necessary to avoid bleeding, transfusions, and rehospitalization.

Clinical Trials

303. Evaluation of potential randomization errors in randomized controlled clinical trials.
Kung Ju Chon, M.S.[1], *Dong Eun Lee, B.S.*[2], Wan Gyoon Shin, Pharm.D., Ph.D.[2], Hye Suk Lee, M.S.[3], Jung Mi Oh, Pharm.D.[2]; (1)Clinical Trials Center Pharmacy, Clinical Research Institute, Seoul National University Hospital, Seoul, South Korea; (2)College of Pharmacy, Seoul National University, Seoul, South Korea; (3)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea

Purpose: Proper randomization in randomized controlled trials (RCTs) eliminates the selection bias to balance both known and unknown prognostic factors in the assignment of treatments. In this study, potential randomization errors that can occur in randomizing patients to their respective groups in RCTs were analyzed.
Methods: This study was carried out to evaluate the clinical trial protocols that were submitted to and managed by the Clinical Trials Center Pharmacy of Seoul National University Hospital from January 2007 to December 2008. Types of randomization errors analyzed included inappropriate random sequence generation, allocation concealment, replacement of subject after withdrawal from the study, revelation of block size in block randomized trials, and pooled analysis of subject in different placebo groups which were not randomized. The prevalence of these possible errors was compared between three types of the trials according to the trial initiators: investigator-initiated trials (IITs), domestic pharmaceutical sponsor-initiated trials (domestic SITs), and international pharmaceutical sponsor-initiated trials (international SITs).
Results: One hundred and eighty six RCTs were included in this evaluation, of which 15 (8.1%) were IITs, 51 (27.4%) were domestic SITs, and 120 (64.5%) were international SITs. There were no RCTs having error regarding random sequence generation. There were five trials with randomization table given to the investigator, and 15 studies where replacement of subject after withdrawal was planned. The sizes of randomization block were described in the protocols of five ITTs, 16 domestic SITs and one international SIT. Pooled analysis of subjects in different placebo groups was planned in six domestic SITs and one international SIT. IITs and domestic SITs had statistically higher prevalence of total potential errors regarding randomization compared to international SITs.
Conclusions: The results of this study highlight various potential errors related to randomization, and suggest every effort is demanded to improve methodological aspects of clinical trials regarding randomization.

Community Pharmacy Practice

304. U.S. Pharmacist patient teaching aids: Are they easy to comprehend?.
Chinelo N. Enwonwu, Pharm.D. Candidate[1], Monina R. Lahoz, Ph.D.[2]; (1)School of Pharmacy – Worcester/Manchester, Massachusetts College of Pharmacy and Health Sciences, Worcester, MA; (2)School of Pharmacy - Worcester/Manchester, Massachusetts College of Pharmacy and Health Sciences, Worcester, MA

Purpose: The purpose of this study was to assess the readability and suitability of the *U.S Pharmacist* patient teaching aids that are published monthly and cover a wide range of medical/health topics. Originally designed as a tear-off page for routine distribution to patients when first published in 1993, the two-page teaching aids are now available via the Internet from the journal's Website starting with the 2003 issues. It is well documented in the literature that such

patient education materials are written at a reading level that is too high for most adult Americans to understand.
Methods: Forty-seven patient teaching aids were randomly selected from an estimated pool of 194 aids published between April 1993 and May 2010. Three readability formulas were used to calculate the reading grade level of these materials: Fry, Flesch Kincaid (FK), and Flesch Reading Ease (FRE). Suitability (content, literacy demand, graphics, layout and typography, learning stimulation/ motivation, and cultural appropriateness) was assessed with the Suitability Assessment of Materials (SAM) instrument, which rates materials as "superior", "adequate" or "not suitable".
Results: To date, the reading grade levels of 30 patient teaching aids have been calculated. They ranged from 7th to16th grade level (Fry), 8th to 13th grade level (FK), and 32.4% to 68.3% (FRE, considered easily understood by 8th graders to college graduates). The SAM scores for the 30 materials ranged from 19.0% to 76.2%, mean = 29.6% ± 11.4 or "not suitable".
Conclusions: Preliminary data indicate that the *U.S Pharmacist* patient teaching aids may not be easy to comprehend and not suitable, especially for patients with low health literacy. Literacy experts recommend that patient education materials should be written at a 6th grade level so as to be readable by the greatest number of patients.

305. Association between Pharmacists Counseling, Awareness and Attitude towards Labeling changes for Over-the-Counter Internal Analgesic, Antipyretic and Antirheumatic drugs.
Ankit J. Shah, B.S., Aditi Kadakia, B.S., Parul Gupta, M.S., Rituparna Bhattacharya, B.S., Sujit S. Sansgiry, Ph.D.; University of Houston College of Pharmacy, Houston, TX

Purpose: Over use of acetaminophen and non steroidal anti-inflammatory drugs (NSAIDs) taken over-the-counter (OTC) is a common problem. FDA in 2009 proposed labeling changes to increase consumer awareness of OTC internal analgesic, antipyretic and antirheumatic (IAAA) drug use. The objective of this study was to assess awareness and attitude of community pharmacists regarding the labeling changes for OTC IAAA drugs and determine association between patient counseling, pharmacist's awareness, and attitude regarding these labeling changes.
Methods: A prospective, cross-sectional study was conducted by surveying community pharmacists working in a 15-mile radius of the Texas Medical Center. The survey instrument consisted of a 25 item questionnaire. Descriptive statistics were used to analyze pharmacist's awareness and attitude, two-sided studentized *t*-test was used to evaluate the association of awareness with attitude, while χ^2 analysis was used to evaluate the association of patient counseling with awareness.
Results: A total of 51 (73%) community pharmacist participated in this study. Around 65% were aware of the labeling changes introduced by the FDA. Overall, attitude of pharmacists towards all labeling changes was positive (Mean=4.2, SD=0.98). Pharmacist's attitude towards the labeling change was affected by their level of awareness of these changes like highlighting ingredient name (p<0.05), and appearance of "See New Warnings" statement (p<0.05). Pharmacists who counseled patients on OTC medications seemed to be aware about certain changes like highlighting ingredient name (p<0.05), appearance of "See New Warnings" statement (p<0.05), drug interaction warnings (p<0.05) and use of NSAID's leading to stomach bleeding (p<0.05).
Conclusion: Pharmacists had positive attitude and were aware regarding the labeling changes for OTC IAAA drug products. Pharmacists who counseled patients on OTC drugs frequently were more aware about the specific changes made on the label and had a positive attitude towards these changes.

306. Establishing the Medication Safety Research Network of Indiana (Rx-SafeNet): perspectives of community pharmacy employees.
Lindsey V. Seel, B.A., Kyle E. Hultgren, Pharm.D., Margie E. Snyder, Pharm.D., M.P.H.; Purdue University College of Pharmacy, West Lafayette, IN

Purpose: To describe stakeholder interest, potential barriers and

facilitators to joining, and research priorities regarding the establishment of a state-wide community pharmacy practice-based research network (PBRN). Study findings will be used to enrich the development of the PBRN by providing insight into the opinions and experience of potential members.

Methods: Community pharmacy employees in Indiana were invited to complete an online survey between March and May of 2010. Recruitment occurred through a series of mailings addressed to the pharmacist-in-charge (n=1125 pharmacies).

Results: Usable responses were received from a total of 180 participants, including 140 pharmacists. The majority (76.4%) of respondents did not have experience with research activities, however 49.1% indicated that they were somewhat or very interested in joining the PBRN. When rated on a scale of one to ten, primary incentives for joining appear to be the potential enrichment of care provided to patients (mean: 8.78), an improved relationship with patients/providers (mean: 8.34), and greater knowledge of medication safety practices (mean: 8.26). Contrarily, the most important barriers were time constraints (mean 7.35) and difficulty recruiting patients (mean: 6.26). As for potential topics to study, respondents rated dispensing errors (mean: 9.25) and medication reconciliation (mean: 8.68) as the most important. Additional analyses are currently being conducted.

Conclusion: We anticipate that survey findings will enhance member recruitment and policy development, while minimizing potential organizational and philosophical difficulties when the PBRN becomes active. Results will also guide project choices, grants pursued, membership benefits and other arenas. We hope this research will also provide a framework for other newly forming PBRNs as an example for how to shape network development based on the opinions of potential members.

307. Evaluating the Impact of Implementing a Pharmacy-Based Immunization Delivery Program into Pharmacy Curriculum on Student Pharmacist Involvement in Immunization Clinics.
Rachael E. Moore-Przyborowski, Pharm.D. Candidate, Christina M. Madison, Pharm.D.; University of Southern Nevada, Henderson, NV

Purpose: The University of Southern Nevada College of Pharmacy (USN-COP) added the nationally recognized American Pharmacists Association (APhA) Pharmacy-Based Immunization Delivery program to the pharmacy curriculum for the 2009–2010 academic year. Student pharmacists were given the opportunity to participate in local immunization clinics before and after the immunization training was conducted on November 18th, 2009. We hypothesize that implementing mandatory immunization training during the pharmacy curriculum increases student involvement in immunization clinics and activities.

Methods: Students were informed at the beginning of the academic year of the immunization training conducted in November 2009. Notifications of immunization clinic opportunities were sent out to students throughout the 2009–2010 influenza season. Records of student pharmacists' involvement were maintained throughout the academic year. A survey will be erected and administered to the student pharmacists who completed the immunization training to determine involvement in immunization clinics and vaccination services. We will be evaluating student involvement before and after immunization training to determine if implementation of mandatory immunization training increases student involvement in immunization clinics.

Results: Survey results and student participation in immunization clinics (including H1N1 clinics) are expected to be completed by September 2010.

Conclusion: Training student pharmacists in immunization practices may impact public health in the future by improving student involvement and advocacy for immunizations services and delivery. Survey results and student participation in immunization clinic results can validate increased student involvement in immunization clinics and subsequently increase vaccination rates in our community.

308. Evaluating Levothyroxine: Is Morning Administration Required?.
Sarah A. Moore-Przyborowski, Pharm, D, Candidate; University of Southern Nevada, Las Vegas, NV

Purpose: When counseling patients on the appropriate administration of levothyroxine, pharmacists recommend taking the medication immediately after waking on an empty stomach and to abstain from food for at least one-half hour after taking the medication. However, new research has demonstrated that levothyroxine may be more efficiently absorbed and effective if taken immediately before bedtime on an empty stomach. A literary review of current studies will be conducted to determine if levothyroxine is best administered upon waking or if bedtime administration is appropriate.

Methods: A PubMed search with the terms "levothyroxine", "administration", "bedtime", and "morning" will be conducted. An extensive literary review of several studies will be performed and the results compiled to determine if either bedtime or morning administration is favored.

Results: Pending with an expected completion date of September 2010.

Conclusions: The prime complaint from patients regarding levothyroxine compliance is that patients must wait to eat after waking, which is challenging for several patients. Recommending that patients take levothyroxine at night will significantly increase medication compliance by eliminating the difficultly of having to take this medication on an empty stomach to avoid interactions that will decrease drug absorption and efficiency. Changing how pharmacist counsel in regards to levothyroxine administration will not only lead to increased patient compliance, but will lead to healthier patients that have an increased quality of life.

309. Ethnic and racial differences in parental willingness to accept obesity counseling from non-physician healthcare providers.
Daniel W. Waller, Pharm.D./M.S.C.R., Candidate, Christopher E Anson, Pharm.D./M.S.C.R. Candidate, Melissa Johnson, Pharm.D., M.H.S., AAHIVE, Tina Tseng, Ph.D., M.S.H.P., Ray Tseng, DDS, Ph.D.; Campbell University, Morrisville, NC

Purpose: Childhood obesity has becoming a significant health concern among children and adolescents. Ethnic or racial differences in attitudes regarding body weight and image may result in the need for customized dietary counseling to address obesity issues with parents of different ethnicities or races. The purpose of this study was to determine if ethnic or racial differences existed with respect to parental perception of child's weight, and to acceptance of obesity counseling from a non-physician healthcare professional. The significance of these findings may identify specific ethnic or racial groups that would significantly benefit from obesity counseling administered by non-physician healthcare professionals, such as a pharmacist.

Methods: A 37-item survey was deployed in a North Carolina Department of Public Health that evaluated parental education level, perception of child's weight status, and willingness to accept obesity counseling. Child's weight and height were measured, and body mass index percentile for age and sex was calculated at time of survey deployment. Bivariate analysis was used to determine if ethnicity or race affected parental knowledge of obesity, perception of child's weight, and parental acceptance of counseling from a non-physician healthcare professional.

Results: There was no difference in prevalence of overweight or obesity among Caucasian, Hispanics and African-American respondents. Hispanics scored lower on the knowledge tests than other groups. Hispanics were more likely to talk to doctors, dentists, or school teachers than other ethnicities. Non-Hispanics were more willing to talk exclusively to doctors than Hispanics.

Conclusion: Caregivers of Hispanic children displayed an increased willingness to speak with non-physician professionals about childhood overweight and obesity compared to non-Hispanic caregivers. This suggests that pharmacists may have a significant role in engaging this group of caregivers in discussions related to the prevention of childhood overweight and obesity.

310. Association between parental education level, perception of child's weight, and acceptance of obesity counseling: opportunities for pharmacists.
Christopher E. Anson, Pharm.D./M.S.C.R., Candidate[1], Daniel W. Waller, Pharm.D./M.S.C.R., Candidate[1], Melissa Johnson, Pharm.D.,

M.H.S.[2], Tina Tseng, Ph.D., M.S.P.H.[3], Ray Tseng, D.D.S., Ph.D.[1]; (1)Campbell University, Morrisville, NC; (2)Duke University Medical Center and Campbell University College of Pharmacy and Health Sciences, Durham, NC; (3)Campbell University School of Pharmacy, Morrisville, NC

Purpose: Childhood overweight/obesity (ow/ob) is a significant public health concern. There may be a link between caregiver education level, having an ow/ob child, and perception of child's weight. Counseling parents about childhood ow/ob is an opportunity that non-physician healthcare professionals, such as pharmacists, may engage in to aid in prevention of ow/ob. The purpose of this study is to characterize the association between a parental level of education and accuracy of perception of child's weight, and parental acceptance of dietary counseling from a non-physician provider.
Methods: A 37-item survey was deployed in a North Carolina Department of Public Health that evaluated caregiver education level, obesity knowledge, perception of child's weight status, and willingness to accept obesity counseling. Child's weight and height and body mass index percentile were calculated. Bivariate analysis was used to determine if parental education level or perception of child's weight were associated with acceptance of counseling from a non-physician healthcare professional.
Results: For caregivers with high school education (HSE) or less, 34.67% of their children were classified as ow/ob, compared to 45.10% (p-value= 0.2393) of children whose parents were college educated (CE). 41.67% of HSE subjects felt comfortable being counseled on ow/ob from a dentist compared to 52% of CE. Of HSE subjects, 67% passed the obesity knowledge test compared to 84.31% of CE subjects (p-value=0.0236). 81.33% of HSE caregivers correctly identified their child's weight classification, compared to 74.51% of CE caregivers.
Conclusion: Caregiver education level influenced didactic knowledge of obesity, but not prevalence of ow/ob among children, nor the likelihood of caregivers to accept counseling from non-physician healthcare providers. These data suggest education level is only one of several factors that should be considered if pharmacists are to engage in counseling caregivers about childhood overweight/obesity.

Education/Training

311. Effects of a deep learning strategy intervention on pharmacy student physiology exam performance.
Kelli Fitterling, Pharm.D. Candidate, Dayton J. Ford, Ph.D., Claude J. Gaebelein, Ph.D.; St. Louis College of Pharmacy, St. Louis, MO

Purpose : This study sought to determine the effect of a mid-semester intervention, which incorporated deep learning strategies into pharmacy students' study habits, on course performance.
Methods : In the fall of 2008, 193 students enrolled in the Advanced Physiology course completed a learning inventory on the first day of class. After the first exam, those students who failed were asked to meet with the instructor. The instructor identified student learning strategies that resulted in 'surface learning' and informed the student of alternate strategies that would result in 'deep learning' and better exam performance. The students then met with the instructor again after their second exam. Course performance was analyzed through the 4 exam scores which were divided into pre-intervention (exam 1 and 2) and post-intervention (exam 3 and 4). The pre-intervention period includes exams 1 and 2 because students did not have enough time to adopt and practice alternate learning strategies until after exam 2.
Results : At midterm, 176 students did not participate in the intervention (non-intervention; average grade = 78.2%) and 17 students did participate (intervention; average grade = 62.2%). The combined post-intervention average exam scores increased significantly by 7.4% in the intervention group, while the non-intervention group exam scores remained stable (average grade = 77.0%) (Treatment X Period Interaction, $F_{1, 190}$ = 24.0, MSe = 25.7, $p<0.05$).
Conclusions : While the sample size was insufficient to compare intervention strategies, it seems clear that an intervention designed to increase course performance may be effective in altering test grades to normal levels. The specifics of this phenomenon remain to be elucidated.

312. Cessation with communication: motivating pharmacy students to counsel for smoking cessation.
Janna L. Currie, Pharm.D./M.S.C.R. Candidate; Campbell University College of Pharmacy and Health Sciences, Lillington, NC

Purpose: Providing formal training to pharmacists regarding smoking cessation would provide another facet to their various abilities to improve public health. The objective of this study is to determine if formal training of pharmacy students will cause an increase in the mean likelihood of the students to counsel patients on smoking cessation.
Methods: The prospective cross-sectional observational study included a training session on smoking cessation counseling available to all Campbell University pharmacy students. A survey was given before and after the training session to assess the students' willingness to offer smoking cessation counseling. The primary analysis used paired t-tests to compare the pre-survey and post-survey results. The secondary analysis assessed the same endpoint regarding generic demographic categories.
Results: The primary analysis used all constructs to develop criteria for determining that pharmacy students were more likely to counsel after the training session. All primary endpoint constructs were significant with p-value <0.001. Some of the secondary endpoints were significant, but due to lack of diversity in demographics, the results of secondary analysis were difficult to interpret.
Conclusion: Potential implications of this study would affect pharmacists and pateints. Formal training increases the likelihood of pharmacists to offer counseling. An increase in counseling will lead to an overall increase in smoking cessation. Training offers pharmacists and/or pharmacy students an opportunity to extend their knowledge base and provide another service to the patient population to promote public health. Smoking cessation will improve health care for patients and society in general.

313. Fast food nutrition facts and obesity awareness in college-aged students.
Malaika R. Turner, Pharm.D. Candidate, Michael J. Gonyeau, B.S.Pharm., Pharm.D., BCPS; Northeastern University School of Pharmacy, Boston, MA

Purpose: The rate of obesity has increased dramatically over the last decade. In 2008, the prevalence of obesity in males and females in the US was 32.2% and 35.5% respectively. This increase is partially attributed to a concomitant increase in the consumption of "fast food". There is also an inverse relationship between age and fast food intake, with a disproportionate increase in consumption in people <18 years old, likely contributing to changes in bodyweight and insulin resistance, leading to increased risk for obesity, type 2 diabetes, stroke and heart disease. Our objectives are to analyze college students' knowledge of fast food nutrition facts and risk factors for obesity via pre- and post-educational intervention surveys. We will also analyze each of three educational intervention methods to discern which is the most effective in disseminating information and in participant knowledge and retention.
Methods: College students' knowledge of fast food nutrition will be assessed via three methods: a 10 minute, in-class live intervention; distribution of written educational materials with identical information and a recorded podcast of the in-class intervention available through Blackboard. Participants will be assessed with pre- and post-educational intervention surveys to evaluate participants' knowledge of fast food nutrition and obesity risk factors as well as frequency of fast food intake and demographics. Data will be analyzed for improvements in nutrition knowledge, obesity awareness and alterations in fast food intake.
Results: The study is still in progress and will be complete by the presentation date.
Conclusion: The objective of this study is to increase college students' knowledge of fast food nutrition facts and obesity awareness.

314. Global health outreach-an international advanced pharmacy practice experience.
Steven Hammond, Zubin Bhakta, Tyler Sledge, Niambi Horton, Shawna King; Texas Tech University Health Sciences Center School of Pharmacy, Euless, TX

Purpose: Through the GHO experience, students are provided insight into some of the complex barriers which exist in healthcare, and tools by which they can help resolve these issues. Through this experiential elective from Texas Tech University Health Sciences Center School of Pharmacy, students provided pharmaceutical care in settings which had limited resources and an array of cultural differences. Students were given the opportunity to learn to incorporate their pharmaceutical knowledge and skills in an unfamiliar setting, which ultimately helped increase their overall cultural competency.

Methods: Students prepared for the trip to Guatemala during several weeks of preparation which included language classes, cultural discussion, local outreach, and work in primary care clinics. Donations of medical/personal hygiene supplies were collected from local businesses to provide for the community clinic in Guatemala. The Central American organization Centro Evangélico De Estudios Pastorales en CentroAmérica (CEDEPCA) provided the itinerary as well as guidance throughout the trip. The majority of outreach efforts took place in the town of Santiago Atitlan in which students/preceptors were able to screen and counsel patients for hypertension, diabetes, and obesity.

Results: Screened a total of 47 patients with 21 referred to local clinic for follow-up. Further data on blood glucose, blood pressure, weight, BMI and other acute health concerns will be included in poster. Research is still in progress.

Conclusion: In conjunction with CEDEPCA, students were given the opportunity to increase their cultural competency by learning about Guatemala's culture and overcoming language barriers. Students were exposed to pharmacy related opportunities in non-traditional settings that focused on an indigent population which have limited resources and access to healthcare.

Geriatrics

315. Reducing propoxyphene use at a longevity clinic: a quality improvement initiative.

Douglas E. Cutsinger, B.S., Pharm.D. Candidate, Lisa C. Hutchison, Pharm.D., M.P.H.; University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR

Purpose: Adverse drug events increase costs and sometimes result in hospitalization or disability. The elderly are particularly prone to the side effects of medicines, and at increased risk of adverse drug events. As a result, certain medications, including propoxyphene, have been identified as potentially inappropriate for elderly patients. Also, studies have shown propoxyphene to be no more effective than other analgesics for mild to moderate pain, but have more significant adverse effects including: constipation, confusion, psychosis, seizures, liver dysfunction, arrhythmias, and dependency. The aim of this study is to reduce the number of patients receiving propoxyphene products at the UAMS Thomas and Lyon Longevity (TLL) Clinic in the Institute on Aging.

Methods: This project will first identify usage of propoxyphene products at the TLL Clinic from July 1, 2009 through August 31, 2009 by a retrospective medical chart review. Second, interventions to reduce propoxyphene usage will be implemented in the TLL Clinic, including in-service presentations, academic physician detailing, and distribution of informational flyers. Effectiveness of these interventions will be assessed to determine if there is a significant reduction in the number of patients on propoxyphene by comparing the data with a subsequent chart review of the timeframe from July 1, 2010 to August 31, 2010.

Results: Of the 2,453 patients seen at the TLL clinic from July 1, 2009 to August 31, 2009, 451 (18.4%) patients had used a propoxyphene product at some point. Seventy-one (2.9%) had current prescriptions for propoxyphene products during the time period investigated. All data collection and analysis will be completed before the meeting.

Conclusion: If educational efforts are effective to reduce propoxyphene use, they may improve quality of care and can be applied to other potentially inappropriate medication use.

Herbal/Complementary Medicine

316. Frequency of over-the-counter and herbal product use in patients with heart failure- predisposing factors.

Leah J. Holschbach, B.S., Pharm.D. Candidate[1], Timothy Miller, Pharm.D. Candidate[1], Nancy K. Sweitzer, M.D.[2], Orly Vardeny, Pharm.D., BCPS[3]; (1)University of Wisconsin School of Pharmacy, Madison, WI; (2)Division of Cardiovascular Medicine, Dept of Medicine, University of Wisconsin, Madison, WI; (3)Pharmacy Practice Division, University of Wisconsin School of Pharmacy, Madison, WI

Purpose: Prior research found that patients with heart failure (HF) concomitantly take over-the-counter (OTC) and herbal products in addition to their prescription medications, potentially causing clinically significant drug and disease interactions. The objectives of this study are to: 1) assess the frequency of OTC and herbal product use among patients with HF; 2) identify predisposing factors which may predict the use of these products; and 3) identify common reasons for under-reporting of OTC and herbal products to health care providers.

Methods: We intend to enroll 80 males and 80 females that are seen at the University of Wisconsin Advanced Heart Disease clinic with diagnosed HF. Surveys will be administered during a clinic visit. Survey questions will consist of participant characteristics such as age, marital status, insurance type, and income as well as herbal and OTC product use such as type, dose, reasons for use, sources of information about these agents, and reporting habits of use to clinic providers. Medical records will be accessed in order to identify HF etiology, New York Heart Association functional class, latest left ventricular ejection fraction, and current prescription medications. Logistic regression models will be constructed to examine associations between OTC and herbal supplement use and participant characteristics and disease-related factors.

Results: Survey results will be reported. Participant recruitment will begin in mid-July allowing three months for surveys to be completed, returned and analyzed.

Conclusion: We expect to gain information about specific socioeconomic factors and disease severity markers which may help predict the use of alternative therapy by patients with HF. We plan to use these data to better target patients who may benefit from education that could prevent potential drug or disease interactions.

317. Evaluation of the Hmong community's perceptions on the usage of endangered wildlife species in traditional Hmong medicinal practices.

Kazong Yang, Pharm.D. Candidate; University of Southern Nevada School of Pharmacy, Henderson, NV

Purpose: In January of 2009, a federal judge sentenced an 86-year-old Hmong woman and her daughter for conspiracy to smuggle protected wildlife into the United States. The wildlife products were sold openly at the International Market Place in St. Paul, MN because of their use in traditional Hmong medicinal practices. The purpose of this study is to assess the Hmong community's 1) level of usage of traditional Hmong medications, 2) belief in the therapeutic value of Hmong traditional medicines, 3) view on Hmong traditional products considered illegal for usage in the U.S. and 4) view of endangered wildlife species used in traditional medicinal practices.

Methods: Self-administered questionnaires are available to participants, at least 18 years old and of Hmong descent.

Results: Results will be presented at the ACCP Annual Meeting.

Conclusion: Conclusions will be presented at the ACCP Annual Meeting.

Indigent Care

318. Evaluating the impact of pharmacist-led short-term medical missions in various world regions.

Christine K. Yocum, Pharm.D., Samantha Bastow, Pharm.D.; Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy, West Palm Beach, FL

Purpose: The study objective was to evaluate the impact of pharmacy led medical mission teams in out-patient clinic settings; specifically number of patients examined and treated by pharmacists, total medications dispensed, and prevalent disease states by region.
Methods: Standardized forms were created in order to report for each patient: demographics, diagnosis and treatment. Each pharmacy-led team utilized the forms so that data would be standardized and analyzed by region visited. Patients were recruited by the religious organizations sponsoring the clinic sites and/or local missionary teams prior to the medical team's arrival by word of mouth and written advertisement. Pharmacists and student pharmacists (under direct supervision) performed clinical duties including triaging of patients, physical exams, medication management, and patient counseling. Upon the clinical discretion of the pharmacist, patients were referred to an on-site physician for follow-up care. All patients, regardless of their diagnosis, were given a 30-day supply of OTC vitamins. This study analyzed data collected from May through August of 2010.
Results: In Costa Rica during 4 clinic days, 354 patients were examined/treated at clinic by pharmacists and 1182 total medications were dispensed. In Zambia during 2 clinic days, 20 patients were examined/treated at clinic by pharmacists and 50 total medications were dispensed. The top three disease states treated at both regions were infectious disease, pain management and gastrointestinal disorders. *Data collection for clinics held in the Amazon, Belize, and Taiwan are still in progress.
Conclusion: Medical mission teams are needed worldwide. Pharmacist led medical teams are able to provide treatment for patients who may otherwise go without care due to social, economic, and/or geographic circumstances. On the medical mission field, pharmacists are able to provide a broad spectrum of care to a large number of patients and allow physicians to better allocate their resources for patients needing specialized care.

Infectious Diseases

319. Review of tigecycline use in a community hospital.
Jessica E. Follmer, Pharm.D. Candidate, Paul Juang, Pharm.D.; St. Louis College of Pharmacy, St. Louis, MO

Purpose: Tigecycline is a relatively novel antibiotic that is indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia caused by susceptible organisms. The purpose of this study was to characterize the usage of tigecycline within a community hospital.
Methods: Single center, retrospective chart audit of patients admitted during 2007 in which there was an administration of tigecycline during the hospital stay. Data collected include demographics, past medical history, length of stay, other antibiotic usage, ordering physician, indication for usage, antibiotic duration, clinical cure, microbiological cure and discharge disposition. Descriptive statistics were performed on the data collected.
Results: There were 71 patients that were identified with an average age of 64.6 ± 17 years and an average weight of 84 ± 30 kg. The most prevalent past medical history were of cardiovascular (67.6%), gastrointestinal (64.8%) and surgical (26.8%) origin. The average length of stay was 10.6 ± 9.7 days while the average length of ICU stay was 20.9 ± 18 days. Most patients (92.9%) were admitted from home and discharged back home (88.7%). The surgical (45.1%) and internal medicine (39.4%) service were the most frequent prescribers. Average duration for tigecycline use was 4.68 ± 2.5 days. It was the first antibiotic used in 73.2% of the patients and in combination with another antibiotic in 23.9% of the patients. Intra-abdominal coverage was the most frequent site for tigecycline usage (64.8% of the patients) while cultures were obtained in only 32.4% of patients who received the drug. Clinical cure was achieved in 100% of the patients.
Conclusion: Tigecyline was efficacious in producing complete clinical cure rates in a community hospital setting. Its usage can be further streamlined as it was frequently used empirically and/or as the first antibiotic used in patients without definitive risk factors for drug resistant infections.

320. Variations in time to blood culture positivity stratified by *Candida* species and fluconazole susceptibility.
Stacey Gordon, B.S.[1], Dhara N. Shah, Pharm.D.[1], Truc C. Tran, Pharm.D.[2], Todd Lasco, Ph.D.[2], Kevin Garey, Pharm.D., M.S.[1]; (1)University of Houston-College of Pharmacy, Houston, TX; (2)St. Luke's Episcopal Hospital, Houston, TX

Purpose: Candidemia is a common nosocomial infection whose clinical outcome can differ drastically amongst infected individuals. Though time to positivity (TTP) has been correlated to bacterial load, few studies have investigated differences in TTP related to *Candida* species or antimicrobial susceptibility. The purpose of this study was to investigate the correlation between TTP of *Candida* samples stratified by *Candida* species and fluconazole susceptibility.
Methods: Ongoing retrospective cohort study of *Candida* cultures obtained from patients at St. Luke's Episcopal Hospital starting April 2010. Each sample was evaluated for the organisms identified, time to positivity (TTP), and fluconazole susceptibility. Time to positivity was defined as the time between the time of culture and the time of yeast identification and susceptibility was performed by the hospital clinical microbiology laboratory using automated techniques.
Results: Twenty eight *Candida* cultures were identified from blood cultures during the study period. Six of 28 (21%) were identified as *C. albicans* and had an average TTP of 35.6 ± 13.7 hrs. The *Candida* non-albicans species had an average TTP of 50.1 ± 32.7 hrs. The average TTP for *C. glabrata* (n=14), *C. parapsilosis* (n=6), and *C. tropicalis* (n=2) was 60.1 ± 35.8 hrs, 30.8 ± 15.0 hrs, and 33.2 ± 13.4 hrs, respectively. Ten of 28 (36%) Candida isolates that were not susceptible to fluconazole had an average TTP of 62.8 ± 41.0. *Candida* samples that were susceptible to fluconazole had an average TTP of 39.0 ± 19.3 hrs. For the *C. glabrata* specifically, the samples with susceptibility to fluconazole (n=6) had an average TTP of 49.2 ± 26.3 while the non-susceptible samples (n=9) had an average TTP of 67.3 ± 40.7.
Conclusion: In this ongoing cohort study, time to *Candida* positivity differed based on *Candida* species and resistance to fluconazole. Increased sample size will enable more definitive conclusions from this dataset.

321. Combined vs Selective Antibiograms for *Pseudomonas aeruginosa*.
Adam C. Sieg, B.S., Pharm.D. Candidate, Patrick D. Mauldin, Ph.D., John A. Bosso, Pharm.D.; South Carolina College of Pharmacy - MUSC Campus, Charleston, SC

Background: Hospital antibiograms summarize susceptibility testing results and are often utilized to make empiric prescribing and/or formulary decisions. Because susceptibility data from diverse patient groups, specimen sources and hospital locations are combined in antibiograms, the validity and utility of the reported susceptibility results have been questioned.
Purpose: To assess the effect combining or excluding various sources of organisms on the antibiogram summary susceptibility data.
Methods: All susceptibility testing results for *Pseudomonas aeruginosa* from 2008 and 2009 were used, according to CLSI standards, to produce annual antibiograms. Differences between these "hospital-wide" antibiograms and more specific or exlusive antibiograms were assessed and tested for significant differences with χ^2 analysis. Differences of $\geq 10\%$ were also noted as this difference could be sufficient to alter therapeutic or formulary decisions. Specific antibiograms, which were compared to the hospital-wide versions or to each other, reflected subgroups such as inpatients, outpatients, adult, pediatric, nursing unit, and source of isolate (e.g., respiratory), among others. The main antibiotic classes reflected in routine susceptibility testing were β-lactams, aminoglycosides and fluoroquinolones.
Results: A number of statistically and/or clinically significant (≥10 % difference) were detected, most commonly when comparing pediatric isolates to those from adults, affecting results with a number of different tested antibiotics. While less frequent, a number of disparities were evident in comparing inpatient and outpatient isolates as well. Differences were not consistent from year to year but did affect all antibiotic classes.

Conclusion: While antibiograms reflecting all tested isolates in a given institution obviously have some practical utility, the diversity of such isolates may mislead decision making for subgroups of patients.

322. Impact of patient populations with varying degrees of renal function on vancomycin potential efficacy and toxcity.
Robert V. DeClue, Pharm.D. Candidate, Margarita P. Taburyanskaya, Pharm.D. Candidate, Heather R. Hummel, Pharm.D. Candidate, Roger White, B.S., Pharm.D.; South Carolina College of Pharmacy, Medical University of South Carolina, Charleston, SC

Purpose: Higher vancomycin (V) dosages are being used to reach AUC/MIC targets associated with better clinical outcomes. Since creatinine clearance (CrCl) affects V concentrations, empiric regimens should consider differences in population renal function. Monte Carlo analysis (MCA) can be used to assess potential efficacy and toxicity of V regimens in these populations.
Methods: MCA was performed on: 3 CrCl distributions (mean ml/min, our institution =67, skewed high=82, skewed low=48, 2 V dosing regimens (1–2 g doses, V1 and V2) with these dosing intervals (hrs): CrCl>60 ml/min, 12; 31–60, 24; 15–30, 48; and <15, 72, 3 V MRSA MIC distributions (our institution=50% MICs 1 and 2, MICs=1, and MIC=2). Population PK values (CrCl - Cl regression, volume) were used to simulate steady-state population PK profiles. MCA was performed to assess target attainment (TA) for efficacy at (AUC/MIC ≥400, V troughs of 15–20) and potential nephrotoxcity (troughs ≥ 15).
Results: TA at MIC=2 was 0% for V1 and 79–87% for V2; however, for MIC=1, TA was 79–87% for V1 and 100% for V2. Percentages of the population with troughs of 15–20 were 25–32% and 15–19% for V1 and V2, respectively. TA (%) at AUC/MIC ≥400 (our institution MICs) and percentage of troughs ≥15 mg/L (% / %) were:

	Skewed Low CrCl	Institution CrCl	Skewed High CrCl
V1	40/32	43/38	44/29
V2	90/93	93/97	94/98

Although one might assume that efficacy and toxicity endpoints would always be higher in populations with lower CrCls, specific CrCl distributions and dose/dosing interval adjustments at specific CrCls have a large impact.
Conclusion: CrCl distributions in patient populations had a minimal impact on assessment of efficacy (AUC/MIC targets or troughs of 15–20 mg/L); however, the impact on potential nephrotoxicity is much greater. Institution-specific CrCl distributions should be considered in the selection of empiric V dosing regimens.

323. In vitro Activity of Cefazolin alone and in Combination with Vancomycin against Heteroresistance Methicillin-Resistant and -Susceptible *Staphylococcus aureus* in an *in vitro* Pharmacodynamic Models.
Risa Hiroshima, B.S., Pharm.D. Candidate[1], Jessica F. Smith, B.S., Pharm.D. Candidate[1], Vanthida Huang, Pharm.D., BSPHM[2]; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2)Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

Purpose: Cefazolin is often recommended for patients who have non-immediate type hypersensitivity to penicillin; however, penicillinase-resistant penicillins are the first-line agents for the treatment of methicillin-susceptible *S. aureus* (MSSA) infections. Vancomycin is often recommended for patients who have immediate type hypersensitivity to penicillin. Increase vancomycin use has led to the development of resistance and heteroresistance among methicillin-resistant and -susceptible *S. aureus* (hCAMRSA and hMSSA) due to selective pressure both in community and nosocomial. Documented cefazolin and vancomycin failure in patients with MSSA infections, predominately endocarditis, have previously been reported. Since treatment options are limited, efforts to investigate various combination therapies against MSSA, hMSSA, and hCAMRSA are warranted.
Methods: One clinical strain each of hMSSA (FS33732) and hCAMRSA (H17) obtained from Henry Ford Hospital, Detroit, MI and ATCC29213 (control) were evaluated. MICs were performed

according to CLSI. An *in vitro* pharmacodynamic model (IVPM) with a starting inoculum of 10^6 CFU/mL was used for all experiments. Human pharmacokinetic regimen simulations were: vancomycin (VAN) 2g q12h, cefazolin (CEF) 2g q8h, and VAN 2g q12h plus CEF 1g q8h. Bacterial density was measured over 120 h.
Results: MICs for VAN and CEF vs. ATCC29213/FS33732/H17 are 1.0/1.0/2.0/ and 0.5/1.0/2.0 mg/L respectively. CEF alone demonstrated bacteriostatic activity against ATCC29213 and FS33732 for the entire duration. VAN alone exhibited bactericidal activity by 120 h against ATCC29213 and FS33732 but not H17. Combination demonstrated bactericidal and maintained up to 120 h for all isolates. No resistance was detected for all experiments.
Conclusion: Combination therapy was highly active against MSSA, hMSSA, and especially hCAMRSA. Further investigations with combination therapies are warranted.

Managed Care

324. Site of care of nanofiltered C1 esterase inhibitor [human] (nf-C1INH) in patients with Hereditary Angioedema (HAE).
Ladonna M. Landmesser, Pharm.D. Candidate[1], Glenn Tillotson, Ph.D.[2], David Mariano, Pharm.D.[2]; (1)Philadelphia College of Pharmacy, Philadelphia, PA; (2)ViroPharma Incorporated, Exton, PA

Purpose: Management of HAE has previously involved therapy with fresh frozen plasma or attenuated androgens. Approval of nf-C1INH in the USA for routine prophylaxis of HAE has progressed its clinical management, allowing self-administration for this unpredictable disease.
Methods: In a dynamic internal nf-C1INH database of HAE patients, demographic data, as reported by patients, was examined to determine the site of care (SOC) of nf-C1INH in the US.
Results: Five hundred and sixteen HAE patients received nf-C1INH. Of those, 243 (47%) administered nf-C1INH at home, 142 (28%) in the physician's office, and 120 (23%) received treatment at an infusion center (6 & 11 patients, age & SOC unknown). Of those treated at home, 42% reported self-administration, while 16% and 23% reported drug administration by a family member or home healthcare, respectively. Age ranged from 5 to 84 years. None in the 0–12 yr or >65 yr age groups reported self-administration. Patients between the ages of 30–64 were the largest age group in which 50% self-administered. Overall, self-administration occurred in 20% of patients. Patients who self-administer ranged geographically, 38%, 45%, 48%, and 55% in Midwest, West, South, and Northeast, respectively.

Age/Gender Breakdown of Patients with Respect to Site of Care

Patients	Home	Infusion Center	Physician's Office
Age 0–12	13/29 (44.8%)	8/29 (27.6%)	7/29 (24.1%)
13–29	73/142 (51.4%)	29/142 (20.4%)	38/142 (26.8%)
30–64	146/314 (46.5%)	77/314 (24.5%)	85/314 (27.1%)
>65	9/25 (36.0%)	6/25 (24.0%)	10/25 (40.0%)
Total	243/516 (47%)	120/516 (23%)	142/516 (28%)
Female	180/384 (46.9%)	91/384 (23.7%)	105/384 (27.3%)
Male	63/132 (47.7%)	29/132 (22.0%)	37/132 (28.0%)

Conclusion: Patients' age and location but not gender may influence the reported site of care for nf-C1INH administration. Self-administration is a feasible and viable option for HAE patients using nf-C1INH.

Medication Safety

325. The development of Korean FDA drug safety information website.
Dong Eun Lee, B.S.[1], Hye Jin Noh, B.S.[1], HyunAh Kim, Pharm.D.[1], Wan Gyoon Shin, Pharm.D., Ph.D.[1], Hye Suk Lee, M.S.[2], Jung Mi Oh, Pharm.D.[1]; (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea

Purpose: The aim of this study was to develop a Korean FDA drug safety information website in Korean language on the most frequently prescribed drugs to be utilized by both patients and healthcare professionals in Korea.

Methods: The most frequently prescribed drugs in Korea having significant clinical importance and/or a high risk of causing significant patient harm when used inappropriately were selected as the candidate drugs for database development. The database on comprehensive and up-to-date drug safety information was developed by reformatting the Korean FDA drug labeling of each drug in a standardized and easily understood format to be utilized by both patients and healthcare professionals. Other information included in the website was drug safety news from drug regulatory agencies abroad. The database on safety information was initially constructed by clinical pharmacists and later validated and confirmed by independent clinical experts.
Results: Searchable drug safety information within the Korean FDA website was developed to include drug safety information, disease information, and the latest safety news. "Drug Safety Information" website included information on drug classification, indication, contraindications, precautions, adverse reactions, pregnancy/lactation safety, and drug interaction information that were provided by Korean FDA drug labeling of each drug. "Diseases Information" website included the definitions and treatment modalities of each diseases treated with drugs of interest. "Safety News" website included the most current and up-to-date drug safety news released from FDA of USA, EMEA of Europe and MHRA of Japan.
Conclusions: Up-to-date Korean FDA drug safety information website with searchable database in Korean language was developed to provide the Koreans with easy access to accurate and important drug safety information.

Oncology

326. The Impact of Standardized Protocol for Oral Chemotherapy Prescription Processing in a Specialty Outpatient Cancer Center Pharmacy.
Angel O. Lam, Pharm., D., Candidate,[1], Grace M. Kuo, Pharm.D., M.P.H.[2], Beatriz Batarse, Pharm.D.[3], Rabia S. Atayee, Pharm.D., BCPS[1]; (1)UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, La Jolla; (2)UCSD and ACCP, La Jolla, CA; (3)Moores UCSD Cancer Center, La Jolla, CA

Purpose: This study was to evaluate the type of effort and the amount of time spent by pharmacists on providing counseling to patients and making recommendations to prescribers using a standardized prescription processing protocol for oral chemotherapy prescriptions versus routine processing of non-oral chemotherapy prescriptions in an outpatient pharmacy.
Methods: This was a retrospective analysis of data originally collected from an internal quality assurance time-monitored study conducted at a cancer center teaching hospital outpatient pharmacy over a 16-day period from July 29, 2008 to August 21, 2008. IRB approval was obtained on July 2, 2009. The numbers and types of pharmacist interventions for prescriptions were documented; the amount of time on filling prescriptions and counseling patients were also analyzed and compared between chemotherapy and non-chemotherapy.
Results: Data from a total of 1,266 prescriptions (86 chemotherapy and 1180 non-chemotherapy) were collected and analyzed. Comparative time data were analyzed using paired t-tests for continuous variables and χ^2 tests for nominal variables. Out of 92 pharmacist interventions 19 (20.7%) were chemotherapy. The majority (4/5) of pharmacist interventions were related to preventable errors. Recommendations provided by pharmacists were fully accepted by prescribers. Of prescriptions needed to be filled immediately, the average filling time for 55 chemotherapy was 76.4 minutes and 29.4 minutes for 723 non-chemotherapy (p-value < 0.001). The average counseling time for 34 chemotherapy was 2.7 minutes and 1.9 minutes for 336 non-chemotherapy (p-value < 0.001).
Conclusion: Potential toxicities, adverse effects and drug-drug interactions of the oral chemotherapy treatments require pharmacist-physician interventions to optimize drug treatment. Feedback, clarification, and recommendation from pharmacists should be emphasized and encouraged because these pharmacist interventions help prevent medication errors despite taking longer time to process the prescriptions Using a standardized protocol for oral chemotherapy prescription processing at outpatient pharmacies is important in order to provide safe and consistent care for cancer patients.

327. Development of a bioreactor system for modeling Glioblastoma Multiforme tumors.
Ghada F. Ahmed, M.S..[1], Walid F. Elkhatib, Ph.D.[2], Ayman M. Noreddin, Ph.D.[3]; (1)University of Minnesota, Minneapolis, MN; (2)University of Minnesota Duluth, Duluth, MN; (3)Hampton University, Hampton, VA

Purpose: The study was designed to develop a three-dimensional tumor model system that could provide application for modeling administration of new anticancer chemical entities. As a first step, the functional and structural distinctions between the formed cell groups and the conventional monolayer cultures were evaluated.
Methods: Glioblastoma Multiforme cells were cultured in a bioreactor system. As a comparator group, cells were also cultured as monolayer by standard methods. Alamar blue fluorometric assay was applied to monitor cell viability and enable measurement of growth rate and metabolism. Scanning electron microscopy was used to examine the topography of the tumors. In-depth characterization of the histological changes under both conditions was investigated using hematoxylin and eosin staining. Statistical analysis was performed using the ANOVA test in GraphPad Prism V software.
Results: The mean difference in fluorescence signal of the monolayer group from the 3D group was 1.59×10^7 Relative Fluorescence Units (CI 1.560×10^7 RFU, 1.619×10^7 RFU). Imaging of the cells grown in bioreactors revealed spherical distributed cell clusters of various sizes across the hollow fiber capillaries (diameter range 0.420 mm to 142.10 mm). The surface of these clusters contained dense folds and polyp-like structures that were interconnected to a cellular matrix. Histological staining of the cross-sections grown in bioreactors revealed densely-packed viable cells near the periphery and necrotic center containing cells with enlarged nuclei. In contrast, monolayer cell cultures were evenly distributed with round shaped nuclei and near-homogeneous viability throughout the cell layer. The rate of metabolism and growth of the monolayer cultures was significantly higher than that of cells grown in bioreactors (P<0.0001).
Conclusion: Cells grown in a bioreactor showed different morphological and histological characteristics from those grown in monolayer cultures, and viability was not homogeneous. Such properties may be useful for modeling drug delivery to solid tumors *in vivo*, where viability usually differs within according to nutrient supply.

Pediatrics

328. Stability of lansoprazole in oral suspension.
Jordan T. Morrison, Pharm.D. Candidate, Jim Thigpen, Pharm.D., Ralph A. Lugo, Pharm.D., Stacy D. Brown, Ph.D.; East Tennessee State University, Johnson City, TN

Purpose: The purpose of this study was to examine the stability of lansoprazole in a 3mg/mL oral suspension under room temperature and refrigerated conditions.
Methods: Lansoprazole suspensions (3 mg/mL) were prepared in triplicate for each storage condition (room temperature and refrigerated). Over a three-month period, duplicate samples (diluted to 20 mg/L) were removed from the bottles and analyzed for lansoprazole concentration by LC-MS/MS using omeprazole as the internal standard. The LC-MS/MS method was validated for precision and accuracy over the calibration range of 5–25 mg/L. The identities of the analyte and internal standard in the samples were verified by monitoring the MS/MS transitions of m/z 370 to m/z 252 and m/z 346 to m/z 198 for lansoprazole and omeprazole respectively.
Results: Preliminary results suggest that the stability of lansoprazole in the oral suspension is compromised prior to the previously reported 14 days under both storage conditions. Beyond the loss of 10% of the active ingredient, the refrigerated condition samples degrade at a faster rate than the room temperature ones. Furthermore, an unknown product of lansoprazole degradation (mw = 298) has been seen in the refrigerated samples. The study will be completed in August 2010.
Conclusions: As a result of this study, an evidence based recommendation on the stability of lansoprazole in oral suspension can be made.

329. A randomized, double-blind, placebo controlled trial to assess

the efficacy of Lactobacillus GG in the prevention of antibiotic-associated diarrhea in the Pediatric Intensive Care Unit (PICU).
Shelley N. King, Pharm.D. Candidate,[1], Allison M. Chung, Pharm.D., BCPS, AE-C[2], Rosa Vidal, M.D.[3], Sarah Walton, Pharm.D.[4], Estaban Bonafante, M.D.[3], Sheryl Falkos, M.D.[3]; (1)Auburn University Harrison School of Pharmacy, Mobile, AL; (2)Auburn University, Department of Pharmacy Practice; University of South Alabama, Department of Pediatrics, Mobile, AL; (3)University of South Alabama Department of Pediatrics, Mobile, AL; (4)Providence St. Peter Hospital, Olympia, WA

Purpose: Lactobacillus has been shown to be effective for outpatient and inpatient antibiotic-associated diarrhea (AAD) in pediatric patients. However, there is very little data on its use in the critically-ill pediatric population who are typically on multiple broad-spectrum antibiotics. The objective of this study is to assess the efficacy of *Lactobacillus GG* to prevent diarrhea in the PICU. For this study, diarrhea is defined as more than 3 loose stools in 24 hours.
Methods: This prospective randomized, double-blind, placebo-controlled trial is occurring in the PICU of two academic institutions. IRB approval has been obtained. Randomization occurs a priori and is assigned by pharmacy personnel. Treatment with *Lactobacillus GG* (30 x 10^9 CFU) or a matching placebo capsule is administered twice daily, initiated within 24 hours of starting antibiotic therapy and is continued for the duration of therapy. Patients that experience diarrhea for more than 72 hours are crossed over to the other treatment arm. The primary outcome is the incidence of diarrhea in the *Lactobacillus* versus placebo groups. Demographics, stool quantity, and potential adverse effects are monitored on a daily basis.
Results: Currently, 28 patients have met the inclusion/exclusion criteria and have been enrolled. Preliminary results have been analyzed and will be presented. Thirteen patients did not complete the study. Fifteen evaluable patients, were randomized to lactobacillus (n=8) and to placebo (n=7). Demographics of these patients include: male to female ratio 9:6, age range 21 days-11 years, weight range 3.1 kg-40.6 kg, majority of patients were on more than one antibiotic. Thus, 7 patients experienced diarrhea, with 42.9% in the active group and 57.1% in placebo.
Conclusion: The preliminary results of this study appear to indicate that *Lactobacillus* GG is safe and effective in reducing the incidence of antibiotic-associated diarrhea in the critically ill pediatric patients at our institution.

330. Evaluation of caffeine and the development of necrotizing enterocolitis.
Nehal G. Hashem, Pharm.D. Candidate[1], P. Brandon Bookstaver, Pharm.D., BCPS, (AQ-ID), AAHIVE[1], Christina C. Piro, Pharm.D.[1], Joshua M. Tebbs, Ph.D.[2]; (1)South Carolina College of Pharmacy, USC Campus, Columbia, SC; (2)Department of Statistics, University of South Carolina, Columbia, SC

Purpose: Necrotizing enterocolitis (NEC) is commonly seen in premature infants (gestational age <37 weeks), with very low birth weight (< 1500 g), and is associated with high rates of morbidity and mortality. While the exact etiology of NEC remains unknown, intestinal ischemia is thought to play a role in the development of NEC. Literature suggests several medications used in this population, including caffeine, may cause changes in mesenteric blood flow, precipitating NEC. The objective of this study is to determine the association between the administration of caffeine and development of NEC in premature infants.
Methods: A retrospective, single-center, cohort study on all neonates admitted to the neonatal intensive care unit from June 1, 2008 through July 1, 2009. All neonates included were stratified into two groups based on caffeine administration (yes or no). Each group was then evaluated for development of NEC based on modified Bell Staging criteria, ICD-9 code for NEC, and indication of medical or surgical management. Patient demographics collected includes: gestational age, birth weight, APGAR scores, renal and hepatic function, maternal history, admitting diagnosis, and transfers from other institutions. Caffeine therapy was evaluated for dosing regimen, therapy duration, and caffeine levels. Logistic regression and time-to-event (NEC) analysis will be used to assess differences in the incidence of NEC for

the caffeine and no-caffeine groups while adjusting for confounders. Confidence intervals for relative risk will be used to quantify the strength of the relationships.
Results: To be presented in full at the 2010 Annual Meeting.
Conclusion: To be presented in full at the 2010 Annual Meeting.

Pharmacoeconomics/Outcomes

331. Cost effectiveness analysis of Plasma Exchange and Intravenous Immunoglobulins in the treatment of a Myasthenic Exacerbation.
Aditi Kadakia, B.S., Yuping Yu, B.S., Sujit S. Sansgiry, Ph.D.; University of Houston College of Pharmacy, Houston, TX

Purpose: Myasthenic exacerbation (ME) refers to respiratory weakness in patients with acquired autoimmune myasthenia gravis. Plasma exchange (PE) and intravenous immunoglobulins (IVIg) are two short term treatments that may be beneficial for patients experiencing a ME. The objective of our study was to conduct a cost effectiveness analysis (CEA) of PE and IVIg in the treatment of ME.
Methods: A decision tree analysis was used for conducting a CEA from the hospital's perspective. The outcome was measured in terms of absolute variation in the mean myasthenic muscular score (MMS) after 15 days of initial treatment and these values were obtained from randomized controlled trials. We considered direct costs for treatment which included cost of treatment for 5 days, hospitalization costs and costs incurred due to side effects. Economic data was collected from recently published literature and the Red book. All costs were adjusted to 2010 dollar value using the Consumer Price Index. In order to evaluate the robustness of the results one-way sensitivity analysis was conducted varying cost of treatment by 30% and analyses of extremes was conducted for effectiveness and response rate using extreme values of ranges provided in literature. An incremental cost effectiveness ratio (ICER) was computed.
Results: The total cost incurred during a five day treatment was $66,673 for PE and $60,508 IVIg and the change in the mean MMS was 16.6 units for PE and 15.7 units for IVIg. The expected cost per unit increase in MMS was found to be $4110 for PE and $3896 for IVIg. One-way sensitivity analysis and two way sensitivity analyses also confirmed that the results obtained were robust. ICER for switching from IVIg to PE was found to be $6852
Conclusion: Our CEA indicated that IVIg is a better option than PE for the treatment of ME.

332. Equality/inequality of inpatient outcomes for major infectious diseases in the United States.
Samuel L. Aitken, Pharm.D. Candidate, Cory E. Fominaya, Pharm.D., Walter Gibson, M.S., Fred Doloresco, Pharm.D., M.S., Jack Brown, Pharm.D., M.S.; University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY

Purpose: A correlation between patient health insurance status (HIS) and/or income level (IL) and healthcare outcomes exists. Infectious diseases account for 2 of the top 10 leading causes of death in the US each year, yet there are few examinations relating socioeconomic factors to their outcomes. We sought to determine if differences in overall inpatient mortality and/or hospital length of stay (LOS) exist among patients of different insurance status or income level for infectious diseases.
Methods: Using the Agency for Healthcare Research and Quality's Nationwide Inpatient Sample, US hospital discharges from 2001 to 2006 were queried for diagnosis-related groups corresponding to a major infectious disease (MID). Weights were applied to produce national *estimates.* Univariate analyses were performed on age, gender, comorbidities, payor, and income level on mortality rates and LOS. ANOVA and logistic regression techniques were performed for multivariate analysis.
Results: A total of 3,133,600 discharges meeting the entry criteria were identified, corresponding to 15,285,156 MID discharges nationwide. Age (1.04 per year, 95% CI 1.04, 1.04), female gender (1.25, 95% CI 1.24, 1.27), black race (1.23, 95% CI 1.21, 1.25) and Elixhauser comorbidity score (1.23 per unit, 95% CI 1.22, 1.23) were found to affect mortality and LOS ($p<0.0001$). Adjusted mortality for private insurance patients was found to be 2.97%, with a mean LOS of

4.6 days. Multivariate analysis associated higher risk of mortality and longer LOS for Medicaid patient discharges (3.51%, 5.8 days) and higher mortality for those without insurance (3.27%) versus private insurance (p<0.0001). Additional analyses addressing HIS and IL for different MID outcomes will be completed by August.

Conclusion: Mortality rates and LOS were increased for patient discharges without private insurance. These observations may be related to access to healthcare. Improving underinsured patients' healthcare access may reduce this gap.

333. Is Fecal Immunochemical Test economically the best screening test for Colorectal Cancer?
Juhi Shah, B.S., Rituparna Bhattacharya, B.S., Sujit S. Sansgiry, Ph.D.; University of Houston College of Pharmacy, Houston, TX

Purpose: In 2008, the American College of Gastroenterology Colorectal Cancer (CRC) screening guidelines recommended Fecal Immunochemical Test (FIT) as a method for CRC screening replacing the older guaiac based Fecal Occult Blood Test (gFOBT), Hemoccult II. The United States Preventive Service Task Force also recommends the use of high-sensitive FOBTs, like FIT and Hemoccult SENSA in place of Hemoccult II. This study compares Hemoccult II, Hemoccult SENSA and FIT.
Methods: A decision analytic model populated with 1000 hypothetical 50 year individuals at average risk for CRC was developed to estimate the total number of true outcomes (positive and negative) measured by sensitivity and specificity of the tests for CRC and adenomas. Every positive outcome was followed by a colonoscopy. Sensitivity, specificity values and costs (in 2010 US Dollars, discounted at 3%) were obtained from clinical trials and published peer-reviewed articles and sensitivity analyses were conducted.
Results: FIT provides 623 true outcomes at a cost of $75,410 (cost/true outcome = $121) while Hemoccult SENSA provides 622 true outcomes at a cost of $97,260 (cost/true outcome = $156) and Hemoccult II provides 500 true outcomes at a cost of $36,980 (cost/true outcome = $74) for 1000 hypothetical patients. Considering Hemoccult II as the base case, the incremental cost-effectiveness ratio for FIT was $314 and that for Hemoccult SENSA was $494. The sensitivity analyses carried out confirmed the robustness of the decision tree model.
Conclusion: Hemoccult II was the most cost effective screening method for CRC. FIT was slightly more cost effective than Hemoccult SENSA. Further considerations with compliance and patient characteristics may be needed to validate these results.

334. Economic impact of strategies for preventing contrast induced nephropathy.
Sandra L. Rowe, Pharm.D. Candidate[1], Kathryn D. Mathews, Pharm.D., BCPS[2]; (1)University of Utah College of Pharmacy, Salt Lake City, UT; (2)Intermountain Medical Center, Murray, UT., Murray, UT
Purpose: The increasing number of diagnostic procedures requiring radiographic contrast has resulted in the increased incidence of contrast induced nephropathy (CIN). Numerous studies have evaluated the use of N-acetylcysteine (NAC), sodium bicarbonate, and normal saline as pretreatment for the prevention of CIN. There is limited consensus that these agents provide additional benefit. This area of practice is not well-defined, therefore practitioners at Intermountain Medical Center utilize a variety of treatment options. The request to standardize a pretreatment strategy was initiated by the cardiovascular medical director. In addition to providing an extensive review of this topic, we sought to determine the economic impact that these agents have on our healthcare system.
Methods: We identified all inpatient doses of NAC and sodium bicarbonate dispensed from June 2009 to May 2010. The data were modified to only include doses dispensed with the indication for pretreatment of CIN.
Results: Within the 22 facility Intermountain system, 7070 doses of NAC and 3886 doses of sodium bicarbonate were dispensed. The estimated cost of NAC ranged from $60,589.90 to $1,731,513.70 depending on the route of administration. The estimated cost of sodium bicarbonate was $267,745.40.

Conclusion: An extensive literature review and these financial data will be presented at the Pharmacy and Therapeutics Committee in September 2010. Although we did not modify the data to reflect the appropriate route of administration with each NAC dose, this information will be provided at the time of presentation. We anticipate that the potential cost savings will be significant and impact the decision to restrict the use of NAC and sodium bicarbonate for CIN.

Pharmacogenomics/Pharmacogenetics

335. The effect of CYP3A5 polymorphism on tacrolimus long-term outcomes of kidney transplantation in Korean adult recipients.
Hye Jin Noh, B.S.[1], *Na Young Han, B.S.*[1], Jin Yi Hong, M.S.[1], Wan Gyoon Shin, Pharm.D., Ph.D.[1], Hye Suk Lee, M.S.[2], Jung Mi Oh, Pharm.D.[1]; (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea

Purpose: The aims of this study were to evaluate the effect of $CYP3A5$ $6986A > G$ (rs776746) polymorphism on the pharmacokinetics of tacrolimus and on the 5 year long term clinical outcomes in Korean kidney transplant recipients.
Methods: Clinical and laboratory data for 138 Korean adult kidney transplant recipients receiving tacrolimus as a immunosuppressive regimen were collected retrospectively for 5 years of transplantation. Genotyping of the $CYP3A5$ allele was also performed. Tacrolimus trough (C_0) levels at days 7, 30, 90, 180 and then every year up to 5 years of transplantation, dose required to reach the target C_0, and dose-adjusted trough levels were compared among the genotypes. The relationship between $CYP3A5$ genetic polymorphism and tacrolimus long-term outcomes in regards to the incidence of biopsy-proven acute rejection, tacrolimus-induced nephrotoxicity and chronic allograft nephropathy were also evaluated.
Results: The frequency of patients with $CYP3A5*1/*1$ or $*1/*3$ allele and $*3/*3$ allele were 42.0% and 58.0%, respectively. There was a significant difference between the genotype groups in the median blood concentration at day 90 after transplantation (*p*-value <0.05), but $CYP3A5$ genetic polymorphism had no impact on the concentration of tacrolimus, thereafter. $CYP3A5*1$ variant required a greater dose to reach target blood tacrolimus concentration at days 7, 30, 90, 180 and every year up to 5 year than $CYP3A5*3/*3$ allele (*p*-value <0.001). There were no significant differences in the incidence of biopsy-proven acute rejection, tacrolimus-induced nephrotoxicity and chronic allograft nephropathy between the genotype groups.
Conclusion: $CYP3A5$ genetic polymorphism had an effect on tacrolimus dose required to reach the target trough concentration in Korean kidney transplant recipients. However, this study failed to find a relationship between $CYP3A5$ genetic polymorphism and long-term clinical outcomes.

336. Assessing Pharmacy Students' Knowledge and Interest of Pharmacogenomics.
Natalya Vaksman, Pharm.D.Candidate, Maggie C Louie, Ph.D., Mitchell Barnett, Pharm.D., Stephen Chiu, Pharm.D. Candidate, Leann Hokabayan, Pharm.D. Candidate, Ilya Kutcher, Pharm.D. Candidate, Judith Liao, Pharm.D. Candidate, Alisha Mai, Pharm.D. Candidate, Aaron Middleton, Pharm.D. Candidate, Khai Pham, Pharm.D. Candidate, Melissa Serino, Pharm.D. Candidate, Chandra Steenhoek, Pharm.D. Candidate; Touro University College of Pharmacy, Vallejo

Purpose: To evaluate the education and interest of pharmacy students in pursuing a career in pharmacogenomics.
Methods: First- and third-year students from eight pharmacy schools in California completed either a hard copy or electronic version of the survey indicating their attitudes towards pursuing a career in pharmacogenomics as well as feelings of preparedness for such a career path.
Results: Statistical analyses showed that if pharmacogenomics was incorporated into the pharmacy curriculum, students were more likely to view pharmacogenomics as important to the future of pharmacy practice. Results from this study also showed that first-year students were also more open to the inclusion of pharmacogenomics in their preference of practice than third-year students.

Conclusion: A curriculum that incorporates pharmacogenomics appears to be related to positive student opinions regarding curricular preparation for a career and importance of pharmacogenomics for future pharmacists; however, it does not cultivate student interest to pursue a residency or fellowship in pharmacogenomics.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

337. Population pharmacokinetics and pharmacogenomic analysis of tacrolimus in Korean adult kidney transplant recipients.

Jin Yi Hong, M.S.[1], *Sang Min Lee, B.S.*[1], Hwi Yeol Yoon, Ph.D.[1], Yoo Jin Moon, M.S.[1], WanGyoon Shin, Pharm.D., Ph.D.[1], Hye Suk Lee, M.S.[2], Jung Mi Oh, Pharm.D.[1]; (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea

Purpose: The aims of this study were to identify the pattern of tacrolimus trough concentrations according to postoperative days, develop a population pharmacokinetics model of tacrolimus, and identify the clinical covariates that explain the variability of pharmacokinetic parameters of tacrolimus in Korean adult kidney transplant recipients.

Method: Clinical data and trough concentrations of tacrolimus were collected retrospectively from 80 Korean adult kidney transplant recipients receiving tacrolimus as part of their immunosuppressive regimen. Patients' genotypes were characterized by allelic discrimination for *ABCB1* C1236T, G2677T/A, *C3435T* and *CYP3A5*. Population pharmacokinetic analysis of tacrolimus was performed using NONMEM, and the influence of clinical and pharmacogenetic covariates was tested. A total of 2,800 trough blood concentrations of tacrolimus were available for population modeling.

Results: Tacrolimus trough concentrations during the first month of transplantation fluctuated the most out of the target concentration range which gradually stabilized thereafter. The population mean clearance and apparent volume of distribution were 27.35 L/hr and 1266.91 L, respectively. CL/F increased immediately after transplantation and reached a plateau after postoperative day 30. CL/F was significantly lower in patients with *CYP3A5*3/*3* genotype and normal hematocrit level. No significant effect was observed for *ABCB1* genotype. The final population-pharmacogenetic model, expressed as: Kel = $(0.0127 \times POD^{0.01}) \times e^{(0.133*CYP3A5)}$ X (1 + donor type); V/F(L) = $3600 * e^{(5.5*CYP3A5)} * (1 + 0.165*Hct)$, included postoperative day, hematocrit level, donor type and *CYP3A5* genotype as the significant covariates associated with the pharmacokinetic parameters of tacrolimus.

Conclusion: The population pharmacokinetic-pharmacogenetic model developed in Korean adult kidney transplant patients demonstrated that individualized tacrolimus dosage should be based on postoperative day, hematocrit level, donor type and *CYP3A5* genotype to accurately predict individual pharmacokinetic parameters of tacrolimus especially during the first month of kidney transplantation.

338. Fixed Dosing Versus Body Size-based Dosing of Anticancer Drugs in Adults: A Population Pharmacokinetic Approach.

Rong Shi, Ph.D. Candidate, Hartmut Derendorf, Ph.D.; University of Florida, Gainesville, FL

Purpose: Dosing of anticancer agents is often normalized to body surface area (BSA) or body weight (BW). Though many studies have evaluated the necessity of BSA/BW based dosing for oncology drugs, the current study for the first time 1) utilizes population pharmacokinetics approach to systemically evaluate intersubject variability for anticancer drugs and 2) provides a model based analysis method on dosing strategies for oncology drugs under development.

Methods: Comparison of fixed dosing and BW/BSA-based dosing in reducing pharmacokinetic (PK) variability in adults was conducted by simulation of published population PK models for 28 anticancer agents. At the population level, the variability of AUC and Cmax were compared for the two dosing approaches. At the individual level, the percentage changes of AUC and Cmax in patients with low or high extreme BW/BSA and those with average BW/BSA were compared.

The contribution by BSA/BW to the interpatient variability was evaluated for the PK parameters.

Results: Fixed dosing performed similarly to BW/BSA-based dosing for the studied anticancer agents at both population and individual levels. BW/BSA does not substantially contribute to the interindividual variability in PK parameters.

Conclusion: Providing convenience, less medical errors, and cost effectiveness, fixed dosing may be preferred for first-in-human studies. In the later phases of the drug development, a model based analysis as presented may be conducted once sufficient data is available.

Social Pharmacy

339. Patients' experiences with antidepressants: an analysis of accounts posted on an Internet website.

Sharmeen Bashey, Pharm.D. Candidate, Michael Montagne, Ph.D.; Massachusetts College of Pharmacy and Health Sciences, Boston, MA

Purpose: The aim of this study is to evaluate patients' experiences with newer antidepressants by examining online discussion boards, blogs, and postings found on a member-community website.

Methods: This study utilized an ethnographic methodology that was adapted to an online setting to gather observational data. Online postings were compiled as transcripts from May 18, 2009 to July 24, 2009 from an online, member-community website called experience project.com. Content analysis was used to examine the transcripts for personal experiences with SSRIs, SSNRIs, and/or a DA/NE Reuptake Inhibitors. A non-numerical coding system was applied to categorize experiences as either satisfactory, unsatisfactory, or neutral. Additionally, the antidepressant used, date of post, number of views and comments the post received, and gender and age group of the participants were recorded to detect trends and patterns within the virtual community. A brief description of each personal account was also noted.

Results: Content analysis of 126 postings by 110 members of the online community revealed 49% of participants reporting an unsatisfactory experience, 37% describing a satisfactory experience, and 14% of patients reporting a neutral experience with an antidepressant. Most unsatisfactory experiences were reported with Paroxetine. Analysis of unsatisfactory experiences revealed the following factors contributing to dissatisfaction: increased depressive symptoms, adverse drug effects, and/or withdrawal syndrome. Adverse effects reported in greater than 30% of the posts were: sexual dysfunction, weight gain, headache, nausea, and dizziness. Approximately 10% of participants described a physical symptom associated with sudden discontinuation of an antidepressant by using the term "brain zap." Women in the 26 to 30 age group were majority of the participants.

Conclusion: Participation in online member-communities permits antidepressant users to seek information, exchange experiences, and obtain advice allowing for open, interactive, and anonymous discussions of medication use.

Student

340. The effect of the combination of pioglitazone and extended-release niacin on HDL cholesterol in diabetes patients in a community based endocrinology practice.

Kiranmai VSN Yarlagadda, Student[1], Scott Gleason, Student[1], June F. Johnson, B.S., Pharm.D.[2], Amy Vaughan, Ph.D.[3], Anuj Bhargava, M.D.[4]; (1)Des Moines University, Des Moines, IA; (2)Drake University College of Pharmacy & Health Sciences, Des Moines, IA; (3)Drake University College of Business & Public Administration, Des Moines, IA; (4)Iowa Diabetes & Endocrinology Center, Des Moines, IA

Purpose: This retrospective study was designed to assess the effects of a pioglitazone and extended-release niacin combination on the lipid panel, particularly HDL-cholesterol, when used in patients with Type 2 Diabetes in an endocrinology specialty practice.

Methods: The electronic medical records of 482 adult patients with

Type 2 Diabetes receiving extended-release niacin and pioglitazone were screened for review. Patients with Type 2 Diabetes and hyperlipidemia were included for review if they received the combination of pioglitazone at doses ≥15 mg/day and extended-release niacin at doses ≥ 500 mg/day for ≥ 6 months. Statistical analysis used paired t-tests with p<0.05 as statistically significant. Both ANOVA and the Tukey-Kramer test for multiple comparisons (p=0.05) were also used.

Results: A total of 53 patients, 83% male with average age of 58, met all eligibility criteria for the study. Compared to baseline, a statistically significant increase in HDL-C (24.08%, p=0.0332) was observed at the conclusion of combination therapy. Significant decreases in total cholesterol (-9.03%, p=0.00642) and triglycerides (-16.15%, p = 0.0219) were detected. HDL-C increased by 0.79% over the course of the study.

Conclusion: The combination of pioglitazone and extended-release niacin at commonly used doses for at least 6 months significantly improved HDL-C, and lowered total cholesterol and triglycerides in patients with Type 2 Diabetes and hyperlipidemia.

Student Chapter Implementation

341. Implementing a Student Chapter of the American College of Clinical Pharmacy at a New College of Pharmacy.
Timothy J. Church, B.S., Pharm.D. Candidate[1], *Brandon L. Mottice, B.S., Pharm.D. Candidate*[2], Patrick J. Gallegos, Pharm.D., BCPS.[1]; (1)Northeastern Ohio Universities College of Pharmacy, Akron, OH; (2)Northeastern Ohio Universities College of Pharmacy, Louisville, OH

Purpose: To describe the implementation of an American College of Clinical Pharmacy student chapter in a new college of pharmacy.
Methods: Governing bodies will be created to reflect the mission and core values of clinical pharmacy. These will also describe leadership positions, functionality of the student chapter, and partnership with the Ohio College of Clinical Pharmacy (OCCP). Student recruitment will be advocated via emails, informational sessions, and during a student organization fair. The student chapter will hold monthly meetings discussing clinical areas of interest, community service, patient care activities, and opportunities within the state as well as national organization of the American College of Clinical Pharmacy. We will also host speakers to lead clinical pharmacy topic discussions and help facilitate student lead journal clubs.
Results: Preliminary interest in forming a student chapter of the American College of Clinical Pharmacy has been expressed by multiple students, faculty, and members of the Ohio College of Clinical Pharmacy.
Conclusion: We anticipate that starting a student chapter of the American College of Clinical Pharmacy will promote student membership and awareness of the state and national organization. In addition, we hope to provide a template for other pharmacy schools interested in forming a chapter.

Transplant/Immunology

342. Thymoglobulin increases risk of bleeding by increasing prothrombin time.
Matthew H. Rim, Pharm.D. Candidate[1], Eglis Tellez-Corales, Pharm.D.[1], Tariq Shah, M.D.[2], David I. Min, Pharm.D., FCCP, FASHP[1]; (1)Western University of Health Sciences, Pomona, CA; (2)St. Vincent Medical Center, Los angeles, CA

Purpose: Thymoglobulin is a purified rabbit immunoglobulin against human thymocytes, and it is widely used for prevention and treatment of acute rejection. After initiation of thymoglobulin, most of T-cell markers disappeared from circulation within days. This may cause leukopenia and thrombocytopenia due to its non-specific polyclonal nature. Also prolonged prothrombin time has been reported while taking thymoglobulin. The purpose of our study is to determine whether the use of thymoglobulin affects prothrombin time with decreasing platelet count, which may increase the risk of bleeding for high risk kidney transplant recipients.

Methods: 120 renal allograft recipients at St. Vincent Medical Center with high-risk criteria were included in this study. The high risk criteria included the following: multiple transplants, African American ethnicity, >24 hr cold ischemic time or >50% PRA. Our study population received Thymoglobin as a part of induction therapy (82%) or treatment of rejection (18%) during January 2007 to December 2009. The patients' demographic data, hematologic data and details of drugs affecting INR are being collected along with Pre-Thymo therapy (baseline) and post-Thymo therapy PTT, PT and INR.
Results: The data collection from 2007 to 2008 has been completed. Based on the current data collection, the baseline PT INR was 1.1 ± 0.3 and post-Thymo PT INR was 1.6 ± 1.6 (p=0.012). The PT INR increased by 45% (0.5 ± 1.6) in 80% of the patients. The Peak PT INR after Thymo therapy will occur at 2.6 ± 2.2 days. The mean platelet count decreased from 241,000 ± 86,982/mm³ to 165,548 ± 70,991/mm³ (p<0.01).
Conclusion: The data from 2009 patients is currently being collected. And the completed results and conclusion will be presented.

343. The tolerability of interferon/ribavirin antiviral combination therapy in post-liver transplant recipients with hepatitis C.
Dennis L. Churchill II, B.S.[1], Charles T. Makowski, Pharm.D. Candidate[2], Iman Bajjoka, Pharm.D.[3]; (1)Henry Ford Hospital Transplant Institute/ Wayne State University, Detroit, MI; (2)Wayne State University Eugene Applebaum College of Pharmacy, Detroit, MI; (3)Henry Ford Health System/ Wayne State University, Detroit, MI

Purpose: The standard anti-viral treatment (AVT) for hepatitis C virus (HCV) is the combination of pegylated interferon and ribavirin. This AVT is often accompanied by an array of side effects, with reports of required dosage adjustments in about a third of all non-transplant patients. However, tolerability data is limited in the post-liver transplant (LTx) population. The purpose of this study is to determine the tolerability of AVT in post-LTx recipients experiencing recurrent HCV.
Methods: This is a retrospective single-center data analysis in which medical records of LTx recipients from Henry Ford Hospital during 2002–2010 were reviewed. Patient demographics as well as incidents of AVT side effects, graft rejections, duration of AVT treatment, dose adjustments and/or discontinuations, and pre- and post-treatment viral loads were collected.
Results: Fifty-six patients were analyzed with a mean age of 52.9 ± 6.2 years. Forty-seven were male, 40 were Caucasian, and 13 African American. Mean duration of AVT was 510 ± 303 days. Forty-eight patients (86%) experienced dose adjustments and 16 patients (29%) required early discontinuation. The major side effects were fatigue, nausea, diarrhea and anemia. Others included infections, depression and anxiety. White blood cell counts <3.0 k/uL were documented in 45 patients (80%), of which 8 patients (14%) had <1.5 k/uL. Six patients were started on filgrastim at some point during treatment. Five patients developed acute rejections during AVT (9%). Quantitative viral loads, AST and ALT values were significantly decreased post-treatment when compared to pre-treatment values (p=0.05), while serum creatinine remained stable (1.1 vs. 1.25 mg/dL), p>0.05.
Conclusion: Post-LTx, the standard AVT seems to be effective in reducing viral loads and liver function tests, but the majority of patients do not tolerate this therapy. This intolerance in the LTx recipients seems to be higher than what has been previously observed in the non-transplant population.

344. Optimal Antiviral Prophylaxis Duration for Kidney Transplant Recipients at High Risk for CMV Infection Remains Elusive.
Adam C. Sieg, B.S., Pharm.D. Candidate[1], David J. Taber, Pharm.D., BCPS[2], Nicole Weimert, Pharm.D., M.S.C.R., BCPS[2], Kevin M. Curler, Pharm.D. Candidate, M.B.A.[1], Kenneth D. Chavin, M.D., Ph.D.[2], Prabhakar Baliga, M.D.[2]; (1)South Carolina College of Pharmacy - MUSC Campus, Charleston, SC; (2)Medical University of South Carolina, Charleston, SC

Purpose: Recently, studies have demonstrated that the duration of universal CMV prophylaxis in high risk patients should be extended in

all patients. The aim of this study was to evaluate only patients at the highest risk for CMV infection (D+/R-) to determine risk factors associated with CMV replication to aid in determining appropriate duration of therapy.

Methods: All adult CMV seronegative kidney transplant recipients from a seropositive donor transplant between 1/01 through 5/08 were evaluated. Patients were excluded if they received a non-renal organ transplant, experienced primary graft non-function, or were lost to follow-up. Student's T-test and χ^2 with Fischer's Exact correction were used where appropriate.

Results: A total of 150 patients were included for analysis; 42 patients (28%) experienced viremia during the mean follow-up of 4 years (± 2years). Baseline characteristics were similar between groups, however, there was a significantly longer follow-up time in patients that didn't develop CMV (4 ± 2 years vs 3 ± 2 years). Also, patients that developed CMV viremia were more likely to have experienced delayed graft function and receive tacrolimus at baseline vs the no viremia group. Interestingly, patients who developed CMV infection had higher 3, 6, and 12 month serum creatinine values (1.9 ± 1 vs. 1.6 ± 0.5 p-value = 0.02, 1.9 ± 1 vs. 1.6 ± 0.7 p-value = 0.05, and 2.1 ± 1.2 vs 1.6 ± 0.4 p-value = 0.007, respectively) when compared to the no CMV group, without an increase in early or late rejection.

Conclusion: (1) DGF and T-cell depleting induction contribute to CMV replication in high risk patients (2) CMV infection has detrimental effects on post-transplant renal function (3) No clear variable exists to aid in determining the appropriate duration of therapy in all high risk patients necessitating additional studies in this patient population.

345. The impact of valganciclovir regimens in high risk kidney transplant recipients: is dosing based on estimated CrCl insufficient to prevent CMV in patients with marginal renal function?.
Kevin M. Curler, Pharm.D. Candidate, M.B.A.[1], Nicole Weimert, Pharm.D., BCPS[2], Adam C. Sieg, B.S., Pharm.D. Candidate[1], David J. Taber, Pharm.D., BCPS[2], Kenneth D. Chavin, M.D.[2], Prabhakar Baliga, M.D.[2]; (1)South Carolina College of Pharmacy - MUSC Campus, Charleston, SC; (2)Medical University of South Carolina, Charleston, SC

Purpose: Cytomegalovirus (CMV) infection is a common complication post-kidney transplant (KTX) in high risk patients (CMV positive donor (D+) transplanted to CMV negative recipient (R-). Our center has noticed early CMV infection in patients receiving valganciclovir therapy with marginal renal function. The **aim** of this study was to evaluate all D+/R- patients transplanted at our center between January 2001 and May 2008 to determine if early low-dose valganciclovir (VCG) dosing may contribute to early CMV infection.

Methods: All KTX recipients who were CMV D+/R- during the study period were evaluated. Patients were excluded if they were <18 years, received a non-renal organ transplant, experienced primary graft non-function, or were lost to follow-up.

Results: A total of 115 patients were evaluated; 78 patients (68%) did not experience CMV replication, while 34 patients developed CMV viremia or syndrome and 3 patients experienced tissue invasive disease. Baseline and transplant demographics were similar between groups, except more patients with CMV infection were on tacrolimus at baseline and received thymoglobulin. Twelve patients in the no CMV group experienced acute rejection within the first 3 months post-transplant compared to 3 in the CMV group (p=0.4). The mean time to CMV infection was 223 ± 344 days. Of the 12 patients who were on low dose VGC at day 30 (450mg twice weekly), 6 experienced CMV infection (50% vs 32% in the total cohort). Nine patients developed syndrome between 50–120 days post-transplant, of these 7 received thymoglobulin and only 2 patients were on full dose VGC by day 30 post-transplant. Average VGC dose at 30 days in the no CMV infection was 708 ± 399mg vs 550 ± 300mg in the CMV infection group.

Conclusion: Early, higher than recommended dosing of VGC in high risk KTX may be warranted in patients with marginal renal function to optimally prevent CMV infection.

LATE BREAKERS

Ambulatory Care

346. Effect of a pill box clinic on emergency department, hospital admissions and urgent clinic visits.
Nathan D. Culver, Pharm.D., Adraine Lyles, Pharm.D.; Virginia Commonwealth University Health System, Richmond, VA

Purpose: Poor adherence to prescribed medications and lifestyle modifications has been shown to result in decreased efficacy and suboptimal outcomes in several disease states. Non-adherence has also been implicated in an increased incidence of adverse events in the elderly, as well as increased hospitalizations rate, and emergency room visits.

Methods: Patients meeting defined criteria were referred to the Pill Box Clinic and are followed bi-weekly by a pharmacist. The primary objective of this project was to document a change in emergency department visits, urgent clinic visits and hospital admissions after patients had been enrolled into the Pill Box Clinic. This was accomplished by documenting the number of urgent clinic, emergency department, and hospital admissions 6 months prior to clinic enrollment and 6 months post initial clinic visit. Descriptive statistics were used to analyze results.

Results: A total of 10 patients were included in this review of clinic outcomes. A total of 38 patient visits were found for patients prior to the first pill box clinic visit and a total of 10 patient visits were found post-initial clinic visit. When the encounters were divided by type and then compared, the amount of urgent clinic visits (10 vs. 1, p=0.39), emergency department visits (18 vs. 8, p=0.33), or hospital admissions (10 vs. 2, p=0.39) were not found to be statistically significant. When the combined endpoint (urgent clinic visits, emergency department visits, and hospital admissions) were analyzed for comparison (39 vs. 13, p<0.05) the results were statistically significant.

Conclusion: Implementation of a pharmacist-led Pill Box Clinic may be of benefit to patients with a combination of low health literacy or no social support and either congestive heart failure or dementia with regards to a reduction in urgent clinic visits, emergency department visits, and hospital admissions.

347. Evaluation of a unique collaborative practice model for tobacco cessation in a veteran population.
Kathryn E. Bremmon, Pharm.D., Roy A. LaBarge, Pharm.D.; William S. Middleton Memorial Veterans Hospital, Madison, WI

Purpose: To evaluate the efficacy of tobacco cessation interventions delivered by pharmacists and Addictive Disorders Treatment Program (ADTP) social workers in a tobacco cessation clinic compared to those offered by standard medical care providers in a Veterans Health Administration hospital.

Methods: A retrospective chart review of patients enrolled in the tobacco cessation clinic between September 1, 2009 and October 1, 2009 and patients prescribed tobacco cessation medication by standard medical care providers between September 1, 2008 and October 1, 2008 was performed. Data collected included age, gender, provider of the tobacco cessation intervention, tobacco cessation medications prescribed, if the patient completed the full tobacco cessation program, and success of the quit attempt. The primary endpoint was a documented successful quit attempt 3 to 12 months after medications were initially prescribed.

Results: 300 patients were initially identified for review, of which 169 were included for statistical analysis. Baseline characteristics were similar between standard medical care and the tobacco cessation clinic with respect to age (54 years vs. 57 years) and gender (91% vs. 97% male). A successful quit attempt was achieved by 22% of patients in the tobacco cessation clinic compared to 10% in standard medical care (p=0.03). Combination medication therapy was used in 35% of successful quit attempts in the tobacco cessation clinic whereas standard medical care utilized monotherapy in all successful quit attempts. Providers in the tobacco cessation clinic illustrated similar rates of successful quit attempts, with 23% for ADTP social workers and 21% for pharmacists (p=0.90). Further analysis showed that patients who completed the full tobacco cessation program had a quit

rate of 46% compared to 4% in those who did not complete the program (p<0.001).
Conclusion: Tobacco cessation interventions delivered by pharmacists and ADTP social workers were superior to those delivered by standard medical care providers.

348E. An evaluation of the effectiveness and safety of varenicline in a veteran population.
Samantha M. Wright, Pharm.D.[1], Molly P. Kurpius, Pharm.D.[2], Jaclyn Y. Ng, Pharm.D.[2], Donna M. Givone, Pharm.D., BCPP[2]; (1)VA Sierra Pacific Network (VISN 21) Pharmacy Benefits Management Group, Reno, NV; (2)Jesse Brown VA Medical Center, Chicago, IL

Purpose: In premarketing trials, varenicline demonstrated efficacy as a smoking cessation aid. However, the exclusion criteria of these trials likely would have disqualified many patients in our veteran population. After its approval, reports of serious neuropsychiatric symptoms, including suicidal ideation/behavior, emerged. Due to limited available data, this study evaluated the use of varenicline in a veteran population.
Methods: Medical records of 276 patients started on varenicline between May 2006 and June 2009 were retrospectively reviewed. Data collected included smoking and psychiatric history, prescription information, quit date, smoking status after the end of therapy, and adverse event (AE) information. Primary endpoints were continuous abstinence rate for the last 4 weeks of therapy, percentage smoke-free at the end of therapy, and occurrence of AEs. Secondary endpoints were median length of therapy, length of abstinence after completing therapy, and categorization and severity of AEs.
Results: Twenty-one percent of patients reported continuous abstinence during the last 4 weeks of therapy and 27% were smoke-free by the end of therapy. Of the approximately one-third who received at least 12 weeks of therapy, 49% reported continuous abstinence during the last 4 weeks and 53% were smoke-free by the end of therapy. Seventy percent of patients who were smoke-free by the end of therapy relapsed, most within the first 3 months. There were 143 AEs reported by 102 patients (37%); the majority were mild. There was no documentation of suicidal ideation or suicide attempts. A similar AE rate and AE-related discontinuation rate was seen in patients with and without a psychiatric diagnosis.
Conclusions: At least 12 weeks of varenicline was shown to have a similar continuous abstinence rate in this veteran population compared to those reported in premarketing trials. However, long-term abstinence was not as well sustained. Study results indicate varenicline therapy warrants close follow-up and monitoring.
Published in Preliminary abstract published in Journal of Pharmacy Practice 2010;23(2):153-87. Poster presented at the College of Psychiatric and Neurologic Pharmacists Annual Meeting, San Antonio, TX, April 17–21, 2010.

Community Pharmacy Practice

349. A survey of NC pharmacists regarding mandatory medication counseling.
Roy A. Pleasants, PharmD[1], Carolyn Robbins, B.S., Pharm, Pharm.D.[2], Brenden Ohara, RPh[3], Dan Garrett, RPH, M.S.[4], Charli Davis, Pharm.D., student[5], Robert Cisneros, Ph.D.[5]; (1)Campbell University, Cary, NC; (2)Lincoln Community Health Center Pharmacy, Durham, NC; (3)Physician's Pharmacy, Cary, NC; (4)American Healthcare, Rocklin, CA; (5)Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC

Purpose: In 2008, a 13-question survey was sent to all registered North Carolina pharmacists regarding mandatory prescription counseling in the outpatient setting.
Methods: The survey had questions concerning the demographics and practice characteristics of the pharmacists along with questions regarding the acceptability and role of mandatory medication counseling. Questions included barriers to counseling, whether all new therapies should require pharmacist counseling vs targeted therapies as well as the role of the pharmacy technician.
Results: 2327 NC pharmacists (21.7% of total) completed the on-line survey. Respondents were chain 41%, independent 19%, clinic 4.3%,

hospital 19%, other 17%. More than 50% of respondents filled > 100 prescriptions/day. Most pharmacists believed that counseling < 25% of all prescriptions would be an acceptable workload. The two biggest barriers identified were workload and lack of interest by the patient. Nearly two-thirds of the survey pharmacists thought that counseling was important or essential for medication safety. Seventy percent stated that a prescription error had been caught by them through counseling. Forty-six % of respondents were supportive or very supportive of mandatory counseling for all new prescriptions in the outpatient setting; 23% were neutral, 31% were against or very against. When asked about mandatory counseling only on targeted therapies, 54% were very supportive or supportive, 23% were neutral, and 23% were against or very against. Chain pharmacists were more likely to be against mandatory counseling compared to independents, clinic pharmacists, or others. Sixty percent of pharmacists were against or neutral regarding counseling by pharmacy technicians.
Conclusion: The survey supports mandatory counseling by pharmacists in NC and a rule is currently under review by the Board of Pharmacy to require pharmacists' counseling on targeted drug therapies (devices, NTIs, controlled substances, anticoagulants, and immunosuppressives). Counseling for targeted therapies may serve to help expand the pharmacis's role with medication safety.

Critical Care

350. Effect of ACE inhibitors on renal function in a surgical critical care population.
April D. Miller, Pharm.D., BCPS, P. Brandon Bookstaver, Pharm.D., BCPS (AQ-ID), AAHIVE, Katie Barber, Pharm.D.; South Carolina College of Pharmacy-USC Campus, Columbia, SC

Purpose: Angiotensin converting enzyme (ACE) inhibitors have beneficial effects on renal function in outpatients. Critical illness and traumatic injury produce physiologic changes in renal blood flow, and the effect of these agents on renal function in a surgical/trauma intensive care unit (STICU) patient population is unknown.
Methods: A retrospective medical record review of STICU patients receiving ACE inhibitor therapy for hypertension between 2007 and 2009 was conducted. Patients were excluded from the analysis if they received known nephrotoxic agents. The primary endpoint was change in glomerular filtration rate (GFR) 72 hours before and after ACE inhibitor initiation, calculated using the Modification of Diet in Renal Disease equation. The secondary endpoint was change in serum creatinine (SCr). Where applicable, the incidence of acute renal failure was classified per Risk, Injury, Failure, Loss, ESRD (RIFLE) criteria. A two-sided, paired t-test with α=0.05 was used to compare groups. Sample size was calculated to achieve 80% to detect a 10% change in GFR.
Results: Thirty patients were included in this analysis (mean age 52 years; 21 males, 9 females). Sixteen patients had a past-medical history of hypertension and 7 had a history of diabetes. Pre-initiation, the mean GFR was 95ml/min/1.73m2; and post-initiation, mean GFR increased to 100 ml/min/1.73m^2 (p=0.35). The mean increase in GFR was 4.97% (4.7ml/min) and mean decrease in SCr was 5.9% (0.1 mg/dl). Seventeen subjects (57%) had an improvement or no change in GFR; 9 (30%) had decreases in GFR too small to be classified according to RIFLE criteria; 3 (10%) had acute renal failure classified as "Risk"; 1 (3.3%) had acute renal failure classified as "injury".
Conclusion: ACE inhibitors are a safe therapy for hypertension in surgery/trauma patients with critical illness. Further study is needed to determine if they have beneficial effects on renal function in this population.

Education/Training

351. The impact of a simulation-based exercise on knowledge retention and confidence regarding medication use and preparation for medical emergencies.
Marilyn Bulloch, Pharm.D.[1], Nathan Pinner, Pharm.D.[1], Stephen Eure, R.Ph.[2]; (1)Auburn University Harrison School of Pharmacy, Tuscaloosa, AL; (2)DCH Regional Medical Center, Tuscaloosa, AL

Purpose: Pharmacists involvement in medical emergencies (ME) is associated with improved patient outcomes. Pharmacists reluctant to participate in ME report inadequate training as the major barrier. Our goal was to implement a hands-on workshop and assess its impact on knowledge retention and confidence in relation to the use, preparation, and labeling of medications most commonly encountered in ME.
Methods: Students, residents, and pharmacists at DCH Regional Medical Center participated in a hands-on, simulation-based workshop where they prepared and labeled parenteral medications commonly used during ME. All investigators were blinded to each participant's identity through random assignment of study numbers. Identical surveys and examinations were administered before and after the workshop. Surveys consisted of 10 questions to assess confidence using a 4-point Likert scale of "not confident" (NC), "somewhat confident" (SC), "confident" (C), and "highly confident" (HC). Exams consisted of questions specific to the compounding, labeling, and use of medications for ME. The paired t-test was used for comparison of mean exam scores.
Results: Sixty subjects participated in the workshop and 54 completed all survey and exam materials. The 54 subjects included in the analysis were comprised of 12 students, 4 residents, and 38 pharmacists. Mean (SD) pre- and post-workshop exam scores (out of 100) were 57.6 (19.9) and 78.2 (17.9), respectively, an improvement of 20.6 points (p<0.0001). Response rates of NC, SC, C, and HC for the pre-survey were 31.1, 30.4, 25, and 13.5% vs. 4.3, 27.6, 32.2, and 35.9% for the post-survey, respectively. Subjects responded C or HC more often after completing the workshop (68.1 vs 38.5%).
Conclusion: Participation in the workshop increased subjects' confidence and knowledge regarding ME. Whether this training and increased confidence translates into more pharmacists participating in ME remains to be determined.

Hematology/Anticoagulation

352. Impact of pharmacist managed heparin-induced thrombo-cytopenia dosing protocols.
Sara R. Tebbe, Pharm.D.[1], Phuong H. Nguyen, Pharm.D.[1], David R. Putney, Pharm.D.[1], Lawrence Rice, M.D.[2]; (1)The Methodist Hospital, Houston, TX; (2)Methodist Academic Medicine Associates - Weill Cornell Medical College, Houston, TX

Purpose: Direct thrombin inhibitors (DTIs) are associated with lack of familiarity with dosing and monitoring, possibly leading to adverse events. In an effort to standardize practices utilizing DTIs in heparin-induced thrombocytopenia (HIT), pharmacy protocols were developed. The purpose of this study was to evaluate the composite endpoints of all-cause death, amputation, and new thrombosis in protocol managed HIT patients with standard care.
Methods: This was a non-randomized, open-label, single-center study evaluating 33 patients treated with argatroban or bivalirudin for HIT from September 2008 to August 2009. 18 patients were managed by pharmacy protocols and 15 patients were managed by physicians. Argatroban was initiated at 0.5 μg/kg/min for critical care or hepatic impairment patients and 1 μg/kg/min for all other patients. Bivalirudin was dosed at 0.1 mg/kg/hour for all patients. Dosing was titrated per protocol according to PTT goals.
Results: 5 (28%) patients in the protocol group and 4 (27%) patients in the physician-managed group met the primary endpoint of all-cause death or all-cause amputation. No patients developed new thrombosis or experienced death due to thrombosis. Both groups had 3 (17%) counts of bleeding events. Length of therapy was similar between both protocol and physician-managed groups at 5.94 (0.79–12.26) days and 6.72 (1.97–11.99) days, respectively. Time to therapeutic PTT was shorter for patients in the protocol group at 5:00 (2:52–14:00) versus 7:41 (3:17–23:23) hours. Days to platelet recovery were 2.50 (0.32–6.62) and 2.53 (0.58–8.47) for patients in the protocol and physician-managed groups, respectively. Mean maintenance doses for both groups reflect similar initiation dosing as used in protocols.
Conclusion: Dosing practices appear to be similar for both pharmacy and physician management. Pharmacy-managed protocols are a safe and effective approach to managing HIT patients with argatroban and bivalirudin.

Nephrology

353. Pilot Evaluation of Renal Function in Hispanic Americans with Diabetes.
Thomas C. Dowling, Pharm.D, Ph.D[1], Magaly Rodriguez de Bittner, Pharm.D.[1], Zhanita Perez, Pharm.D.[2], Andrew Briglia, M.D.[3], Ligia Peralta, M.D.[4]; (1)Department of Pharmacy and Therapeutics, University of Maryland, Baltimore, MD; (2)University of Maryland, Baltimore, MD; (3)Annapolis Nephrology Associates, Annapolis, MD; (4)Department of Medicine, University of Maryland, Baltimore, MD

Purpose: Detection and treatment of Type 2 diabetes and the high prevalence of diabetic nephropathy in the Hispanic population is problematic. The purpose of this pilot study was to evaluate renal function and selected CYP genotype and phenotype in a cohort of Hispanic Americans with known or self reported diabetes.
Methods: Subjects were recruited from the Hispanic community as part of outreach care clinics. The research study visit included biochemical evaluation, glomerular filtration rate (GFR) measurement using iothalamate clearance, and hepatic CYP3A phenotype using the erythromycin breath test (EBT). Variant allele frequencies for CYP2B6*6 (rs3745274), CYP3A5*3 (rs776746), CYP3A5*6 (rs10264272) and CYP2C9*3 (rs1057910) were determined using real-time PCR (TaqMan).
Results: Renal function was measured in 14 subjects with fasting blood glucose of 189 ± 75 mg/dL and HgA1C of 9.1 ± 3.1%. GFR values were 138 ± 23 mL/min and urinary albumin to creatinine ratio was 24 ± 42 μg/mgC. EBT values were marginally lower than a historical control group (2.1 ± 0.4 vs. 2.7 ± 1.0, p=0.08). A high frequency of CYP2B6*6 homozygotes (64%) and *6 carriers (91%) was observed. All subjects carried the CYP3A5*3 allele and 64% were homozygous (*3/*3). There were no carriers of risk alleles for CYP3A5*6 or CYP2C9*3 in this population.
Conclusion: Comprehensive evaluation of renal function and drug metabolism in a Hispanic diabetes population showed glomerular hyperfiltration with polymorphic variants of CYP2B6 and CYPA5 that are associated with reduced CYP enzyme activity. Further study in a larger cohort using outreach approaches is warranted, to determine implications in drug selection for Hispanic patients with diabetes.

Pharmacoeconomics/Outcomes

354. Association of access to medications and health care utilization: impact on emergency room visits for those unable to obtain medications.
Jonathan H. Watanabe, Pharm.D., M.S., Ph.D., Candidate, John Ney, M.D.; University of Washington, Seattle, WA

Purpose: Several studies have investigated the impact of prescription drug benefit on utilization. Most of these studies have used drug expenditures and utilization as the outcome measure[1, 2]. Although research has taken place on the effect of insurance on utilization[3] little research has been done evaluating access to medications and health effects. Our goal was to evaluate the association between members of the US population who were not able to obtain their medications and emergency room (ER) visits.
Methods: We applied a cross-sectional analysis using 2006 Medical Expenditure Panel Survey (MEPS). Multiple logistic regression using survey adjustment was used to assess association between individuals responding they were 'unable to obtain meds' and having any ER visit during 2006. A priori adjustment was not made for presence or absence of insurance as it is present in the causal pathway. Sensitivity analysis was undertaken to evaluate adjusting for insurance status.

Results:
Odds Ratios

	Variable	Point Estimate	CI
Unable to obtain medications versus able to obtain	1.903	1.366	2.650
Less than 200% federal poverty level (no vs yes)	0.522	0.412	0.662
Under 65	0.694	0.602	0.800
Health Status (SF-12)			
excellent vs very good	1.075	0.698	1.654
poor vs very good	3.683	2.604	5.209
black vs white	1.155	0.939	1.420

Adjusted for age, race, poverty level, and health status people unable to obtain medications were associated with an increase in odds of an ER visit (OR=1.9, 1.4–2.7). Adjusting for insurance did not alter the odds ratios markedly. Majority (80.3%) of those unable to obtain medications stated 'could not afford' as the reason. Causality cannot be determined as this was a cross-sectional study.
Conclusion: Individuals without access to medications are at increased risk of catastrophic health outcomes. Additional measures are needed to ensure access to medications to reduce poor health outcomes and costs.

355. Economic evaluation of tocolytic agents for delaying preterm labor—a cost minimization analysis of atosiban and nifedipine.
Shivani K. Mhatre, B.Pharm., Ruchika N. Agrawal, B.Pharm., Sujit S. Sansgiry, Ph.D..; University of Houston, Houston, TX

Purpose: The aim of the study is to carry out cost minimization analysis of tocolytic drugs-atosiban and nifedipine for delaying preterm labor by 48 hours.
Methods: The decision tree analysis model was developed from a hospital perspective using TreeAge Pro. The outcome considered was delay of preterm labor by 48 hours as per the clinical requirements of the condition. A comprehensive literature review of Pub Med, Medline, and Cochrane Library was conducted to obtain clinical (response rates, adverse events rates, and compliance rates) and economic (drug acquisition cost, hospitalization cost, cost for treatment of adverse effects resulting from tocolytic treatment) data from validated meta-analyses and randomized controlled trials. A tornado sensitivity analysis and one way sensitivity analysis (varying costs, adverse effects, and compliance rate) was carried out to ascertain the robustness of our results.
Results: The model predicted that treatment with nifedipine was more costly ($4,762 per patient) as compared to treatment with atosiban ($4,587 per patient). This yielded an augmented cost saving of $175 per patient, thus favoring atosiban treatment. The sensitivity analyses were robust to the results that atosiban was a drug of choice when costs, compliance rates, and adverse events rates were considered. However, an 8% increase in response rate of nifedipine may favor the result towards nifedipine.
Conclusions: Treatment with atosiban was found to be more economical for delaying preterm labor by 48 hours in contrast to treatment with nifedipine.

356. A cost effective analysis of pegfilgrastim versus filgrastim within Veteran Affairs Northern California Health Care System (VANCHCS).
Carrie A. Nolan, Pharm.D., Joy L. Meier, Pharm.D.; VA Northern California Health Care System, Martinez, CA

Purpose: Pegfilgrastim is promoted as advantageous compared to filgrastim to help prevent neutropenia, due to its reduced dosing frequency and potential decrease in toxicity. However its acquisition cost is high. Currently, VANCHCS designates filgrastim as its preferred formulary agent. This study aimed to examine utilization and costs involved for granulocyte colony stimulating factors (G-CSF) to determine which agent would be most appropriate for the patient population within VANCHCS.
Methods: To determine adherence, all patients with a prescription for filgrastim between September 2009 and March 2010 were contacted by telephone shortly after treatment and asked how many vials they

had remaining. In addition, a retrospective chart review was conducted, which included the recent patients on filgrastim and historical data for patients on either filgrastim or pegfilgrastim, to investigate potential complications, such as febrile neutropenia, hospitalizations or delays in treatment. Finally, a cost analysis was performed to better understand the direct costs involved.
Results: Results show that patients were competently injecting filgrastim as directed with few adverse effects. The chart review showed that the incidence of fever, neutropenia, or febrile neutropenia combined was not statistically significant between the filgrastim and pegfilgrastim groups (14% vs. 13%, p=0.89). When examining common dosing regimens, filgrastim is almost always less costly compared to pegfilgrastim. The one exception occurs when filgrastim 480mcg is used over 8 days, which is rare within VANCHCS.
Conclusions: This data will help direct future prescribing patterns for granulocyte colony stimulating factors within the VA. At this time, filgrastim will remain the formulary drug of choice for VANCHCS.

Pharmacoepidemiology

357. Assessment of seasons as a factor for variation of international normalized ratio outside the therapeutic range.
Zenobia J. Dotiwala, B.Pharm, Edith A. Nutescu, Pharm.D., Daniel R. Touchette, Pharm.D., Bruce L. Lambert, Ph.D.; University of Illinois at Chicago, Chicago, IL
Background: Previous studies point to a possible association between seasonal and temperature variations and blood coagulation. In addition, limited data exists suggesting that international normalized ratio (INR) variation which is not explained by usual factors such as dietary changes, missed medications, and concomitant drugs, occurs more frequently with weather changes. However, a relationship between INR variation and seasonal temperatures has not been established in venous thromboembolism (VTE) patients treated with warfarin.
Purpose: The aim of this study is to evaluate the association between seasonal temperature and blood coagulation as expressed by INR, in VTE patients on warfarin therapy. Method: A retrospective cohort study of outpatients managed at the Antithrombosis Clinic of the University of Illinois Medical Center has been conducted. One-hundred patients with a diagnosis of VTE and treated with long-term warfarin were included. Patients had to have at least two consecutive INR values not less than 15 days apart, within the therapeutic INR range of 2–3. Data was collected for a 12 month period for the following variables: demographics, INR values, variation in Vitamin K intake, alcohol use, smoking status, concurrent medications, and co-morbidities. Temperature data corresponding to patients' date of INR measurements was extracted from the National Oceanic and Atmospheric Administration division of the National Climatic Data Center. To date, data collection has been completed. We will use SuperMix to construct mixed effects linear regression models to measure the association between INR (the outcome), temperature and season, while controlling for a large number of clinical and demographic covariates.
Results: Data analysis will be completed and results will be presented at the ACCP conference.
Conclusion: Our study will test the hypothesis of seasonal temperature association with anticoagulation variability. If an association is found, then more informed clinical dosing decisions can be made for VTE patients treated with warfarin.

Pharmacogenomics/Pharmacogenetics

358. Inhibition of tacrolimus gut metabolism by ketoconazole is modified by ABCB1 haplotype in CYP3A5 nonexpressors.
Sony Tuteja, Pharm.D., BCPS[1], Daryl J Murry, Pharm.D.[1], William Wolowich, Pharm.D.[2], Mahfoud Assem, Pharm.D., Ph.D.[1], Tatian Kirresh, Pharm.D.[1], Alan Reed, M.D.[3], Christie Thomas, M.D.[3]; (1)University of Iowa College of Pharmacy, Iowa City, IA; (2)Nova Southeastern University, Ft. Lauderdale, FL; (3)University of Iowa College of Medicine, Iowa City, IA

Purpose: Tacrolimus (tac) is the cornerstone of immunosuppressive

therapy in solid organ transplant recipients. Tac is a substrate for CYP450 3A4/5 and for the membrane transporter p-glycoprotein (Pgp) and is subject to numerous drug interactions and erratic bioavailability. This study was conducted to determine if haplotypes derived from three frequent polymorphisms in the ABCB1 gene (C1236T, G2677T, C3435T) could predict the degree of drug interaction between tac and ketoconazole (keto) in patients who are cytochrome P450 3A5 (CYP3A5) nonexpressors (*3/*3)

Methods: A prospective pharmacokinetic / pharmacogenomic drug interaction study was performed in 8 kidney transplant recipients. Pharmacokinetics of tac were assessed on 2 occasions with and without keto coadministration separated by 1 week. A semi-simultaneous method was employed, where the IV drug was given on the same day, 6 hours after the oral dose. Tac concentrations were analyzed by a HPLC-MS assay. Pharmacokinetic data were fit to a 1 compartment model using ADAPT 5. DNA was extracted from blood utilizing the QIAamp DNA mini kit (Quiagen). Polymerase chain reaction followed by direct sequencing was used for genotyping CYPA3A5 intron 3 (22893A>G) and ABCB1 exon 12 (1236 C>T), exon 21 (2677 G>T,A) and exon 26 (3435 C>T).

Results: Bioavailability (F) of tac increased from $27 \pm 11\%$ at baseline to $37 \pm 23\%$ following keto (p=ns). In the ABCB1 low expressor group (TTT haplotype) the change in F was attenuated ($25 \pm 11\%$ to $29 \pm 15\%$) vs the high expressor (GCG) group ($30 \pm 13\%$ to $52 \pm 30\%$).

Conclusion: The magnitude of drug interaction by the inhibitor keto had a greater effect in kidney transplant recipients who are high expressors of Pgp and thus these patients experienced a greater increase in bioavailability. The ABCB1 gene may serve as a genomic marker for prediction of drug-drug interactions. Further investigation in a larger study population will be needed to confirm these findings.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

359. Comparison of Cockcroft-Gault and Modification of Diet and Renal Disease Equations for Use in Medication Dosing in a Veteran Population.
Karsten R. Duncan, Pharm.D., Richard Pham, Pharm.D., Jannet Carmichael, Pharm.D.; Veterans Health Administration, Reno, NV

Purpose: This study compares the Crockcroft-Gault (CG) equation with the newer 4-variable Modification of Diet and Renal Disease (MDRD) equation for use in medication dosing of patients with renal impairment. Though recent guidelines have changed allowing use of MDRD for renal dosing, most drug package inserts use dosing adjustments derived from the CG equation. Comparison of these equations in a large population has not been undertaken.

Methods: Regional VA databases were queried to extract all patients with serum creatinine lab values within a 5-year period. Patients with any missing demographic values necessary for calculating either the MDRD or CG equations were excluded along with extreme outliers. An identical patient cohort was used to calculate MDRD, MDRD converted to mL/min and the CG using ideal body weight (IBW), actual body weight (ABW), and a hybrid body weight (HBW) comprised of IBW, ABW and an adjusted body weight. These groups were then divided into <30, 30–50, and >50 ml/min groups as identified by the FDA as categories to identify dosage adjustment for impaired renal function. The Stuart-Maxwell and the Kolmogorov-Smirnov tests were used to detect differences and determine concordance between the equation's outputs.

Results: A final cohort of 42,396 patients was found to have statistically significant differences (p=<0.05) between all the equations. Highest concordance was reached with the HBW CG equation in the <30 mL/min category and with the IBW CG equation in the 30–50 mL/min category with a concordance of 83% and 61% respectively. In the >50 mL/min category all variations of the CG resulted in concordance percentages above the 90th percentile.

Conclusion: This study revealed that within specific renal function ranges the MDRD derives different values and thus different dosing recommendations than the CG using various weight calculations. The greatest difference in the equations occurred at the 30–50 mL/min group.

360E. Interactions between roflumilast and cytochrome P450 inducers and inhibitors: overview of existing studies.
Gezim Lahu, Ph.D.[1], Andreas Hünnemeyer, M.D.[1], Nassr Nassr, M.D.[1], Nigel McCracken, Ph.D.[2]; (1)Department of Pharmacometrics and Pharmacokinetics, Nycomed GmbH, Konstanz, Germany; (2)Department of Exploratory Clinical Development, Nycomed GmbH, Konstanz, Germany

Purpose: Roflumilast (ROF) is a selective oral phosphodiesterase 4 (PDE4) inhibitor developed for the anti-inflammatory treatment of COPD. It is catalyzed by cytochrome P450 (CYP) 1A2 and 3A4 to its active metabolite roflumilast N-oxide (RNO), which accounts for >90% of ROF total PDE4 inhibitory activity (tPDE4i), and is subsequently cleared by CYP3A4, with a minor contribution from CYP2C19. This analysis investigated the pharmacokinetic (PK) effects of coadministration of ROF with CYP inducers and inhibitors.

Methods: The coadministration of single-dose ROF 500µg with steady-state CYP inducers and single and multiple pathway inhibitors was analyzed in Phase I studies to evaluate the consequences on PK of ROF and RNO.

Results: Coadministration of ROF with inducers and inhibitors only moderately altered the tPDE4i; only fluvoxamine and rifampicin altered tPDE4i by approximately 60%.

Coadministered drug	Effect on CYP family	Effect on ROF
Rifampicin	Potent 3A4 inducer	58% decrease in tPDE4i
Enoxacin	Potent 1A2 inhibitor	25% increase in tPDE4i
Ketoconazole	Potent 3A4, weak 1A2, 1A1 and 2C19 inhibitor	No interaction
Fluvoxamine	Potent 1A2 and 2C19 inhibitor	59% increase in tPDE4i
Cimetidine	Weak 3A, 1A2 and 2C19 inhibitor	47% increase in tPDE4i

Conclusion: A feature of ROF is its metabolism by parallel CYP pathways; only strong inhibitors blocking more than one relevant CYP isozyme seem to alter tPDE4i in a clinically relevant manner. Increases in tPDE4i of over 2-fold may result in decreased tolerability. Alterations in tPDE4i of under 2-fold are not expected to result in changes in ROF safety and tolerability. The use of rifampicin may reduce ROF therapeutic efficacy.
Presented at the European Respiratory Society Meeting, September 18–22, 2010, Barcelona, Spain.

361E. Roflumilast in coadministration with medications commonly prescribed for COPD: an overview of existing studies.
Gezim Lahu, Ph.D.[1], Udo-Michael Goehring, M.D.[2], Andreas Hünnemeyer, M.D.[1], Nassr Nassr, M.D.[3]; (1)Department of Pharmacometrics and Pharmacokinetics, Nycomed GmbH, Konstanz, Germany; (2)Department of Medical Scientific Strategy/Respiratory, Nycomed, GmbH, Konstanz, Germany; (3)Department of Exploratory Clinical Sciences, Nycomed GmbH, Konstanz, Germany

Purpose: Roflumilast (ROF) is an oral, selective phosphodiesterase 4 (PDE4) inhibitor developed for anti-inflammatory COPD treatment. It is catalyzed by cytochrome P450 (CYP) 1A2 and 3A4 to its active metabolite roflumilast N-oxide (RNO). This analysis evaluated the safety and the potential for pharmacokinetic (PK) interactions when ROF is coadministered with typical representatives of drug classes commonly used in COPD.

Methods: Drug−drug interaction studies of ROF with antibiotics, bronchodilators, inhaled corticosteroids and other medications commonly prescribed in COPD were analyzed for PK parameters of ROF, RNO and concomitant drugs. Safety outcomes were evaluated throughout each study.

Results: PK results are summarised in the table below. No clinically relevant interactions were observed for ROF and RNO with any of the coadministered drugs. The use of rifampicin may reduce the therapeutic efficacy of ROF. No safety concerns were revealed and coadministration of ROF was generally well tolerated with each drug class.

Coadministered drug	Result
Rifampicin	Decreased AUC and C_{max} (ROF and RNO)
Erythromycin	No interaction
Enoxacin	Weak interaction
Salbutamol	No interaction
Formoterol	No interaction
Montelukast	No interaction
Budesonide	No interaction
Warfarin	No interaction
Midazolam	No interaction
Digoxin	No interaction
Sildenafil	No interaction
Antacid	No interaction
Theophylline	No interaction

Conclusion: Roflumilast is generally well tolerated and does not show any clinically relevant interaction in healthy volunteers when coadministered with medications likely to be prescribed to COPD patients.

Presented at the European Respiratory Society Meeting, September 18–22, 2010 in Barcelona, Spain.

Psychiatry

362E. Prescribing prevalence of low-dose quetiapine in a large academic medical center.
Ashley L. Mains, Pharm.D., Karen E. Moeller, Pharm.D., BCPP, *Allison R. King, Pharm.D.;* University of Kansas Hospital, Kansas City, KS

Purpose: The primary objective of this study was to determine the frequency of prescribing and indications for use of low-dose quetiapine in the inpatient setting.
Methods: A one year retrospective chart review was conducted on hospitalized patients 18 years of age or older admitted to The University of Kansas Hospital who received low-dose quetiapine (< 200 mg per day) to evaluate frequency of use, indication for use, and other prescribing trends (e.g., services prescribing quetiapine and whether medication was initiated while in hospital). Comorbid disease states such as diabetes, hyperlipidemia, and cardiovascular diseases were also evaluated due to quetiapine's risk for increasing blood sugar and cholesterol levels. The protocol was approved by the Human Subjects Committee at the University of Kansas Hospital.
Results: One hundred six patients met study inclusion. Of the patients who received low-dose quetiapine, only 33% had a documented psychiatric disorder. The majority of low-dose prescribing was for insomnia (68%), followed by unknown indication (18%), agitation (9.3%), and anxiety (3.3%). Of the patients prescribed low-dose quetiapine, only 40% of patients were started in the hospital, indicating a greater trend for initiation in the outpatient setting.
Conclusion: Quetiapine is commonly prescribed off-label for the treatment of insomnia, anxiety, and acute agitation despite a lack of published literature and documentation. Although quetiapine may be effective in the treatment of these conditions, other medications (e.g. diphenhydramine, trazodone) exist with potentially less harmful side effects and lower cost.

Presented at Encore Poster Presentation at College of Psychiatric and Neurologic Pharmacist 13th Annual Meeting. San Antonio, Texas, April 2010. Presented at The University of Kansas Graduate Research Symposium. April, 2010.

363. Switching from olanzapine to another antipsychotic: a naturalistic study assessing success, safety, and cost of conversion.
Ashley M. LaFlame, Pharm.D.[1], Bethany Dipaula, Pharm.D.[2], Jason Noel, Pharm.D.[2]; (1)Spring Grove Hospital Center, Catonsville, MD; (2)University of Maryland School of Pharmacy, Baltimore, MD

Purpose: The purpose of this study was to analyze outcomes associated with patient tailored therapeutic antipsychotic regimens in a Maryland state psychiatric facility and determine the impact of the formulary removal of olanzapine on patient care and cost.
Methods: A retrospective cohort investigation was conducted to evaluate the medical records of 20 patients during the 6 weeks prior to olanzapine discontinuation (pre-conversion period) and the 6 weeks following therapy on an alternative antipsychotic agent (post-conversion period). A pre- and post- analysis was conducted to assess whether the alternative antipsychotic regimens were equally efficacious and safe when compared to olanzapine.
Results: Data from patients actively switching therapy between December 2008 to April 2009 were reviewed. In assessing success, there was no differences found between pre- and post-conversion seclusion/restraint episodes, use of 'prn' antipsychotics (Z-score = 1.89, p=0.06), use of 'prn' anxiolytics (Z-score = -0.845, p=0.40), and use of adjunctive antipsychotic agents (% difference = 15%, 95 % CI -10.38, 24.75, p=0.38). There was significant improvement in several safety measures including weight (t = 2.51, p=0.022), BMI (t = 2.27, p=0.037), and HDL (t = -2.25, p=0.05). No significant difference was detected in total cholesterol (t = 0.381, p=0.71), triglycerides (t = 1.77, p = 0.12), and LDL (t = 0.652, p=0.53). There was a significant difference in the average cost of antipsychotic agents pre-conversion ($1,626.19 ± $385.78) and post-conversion ($233.97 ± $344.24); t = -14.05, p≤0.0001.
Conclusions: There was significant cost savings following the formulary change. It appeared that the switch was successful as no significant difference in decompensation markers were detected. Switching from olanzapine to an alternative antipsychotic agent also resulted in a significant reduction in weight/BMI and improvement in HDL cholesterol.

Pulmonary

364E. Brand or Generic? Evaluation of an Epoprostenol Formulary Change.
Laura A. Duvall, Pharm.D., BCPS, Namita Sood, M.D., FCCP; The Ohio State University Medical Center, Columbus, OH

Purpose: Flolan® (epoprostenol sodium) is a highly effective therapy for the treatment of pulmonary arterial hypertension. Generic epoprostenol was FDA approved in April 2008 as therapeutically equivalent (AP rated) to Flolan®. Small epoprostenol dosing measurements have lead to concern regarding whether or not differences between products would adversely affect patient outcomes. Safety interchanging products in the inpatient setting is unknown. At The Ohio State University Medical Center (OSUMC), generic and brand epoprostenol products were kept on formulary for a 6-month trial period. Patients newly initiated on epoprostenol were started on generic product, while all patients previously prescribed epoprostenol were maintained on their home regimens. Following the trial period, OSUMC began exclusively using generic epoprostenol for inpatient use. We assessed safety of interchanging between brand and generic epoprostenol.
Methods: A retrospective analysis of all admissions between June 9, 2009 and December 9, 2009 was conducted to evaluate home epoprostenol medication (brand or generic) versus OSUMC inpatient epoprostenol medication (generic only).
Results: Twenty-four admissions were evaluated to compare home epoprostenol medication, dose, rate, dosing weight, and medication concentration with the generic epoprostenol that was initiated at admission to OSUMC. Adverse events during patient transition to inpatient supply were also evaluated. On 12 admissions, the patient was interchanged from Flolan® to the OSUMC supply of generic epoprostenol. In each case, the dose, rate, dosing weight and medication concentration remained the same as what the patient had been receiving at home. None of the patients needed acute dose adjustments and there were no documented adverse events in any of these patients when transitioned to inpatient supply. Supplying generic product only at OSUMC has led to a 35% cost savings.
Conclusion: This preliminary data suggest that brand and generic epoprostenol can be used interchangeably without adverse effects and results in significant cost savings.

Presented at Pulmonary Hypertension Association 9th International Meeting, The Pulmonary Hypertension Association, Garden Grove, California, June 25–27, 2010

Women's Health

365. Emergency contraception skills workshop for first-year pharmacy students.

Melissa Natavio, M.D., M.P.H., Kimberly A. Moore, Research Assistant, Penina Segall-Gutierrez, M.D., M.Sc., Hannah Moon, M.D., Kathleen H. Besinque, Pharm D., Nicole M. Bender, M.D., Neisha R. Opper, M.P.H., Deshawn Taylor, M.D, Kathleen A. Johnson, Pharm, D., Ph.D., M.P.H.; USC, Los Angeles, CA

Purpose: Half of pregnancies in the United States are unintended and carry socioeconomic and physical ramifications.The use of oral emergency contraception (OEC) can significantly reduce the rate of unintended pregnancies. OEC is currently available without a prescription to patients ≥17 years , therefore it is important that pharmacists are confident and willing to provide OEC and to counsel patients about OEC use and answer questions. The purpose of this study is to determine whether a novel educational intervention improves knowledge, behavior, confidence, and professional responsibility (KBCPR) regarding emergency contraception in first-year pharmacy students.

Methods: First year pharmacy students participated in a didactic session followed by an interactive role-playing workshop led by a team of family planning physicians and pharmacists. Pharmacy students completed a 33 item survey on KBCPR regarding emergency contraception prior to and following the educational intervention, with knowledge assessed via true/false questions and BCPR questions assessed via a 4- or 5-point Likert scale. Pre-post response pairs were analyzed using student's paired t-test.

Results: 182 of 188 students completed both surveys. There was a positive change from 5 to 8 correct answers in the 9 knowledge questions from pre to post survey ($p<0.0001$). In the behavior portion, the mean increase was 0.79 from 2.67 to 3.47 on a scale of 1–4 ($p<0.0001$). On a scale of 1-5, the mean confidence increased by 1.85, from 2.4 to 4.3 ($p<0.0001$). Scores on professional responsibilities were already high at baseline and improved slightly ($p<0.001$).

Conclusion: A novel education intervention utilizing didactics and a small group interactive workshop was successful in improving knowledge and skills of student pharmacists in counseling patients about OEC. Future studies will assess the long-term implications of this intervention. If effective at sustaining improvement In KBCPR,other pharmacy schools should consider adopting this curriculum.

Index of Corresponding Authors