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## 2009 ACCP/ESCP International Congress on Clinical Pharmacy

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### ORIGINAL RESEARCH

#### ADR/Drug Interactions

1. Use of oral and intravenous N-acetylcysteine for prevention of contrast-induced nephropathy in a Singapore hospital. *Candice Yong, B.Sc.Pharm.(Hons), Ian Wee, M.Pharm.(Clin Pharm.), Michelle See, B.Sc.Pharm.(Hons); Department of Pharmacy, Changi General Hospital, Singapore, Republic of Singapore.*

**OBJECTIVES:** Given the varying regimens used in practice and the lack of clear guidelines, this study aimed to review the appropriateness of use of N-acetylcysteine (NAC) for prevention of contrast-induced nephropathy (CIN) in an acute care hospital in Singapore, and provide recommendations for its use.

**METHODS:** This was a prospective observational study conducted over a 4-month period. Patients who received NAC and underwent a procedure requiring radiocontrast media (e.g., cardiac catheterization, computed tomography) were included. Patients were categorized into four dosing regimens: 600 mg or 1200 mg twice-daily for patients on oral NAC; low-dose (600 mg/1200 mg twice daily) or high-dose (up to 200 mg/kg) for patients on intravenous (IV) NAC. Serum creatinine (SCr) levels and estimated creatinine clearance were used as indicators of renal function. The primary outcome measure was incidence of CIN (>25% increase in SCr from baseline) at 48 hours post-procedure.

**RESULTS:** Thirty-four patients on oral NAC and 13 patients on IV NAC were included. At 48 hours post-procedure, SCr levels were available for 21/34 (61.8%) and 11/13 (84.6%) of the patients on oral and IV NAC respectively. Three (18.8%) patients on oral 600 mg twice daily developed CIN versus one patient (20.0%) for oral 1200 mg twice daily ( $p>0.05$ ). None of the patients who received low-dose IV NAC developed CIN, whereas two (50.0%) high-dose IV NAC recipients experienced CIN ( $p=0.039$ ).

**CONCLUSIONS:** The use of NAC for prevention of CIN is recommended in at-risk patients undergoing procedures that require contrast. Oral NAC should be administered at 600 mg twice daily for 2–4 days (at least on the day before and the day of the procedure). Alternatively, an IV dosing of 600–1200 mg twice daily may be considered. High-dose IV NAC should only be used for patients undergoing emergency procedures. Patient's renal function should be monitored at least once during the first 48–72 hours post-procedure.

#### Adult Medicine

2. Financial impact of venous thromboembolism prophylaxis strategy on costs associated with heparin induced thrombocytopenia: A Monte Carlo simulation. *Eli N. Deal, Pharm.D., James M. Hollands, Pharm.D., Angela R. Wills, Pharm.D., Lee P. Skrupky, Pharm.D., Scott T. Micek, Pharm.D.; Barnes Jewish Hospital, Saint Louis, Missouri, USA.*

**OBJECTIVES:** To determine the financial impact of switching from low-molecular weight heparin (LMWH) to low-dose unfractionated heparin (LDUH) for venous thromboembolism (VTE) prophylaxis in patients for whom similar efficacy and bleeding rates have been described (no-preference population).

**METHODS:** A Monte Carlo simulation model was created based on VTE prophylaxis practices at a large, tertiary teaching hospital to estimate yearly costs within 95%. Medication expenditures related to VTE prophylaxis and overall net expenditures were explored when use of LDUH was maximized (24% to 46%) and LMWH was reduced (25% to 5%) in the no-preference population, while tolerating an increase in LMWH (31% to 41%) use in other populations in whom LMWH use is preferred. The overall impact of this approach on expenditures was also analyzed using literature-based estimates of heparin-induced thrombocytopenia (HIT) and associated costs in this population.

**RESULTS:** Decreasing LMWH use in the no-preference population

resulted in a decrease in drug expenditure for VTE prophylaxis of \$581,021 (95% confidence interval [CI] \$332,696–\$791,577; 95% chance of decreased costs). Using this model with contemporary estimates of HIT incidence and costs, the LDUH switch would result in net increased expenditures of \$1,564,175 (95% CI –\$65,381 –\$847,016; 1.7% chance of net savings). Decreased drug expenditures for VTE prophylaxis from a LMWH to LDUH switch in the no-preference population would be offset if 30 cases of HIT (95% CI 16–40) per year were treated or if LDUH-induced HIT incidence in this population was >0.12%.

**CONCLUSIONS:** LMWH use in no-preference populations is the driver for pharmacy expenditures for VTE prophylaxis. Use of LMWH in this population demonstrates cost benefits when contemporary estimates of HIT incidence and costs are utilized in this analysis as the factors related to HIT are the drivers for the overall net costs. Future studies should focus on delineating HIT incidence in this patient population.

#### Ambulatory Care

3. Cardiometabolic risk factor knowledge of participants in a worksite health screening. *Amy M. Franks, Pharm.D., T. Scott Warmack, Pharm.D., Donna S. West, Ph.D.; University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, Arkansas, USA.*

**OBJECTIVES:** Despite the widespread prevalence of diseases such as coronary disease and diabetes, there is a disparity in layperson knowledge regarding cardiometabolic risk factors. The objective of this study was to describe worksite health screening participants' knowledge of cardiometabolic risk factors. This information provides important insight into the lay public's knowledge of risk factors and may impact educational methods for relaying information during health screening programs.

**METHODS:** The study employed a cross-sectional survey of employees of a public school system who presented to a worksite health screening. Participants were asked to complete a written questionnaire to assess their knowledge of cardiometabolic risk factors by identifying risk factors from a list of conditions. Descriptive statistics were used to analyze the data obtained.

**RESULTS:** One-hundred-five participants (85% female; mean age 44.5 ± 10.4 years) completed the questionnaire. The most frequently identified cardiometabolic risk factors were: overweight (95% of respondents), obesity (92%), high blood pressure (92%), high cholesterol (90%), lack of exercise (85%), sedentary lifestyle (82%), large or "thick" waist (70%), diabetes (65%), and high triglycerides (58%). Less frequently identified risk factors were: high blood sugar without diabetes (48%), pre-diabetes (41%), metabolic syndrome (29%), impaired fasting glucose (23%), and low high density lipoprotein (HDL) cholesterol (20%).

**CONCLUSIONS:** Worksite screening participants in this study frequently identified many traditional cardiometabolic risk factors, including overweight, obesity, hypertension, and hypercholesterolemia. Participants less frequently identified risk factors such as pre-diabetes, metabolic syndrome, impaired fasting glucose, and low HDL cholesterol. Practitioners should continue to reinforce education regarding traditional risk factors but also focus on improving recognition and knowledge of other high risk-conferring conditions.

4. Comparison of safety outcomes in three models of anticoagulation management. *Kelly M. Rudd, Pharm.D., BCPS; Bassett Healthcare, Cooperstown, New York, USA.*

**OBJECTIVES:** Both pharmacy and medical literature suggest that specialized anticoagulation clinics improve the efficacy of therapy management. However, no direct comparisons exist to determine if pharmacist-managed clinics improve the quality of care over existing models. This study was designed to produce a head-to-head comparison of three anticoagulation management models: (1) usual care by physicians and/or mid-level providers; (2) a specialty clinic staffed by nurses operating a simple protocol with physician support; and (3) a specialty clinic staffed by a pharmacist and a nurse, operating on the clinical judgment of a pharmacist in a collaborative practice arrangement.

**METHODS:** The three models were compared using the number of hospitalization and emergency department (ER) visits directly related to anticoagulation therapy. One year's results of international normalized

ratios (INR) from chronically anticoagulated Internal Medicine patients were queried in each group. Anticoagulation indication, INR goal, baseline characteristics, admission diagnosis, and duration of admission were extracted from the medical record. If the INR goal was not documented, a range was assigned as appropriate from the American College of Chest Physicians CHEST anticoagulation guidelines.

**RESULTS:** Baseline characteristics were similar between the study groups. The Pharmacist and Nurse Clinic (n=6243) yielded the lowest rates of both hospitalization and ER visits. The number of hospitalizations was reduced by 56% versus the Nurse and Protocol (n=3618), and 61% versus Usual Care (n=3142) (p <0.01). The number of ER visits for the Pharmacist and Nurse Clinic group was reduced by 78% versus Nurse and Protocol, and 67% versus Usual care (p<0.05).

**CONCLUSIONS:** Specialized anticoagulation clinics using the services of a pharmacist statically and clinically reduced the number of both ER visits and hospitalizations due to anticoagulation problems. Based on the results of this study, it is recommended that all anticoagulated patients within our system be managed by a specialized Anticoagulation Clinic, operating under the clinical judgment of a pharmacist, with nursing and physician support.

**5. Warfarin therapy in atrial fibrillation: a comparison between established and new patients.** Julie M. Sease, Pharm.D., S. Scott Sutton, Pharm.D.; South Carolina College of Pharmacy, Columbia, South Carolina, USA.

**OBJECTIVES:** To describe the difference in rates of subtherapeutic international normalized ratio (INR) values in established patients versus new patients on warfarin for atrial fibrillation.

**METHODS:** This was a retrospective observational analysis of atrial fibrillation patients receiving warfarin therapy. The areas of interest were: diagnosis of atrial fibrillation; pharmacy claim for warfarin; refill records indicating the patient had refilled their medication within the past 4 months; duration of diagnosis of atrial fibrillation; and treatment with warfarin. Established patients were defined as having a diagnosis of atrial fibrillation and having received warfarin for greater than 1 year. New patients were defined as having a diagnosis of atrial fibrillation and having received warfarin for less than 1 year.

**RESULTS:** There were 119,451 patients with a diagnosis code for atrial fibrillation. There were 81,441 established patients and 2,019 new patients that had been compliant with warfarin according to pharmacy refill records. There were 27.6% established patients with a subtherapeutic INR compared with 54.5% of new patients.

**CONCLUSIONS:** The high prevalence of atrial fibrillation within medicine presents challenges to ensure optimal outcomes. The majority of our patients were treated with warfarin therapy appropriate with treatment guidelines. However, established patients had fewer subtherapeutic INRs. Warfarin therapy may be affected by several factors (e.g., patient co-morbidities, drug interactions, diet). Counseling patients and developing anticoagulation clinics have been shown to decrease variation in INR values subsequently leading to better patient outcomes involving warfarin. This analysis demonstrates that new patients are not able to maintain therapeutic control as well as established patients, and enforces the importance of appropriate counseling and monitoring by primary care clinicians.

**6. Evaluation of guideline adherence for the treatment of asthma in family medicine clinics.** Sandra L. Kim, Pharm.D., Mitzi Wasik, Pharm.D., BCPS, Marlowe Djuric, Pharm.D., Kristen L. Goliak, Pharm.D., Seema Patel, Pharm.D., Lori A. Wilken, Pharm.D., CDE, AE-C, Leslie A. Briars, Pharm.D., Louise Parent-Stevens, Pharm.D., BCPS; University of Illinois at Chicago, Chicago, Illinois, USA.

**OBJECTIVES:** The primary objective of this study was to evaluate clinician compliance with the National Heart, Lung and Blood Institute (NHLBI) asthma guidelines for the treatment and management of asthma by reviewing medical charts and pharmacy records for documentation of a patient's stage of asthma and the existence of asthma action plans. The secondary objective was to assess for improvement in clinician compliance with national guidelines 6 months post-education.

**METHODS:** A retrospective chart review was conducted using medical and pharmacy records of patients with a diagnosis of asthma who were seen in the Family Medicine clinics and who had their asthma

prescriptions filled at a University of Illinois Medical Center at Chicago (UIMCC) pharmacy. The chart review prior to clinician education included records from August 16, 2006 to August 15, 2007. After presenting the results and the updated NHLBI asthma guidelines to the Family Medicine clinicians, a chart review was conducted from January 23, 2008 to June 30, 2008 to assess for improvements in prescribing patterns.

**RESULTS:** The retrospective chart review from August 16, 2006 to August 15, 2007 showed that 45% (62/137) of eligible patients had documentation of their stage of asthma. Ninety-one percent (29/32) had documentation of an inhaled corticosteroid and 9% (3/32) had documentation of a short-acting beta agonist and a leukotriene modifier. Of the patients who did not have a documented stage of asthma, 92% (69/75) had documented medications. Only 15% (20/137) of the patients who were eligible had a documented asthma action plan. Results for the retrospective chart review post-education is in progress and will be finalized by November 30, 2008.

**CONCLUSIONS:** Results from the retrospective chart review show a need to improve the prescribing and documentation patterns, such as documentation of stage of asthma, appropriate medications and an asthma action plan, in the Family Medicine clinics studied.

**7. Evaluation of antihypertensive medication adherence and intensity of treatment in the Improving Blood Pressure in Colorado Hypertension study.** Lesley K. Welch, Pharm.D.<sup>1</sup>, Kari L. Olson, Pharm.D.<sup>2</sup>, Karen Snow, Pharm.D.<sup>3</sup>, Mary E. Plomondon, Ph.D.<sup>1</sup>, Anne Lambert-Kerzner, M.S.P.H.<sup>3</sup>, David W. Brand, M.S.P.H.<sup>2</sup>, Edward P. Havranek, M.D.<sup>3</sup>, David J. Magid, M.D., M.P.H.<sup>2</sup>, P. Michael Ho, M.D., Ph.D.<sup>1</sup>. (1) Denver Veterans Affairs Medical Center, Denver, Colorado, USA; (2) Kaiser Permanente Colorado Region, Aurora, Colorado, USA; (3) Denver Health Medical Center, Denver, Colorado, USA.

**OBJECTIVES:** To evaluate the impact of a pharmacist-led intervention on patient medication adherence and intensification of antihypertensive therapy compared to usual care (UC). The intervention consisted of home blood pressure (BP) monitoring using validated BP cuffs, reporting home BP readings via interactive voice response (IVR) telephone technology, and antihypertensive medication management by pharmacists.

**METHODS:** The Improving BP in Colorado study was a randomized trial involving three healthcare systems in Colorado. The results for the Denver VA Medical Center are reported here. Patients with uncontrolled hypertension were randomized to UC or intervention for 6 months. Antihypertensive medication adherence was calculated using the medication possession ratio (MPR) method. Intensity of antihypertensive medication therapy was based on the dose of medication prescribed and categorized as low, medium or high intensity corresponding to 1, 2, or 3 points, respectively.

**RESULTS:** Of 91 patients enrolled, 76 (83.5%) completed the study (intervention 39; UC 37). There was a trend towards higher medication adherence (median MPR 97% vs. 87%; p=0.06) and a higher proportion of adherent patients based on a MPR >0.80 (59.0% vs. 46.0; p=0.29) in the intervention group. Mean intensity of antihypertensive therapy was similar (3.5 vs. 3.2 for UC vs. intervention) at baseline; however, the intervention group had greater intensification of therapy during the study (0.74 vs. 0.12; p<0.01) compared with the UC group. Finally, the intervention group had a larger change in systolic BP (-18.1 vs. -5.7 mmHg; p<0.01) and diastolic BP (-10.1 vs. -2.9 mmHg, p<0.01) compared with the UC group.

**CONCLUSIONS:** A pharmacist-led intervention utilizing IVR and home BP monitoring resulted in a trend toward better medication adherence, higher intensity of antihypertensive therapy, and greater BP reductions. Larger studies are needed utilizing this multi-modal intervention to further assess the clinical and cost-effectiveness of such an approach to hypertension management.

## Cardiovascular

**8E. Correlation of thiazide-induced potassium changes with glucose changes.** Steven M. Smith, Pharm.D., John G. Gums, Pharm.D.; University of Florida, Gainesville, Florida, USA.

**OBJECTIVES:** Thiazide diuretics (TD) are recommended as initial antihypertensive therapy by The Seventh Report of the Joint National

Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). However, concern over incident diabetes may limit their use. A recent meta-analysis correlated ( $r=-0.28$ ) aggregate study level serum potassium ( $K^+$ ) with fasting blood glucose, suggesting that maintenance of normal serum  $K^+$  may prevent TD-induced dysglycemia. However, this correlation has not been replicated in individual study subjects. The primary objective of this study was to investigate the correlation of serum  $K^+$  changes with fasting serum glucose (FSG) changes in hypertensive patients after hydrochlorothiazide (HCTZ) treatment.

**METHODS:** Participants were age 17–65 with mild-to-moderate hypertension without significant comorbidities in the HCTZ arm of the Pharmacogenomic Evaluation of Antihypertensive Responses study. After a 3–6 week washout, HCTZ was initiated at 12.5mg and titrated to 25 mg after 3–4 weeks. Fasting serum  $K^+$ , FSG and insulin were measured at baseline and after at least 9 weeks' total treatment. Mean changes from baseline were tested using a paired *t*-test. Correlations were determined for patient-level changes from baseline using Spearman's Hho. Significance was set at  $p<0.05$ .

**RESULTS:** Mean changes from baseline were  $-0.31 \pm 0.42$  mEq/L ( $p<0.0001$ ) for serum  $K^+$  ( $n=180$ );  $3.16 \pm 13.76$  mg/dL ( $p<0.0001$ ) for FSG ( $n=180$ ); and  $2.37 \pm 12.53$  mIU/ml ( $p=0.0001$ ) for insulin ( $n=180$ ). There was no significant correlation between changes in serum  $K^+$  and FSG ( $r=0.0289$ , [95% CI -0.118, 0.174],  $p=0.61$ ), nor with changes in serum  $K^+$  and insulin ( $r=-0.0874$ ;  $p=0.326$ ). A significant positive correlation was found between changes in FBG and insulin ( $r=0.421$ ;  $p<0.0001$ ).

**CONCLUSIONS:** One proposed mechanism of diuretic-induced dysglycemia is through reduced insulin secretion secondary to serum  $K^+$  depletion. Our results suggest that no correlation exists between serum  $K^+$  changes and either FBG or insulin changes. Prevention of incident diabetes may require exploring alternative causal relationships for TD-induced dysglycemia.

Presented at the American College of Clinical Pharmacy Annual Meeting, Louisville, Kentucky, USA, October 18–22, 2008.

**9. Rebound in thrombotic potential while on clopidogrel therapy.** Nicholas B. Norgard, Pharm.D.<sup>1</sup>, Shoab Saya, M.D.<sup>2</sup>, Eliot Schechter, M.D.<sup>2</sup>, George L. Dale, Ph.D.<sup>2</sup>. (1)University at Buffalo-School of Pharmacy and Pharmaceutical Science, Buffalo, New York, USA; (2)University of Oklahoma Health Sciences Center, Department of Medicine, Oklahoma City, Oklahoma, USA.

**OBJECTIVES:** Coated-platelets are a subclass of highly thrombotic, activated platelets. Excessive numbers of coated-platelets are believed to increase thrombotic risk. Administration of a clopidogrel loading dose has been shown to quickly reduce coated-platelet production. This study evaluates the effect of continued clopidogrel administration on coated-platelet generation.

**METHODS:** Coated-platelet levels were determined in patients undergoing elective coronary angiography. A total of three coated-platelet levels were taken from eligible patients: baseline (pre-clopidogrel), 24-hours post-clopidogrel (pre-angiography) and 14-days post-angiography. After angiography, study patients were divided into two groups: those who had discontinued clopidogrel (Discontinued group) and those who had continued clopidogrel (Continued group). Platelet samples were stimulated with 500 ng/mL convulxin and 0.5 U/mL thrombin with 1.5  $\mu$ M adenosine diphosphate (ADP). Coated-platelet levels were quantitated by flow cytometry and expressed as % of the total number of platelets.

**RESULTS:** All study patients ( $n=13$ ) experienced an initial coated-platelet reduction after a clopidogrel load. Five of 6 patients in the Discontinued group had a return toward baseline on the 14-day coated-platelet assay after the initial reduction. One patient had a coated-platelet level that remained reduced despite clopidogrel discontinuation. Three patients in the Continued group ( $n=7$ ) had a continued reduction with sustained clopidogrel therapy. Four patients had a significant rebound in coated-platelet level from the 24-hour level to 14-day level despite continued clopidogrel therapy.

**CONCLUSIONS:** The inhibitory effect of clopidogrel on coated-platelets appears transient in a number of patients and could signify an increase in thrombotic risk. Larger studies are needed to establish the frequency and significance of a coated-platelet rebound.

**10E. Combination of angiotensin-receptor blocker, Calcium-channel blocker and Diuretic is Safe and Effective in the Management of Severe Hypertension in Blacks.** John Flack, M.D., M.Ph.<sup>1</sup>, David Calhoun, M.D.<sup>2</sup>, Lisa Satlin, M.S., R.D.<sup>3</sup>, Michaela Barbier, Ph.D.<sup>4</sup>, Patrick Brunel, M.D.<sup>4</sup>, Robert Hilker, M.D., FACC<sup>3</sup>. (1)Wayne State University School of Medicine, Detroit, Michigan, USA; (2)University of Alabama at Birmingham, Birmingham, Alabama, USA; (3)Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA; (4)Novartis Pharma AG, Switzerland.

**OBJECTIVES:** Black hypertensives have greater severity and higher prevalence of complications than whites. Thus aggressive blood pressure lowering, often requiring 2 or more agents, is recommended for patients to achieve their target blood pressure (Wright J Clin Hypertens. 2003;5(S1):18–25).

**METHODS:** We conducted a 12-week study to investigate whether the combination of amlodipine/valsartan (A/V) 10/160 mg or 10/320 mg is able to improve blood pressure (BP) reduction in black patients with stage 2 hypertension compared to amlodipine (A) monotherapy. Five-hundred-seventy-two patients with a mean sitting systolic blood pressure (SBP)  $\geq 160$  mmHg and  $< 200$  mmHg entered double-blind treatment with either A/V 5/160 mg or A 5 mg; force titrated to A/V 10/160 mg or A 10 mg at week 2 and optional A/V 10/320 mg and A 10 mg at week 4 if SBP is  $\geq 130$  mmHg. Hydrochlorothiazide (HCTZ) 12.5 mg open label medication was added at the physician's discretion for patients with SBP  $> 130$  mmHg at week 8, with more patients in the A group (65%) than in the A/V group (51.4%) receiving add-on HCTZ.

**RESULTS:** SBP at week 8 (pre-HCTZ) decreased from 171.6 mm Hg at baseline to 146.3 in the A/V group and from 171.1 at baseline to 150.7 in the A group. The addition of HCTZ to A/V resulted in further significant reductions (-6.5 mm Hg versus -4.4 mm Hg in the A group;  $p=0.01$ ). Common adverse events reported for patients receiving triple therapy (A/V+ HCTZ) were peripheral edema (9.5%), non-peripheral edema (3.4%) and headache (2.7%).

**CONCLUSIONS:** In black patients with difficult-to-treat hypertension, the addition of HCTZ to an angiotensin-receptor blocker and calcium channel blocker is safe and results in additional BP reduction.

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**11E.  $\beta$ -adrenergic receptor mediated alterations of  $I(K_s)$  activity during  $I(K_r)$  inhibition.** Brian R. Overholser, Pharm.D.<sup>1</sup>, Xiaomei Zheng, M.S.<sup>1</sup>, Lang Li, Ph.D.<sup>2</sup>, James E. Tisdale, Pharm.D.<sup>1</sup>; (1)School of Pharmacy & Pharmaceutical Sciences, Purdue University and School of Medicine, Indiana University, Indianapolis, Indiana, USA; (2)School of Medicine, Indiana University, Indianapolis, Indiana, USA

**OBJECTIVES:** A relationship exists between sympathetic activation and an increased risk of proarrhythmia. The objective of this study was to characterize the effect of a  $\beta$ -adrenergic receptor ( $\beta$ AR) mediated alteration on the slow component of the delayed rectifier current ( $I_{K_s}$ ) in ventricular repolarization in the presence of rapid component ( $I_{K_r}$ ) inhibition.

**METHODS:** Male guinea pig hearts ( $n=20$ ) were perfused in a retrograde manner with oxygenated buffer at constant pressure and temperature. Left ventricular monophasic action potentials and ECGs were recorded in paced hearts. Following equilibration, hearts were administered: Control, sparfloxacin (SPAR;  $I_{K_r}$  inhibitor) or SPAR and HMR 1556 ( $I_{K_s}$  inhibitor). Twenty minutes later bolus doses of (ISO) or vehicle were randomly infused in 15 minute intervals in each group.

**RESULTS:** APD90 increased in all patients whose hearts were exposed to SPAR (12.9 %  $\pm$  11.5) or the combination of SPAR and HMR 1556 (25.1 %  $\pm$  15.0);  $P<0.05$ . Maximum APD90 changes from baseline following ISO are presented in the table. One heart spontaneously developed polymorphic ventricular tachycardia during the ISO infusion with dual  $I_{K_r}$  and  $I_{K_s}$  inhibition. With whole-cell action potential simulations of  $I_{K_s}$  activation during  $I_{K_r}$  inhibition corresponded with the experimental results to further demonstrate the role of  $I_{K_s}$ .

**Table. Mean  $\pm$ SD% APD90 Max change from baseline following ISO**

ISO	Control	I(Kr)	I(Kr)/I(Ks)
		Inhibition	Inhibition
Vehicle	-1.0 $\pm$ 1.8	-0.9 $\pm$ 1.3	-0.1 $\pm$ 0.8
0.0025 ng/mL	-0.7 $\pm$ 2.0	-3.5 $\pm$ 3.3	-4.1 $\pm$ 3.3
0.025 ng/mL	-3.1 $\pm$ 3.6	-8.3 $\pm$ 5.6	-0.2 $\pm$ 3.8
0.25 ng/mL	-1.1 $\pm$ 3.5	-14.2 $\pm$ 8.1*†	1.2 $\pm$ 6.3

\*P <0.05 compared with control group

†P <0.05 compared with corresponding vehicle

**CONCLUSIONS:** The  $\beta$ AR mediated decrease in APD90 during IKr inhibition is reversed in the presence of I<sub>Ks</sub> inhibition.  $\beta$ AR activation may have a higher propensity to initiate during dual inhibition of IKr and I<sub>Ks</sub>.

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## Community Pharmacy Practice

**12. Over-the-counter medicines and the patient: distribution and services in Flemish community pharmacy.** Steven RA Simoens, M.Sc., Ph.D.<sup>1</sup>, Marieke Lobeau, Pharm.D.<sup>2</sup>, Koen Verbeke, Pharm.D., Ph.D.<sup>3</sup>, Arthur van Aerschoot, Pharm.D., Ph.D.<sup>1</sup> (1)Katholieke Universiteit Leuven, Leuven, Belgium; (2)Royal Pharmaceutical Society of East-Flanders, Ghent, Belgium; (3)Pharmaceutical Society of Bruges and Ostend, Bruges, Belgium.

**OBJECTIVES:** Little is known of patient experiences of pharmacy distribution and services related to over-the-counter (OTC) medicines. The aim of this study was to explore patient experiences of purchasing OTC medicines in Flemish community pharmacies.

**METHODS:** Data were gathered from an anonymous postal questionnaire survey of patients purchasing OTC medicines in a random sample of Flemish community pharmacies in April 2008. Questions related to sources of information about OTC medicines, the patient relationship with pharmacist and physician, organization and layout of the pharmacy, distribution channels and patient satisfaction. Questions were generally measured using Likert scales and the questionnaire was piloted among patients.

**RESULTS:** One hundred and fifty-five pharmacies consented to distribute questionnaires to five patients each, yielding a total of 358 useable questionnaires (response rate of 46%). The first point of contact in relation to OTC medicines was the pharmacist (61% of patients) followed by the physician (29%). Newspapers and the Internet were not viewed as primary sources of advice on OTC medicines. Patients tended to purchase OTC medicines for the acute treatment of pain, gastrointestinal conditions, common cold, cough, or musculo-skeletal pain. More than 75% of patients felt that pharmacists provided sufficient information about the health condition and OTC medicine use. About one third of patients did not wish the physician to be informed of their OTC medicine use. Patients did not seem to agree with distribution channels for OTC medicines other than the community pharmacy.

**CONCLUSIONS:** Flemish patients were satisfied with pharmacy distribution and services related to OTC medicines. They see an important role for pharmacists and physicians to accompany them in their OTC medicine use. Our results highlighted the need to strengthen communication between patients, pharmacists, and physicians. It is also recommended that pharmacists keep an individual record detailing patient use of OTC and prescription medicines.

**13. Prevalence of Drug-Related Problems in Self-medication (OTC Use).** Nina Griese, Ph.D., Karin Berger, R.Ph., M.P.H., Christiane Eickhoff, Ph.D., Ralf Goebel, Ph.D., Andrea Haemmerlein, Ph.D., Uta Mueller, Ph.D., M.P.H., Christiane Sauerwein, R.A., Susanne vom Scheidt, R.A., Margit Schmidt, R.A., Martin Schulz, Ph.D.; Center for Drug Information and Pharmacy Practice (ZAPP), ABDA - Federal Union of German Associations of Pharmacists, Berlin, Germany.

**OBJECTIVES:** The prevalence of drug-related problems (DRPs) in OTC use in German community pharmacies is not known yet. Hence, our primary study objective was to quantify DRPs in self-medication. Our secondary objective was to assess factors having an impact on safe OTC use.

**METHODS:** Community pharmacists (CPs) were asked to document 100 consecutive customers presenting symptoms or requesting OTC (pharmacy-only) drugs by means of a standardized documentation form. A number of 10,000 encounters seemed reasonable in order to evaluate the set objectives. For each encounter, data such as age, gender, first or repeated request, availability of a patient file including drug history were documented. Furthermore, identified DRPs, problem descriptions, and solutions were documented. Data were transcribed electronically, coded if necessary, checked for validity and analyzed (SPSS 15.0TM).

**RESULTS:** In total, 109 CPs documented 12,567 encounters identifying DRPs in 17.6% of all cases. Four indications comprised more than 70% of all DRPs: pain, respiratory, gastrointestinal, and skin disorders. Four DRPs were responsible for almost 75% of all DRPs identified: self-medication inappropriate (29.7%); requested product inappropriate (20.5%); intended duration of drug use too high, including abuse (17.1%); and wrong dosage (6.8%).

If a drug history was available in the pharmacy, significantly more cases with wrong dosage (p<0.05) and drug-drug interactions (p<0.001) were detected, whereas wrong use of drugs was less frequent (p<0.05).

In all cases, patients with identified DRPs were counseled accordingly. Furthermore, the most frequent interventions were referral to a physician (39.5%) and switching patients to a more appropriate drug product (28.1%).

**CONCLUSIONS:** In nearly 1 out of 5 encounters, direct pharmacist-patient interaction in self-medication revealed relevant DRPs in German community pharmacies. Having access to the patient file including data on both prescription-only and OTC products seem to increase patient safety.

**14E. The culture of safety: results of a cross-sectional survey of 998 community pharmacists.** Darren M. Ashcroft, Ph.D., Dianne Parker, Ph.D.; School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester, United Kingdom.

**OBJECTIVES:** To understand attitudes of community pharmacists towards patient safety culture and ways in which attitudes vary by demographic and organisational factors.

**METHODS:** Nine-hundred-ninety-eight pharmacists working in community pharmacies in England completed the Pharmacy Safety Climate Questionnaire (PSCQ), a 34-item tool covering seven safety domains. Multivariate regression analysis was performed to examine the impact of six organisational and demographic factors (age of pharmacist, gender, length of time qualified as pharmacist, length of time worked in community pharmacy, job status, and type of community pharmacy) on safety climate ratings.

**RESULTS:** Respondents included pharmacy owners (159; 16%), employees (402; 40%), and "locum/floater" pharmacists (437; 44%). Mean age was 48 years (SD = 10.4) with 607 female pharmacists among the respondents (60.8%). The pharmacists had been qualified, on average, for 25 years (SD = 10.8).

Selected findings revealed that: 29% of respondents felt that similar patient safety incidents tend to reoccur; 25% felt that staff worked longer hours than is sensible; 24% reported that there were tensions between staff members in the pharmacy; and 25% reported that when an incident is reported, it felt like the person was being reported, not the problem. The regression analysis showed that being a locum pharmacist and working in a national pharmacy chain were both significant predictors of lower safety climate ratings across all seven safety domains. Age, gender, and length of time the pharmacist had been qualified or worked in community pharmacy did not significantly influence safety climate ratings.

**CONCLUSIONS:** Findings from this study provide the first detailed insights into attitudes towards patient safety culture in community pharmacies relating to seven safety domains. Job status and the type of organisation in which the pharmacist worked were the key determinants of safety ratings, rather than individual demographic factors.

Presented at the ASHP Midyear Meeting, Florida, USA, December 7-11, 2008.

**15. Impact of access to clinical information on community pharmacists' interventions with polymedicated patients: a randomized controlled trial.** Natacha Beaulieu, B.Pharm., M.Sc.<sup>1</sup>, Catherine Cellini, B.Pharm., M.Sc.<sup>2</sup>, Amélie Garneau, B.Pharm., M.Sc.<sup>3</sup>, Lyne Lalonde,

B.Pharm., Ph.D.<sup>4</sup>, Olivier Turpin-Lavallée, B.Pharm., M.Sc.<sup>3</sup>, Hélène Lachance-Demers, B.Pharm., M.Sc.<sup>3</sup>, Alain Turcotte, M.D.<sup>3</sup>, Marie-Claude Vanier, B.Pharm., M.Sc.<sup>4</sup>; (1)Pharmacie Jean-François Guévin, Montréal, Quebec, Canada; (2)Pharmacie Marc Champagne, Montreal, Quebec, Canada; (3)CSSS de Laval-Cité de la Santé, Laval, Quebec, Canada; (4)CSSS de Laval-Cité de la Santé et Faculté de Pharmacie, Université de Montréal, Montréal, Quebec, Canada.

**CONTEXT.** Community pharmacists do not systematically have access to patient's clinical information. We hypothesized that "enriched prescription" and access to a liaison pharmacist may allow community pharmacists to better manage pharmacotherapy.

**OBJECTIVES:** Compare the rate of medication related problems (MRP) detection, pharmacist interventions and pharmacotherapeutic changes in patients receiving enriched versus usual prescription.

**METHODS:** Pharmacists surrounding a family medicine clinic were invited to participate to a workshop on medication assessment and to participate in the trial. Patients of participating pharmacies and taking at least 5 chronic medications were recruited during a medical visit and randomly assigned to one of two study group: 1) usual prescription; or 2) enriched prescription. For all patients, pharmacists were asked to conduct a medication assessment and had access to the clinic's liaison pharmacist. Follow-up duration was 2 months. Enriched prescription included a list of patient's health problems, medications documented in the medical chart, and recent laboratory test results. Number of MRP detected by pharmacists, pharmacotherapeutic changes as well as number and type of pharmacist's interventions were documented using pharmacist's intervention forms, liaison pharmacist's diary, patient's chart and pharmacy files. Pharmacotherapeutic changes were blindly and independently assessed by two researchers.

**RESULTS:** Forty-two pharmacies, 66 pharmacists, 36 physicians, and 144 patients participated in the study. More MRP per patient were detected when pharmacists received enriched prescriptions (0.96 vs. 0.49; 95% CI: 0.12 to 0.81) and they intervened for a larger proportion of patients (52.0% vs. 26.1%; 95% CI: 8.9% to 40.9%). The number of pharmacotherapeutic changes did not differ between groups.

**CONCLUSIONS:** Community pharmacists having access to clinical information detected more MRP and intervened more frequently. However, modification to pharmacotherapy was not more frequent over a short 2-month follow-up duration. These promising results suggest that providing pharmacists with relevant clinical information may allow them to better manage MRP.

**16. Embarrassment and purchasing of contraceptives: a study of access and provision of information in pharmacies.** Daniel Ashwood, BA<sup>1</sup>, Karen Farris, Ph.D.<sup>1</sup>, Anne Bonsall Hoekstra, MA<sup>2</sup>, Mary Losch, Ph.D.<sup>2</sup>; (1)University of Iowa, Iowa City, Iowa; (2)University of Northern Iowa, Cedar Falls, Iowa, USA

**INTRODUCTION:** Contraception is fundamental to reducing unintended pregnancies, and understanding factors that contribute to the purchase and use of contraceptives is vital to know how pharmacists may help patients.

**OBJECTIVES:** Explore (1) where women are purchasing contraceptives and what types were purchased, (2) if embarrassment concerning purchase of contraceptives varies by age, marital status, education, insurance coverage, income, race, and rural/urban, (3) if embarrassment is related to contraceptive availability or information in pharmacies.

**METHODS:** Design. Secondary data analysis of a cross-sectional, 89-item telephone survey. Subjects. 796 Iowa women age 18–30. Data Collection: Location of purchase as well as type of contraception recently purchased was obtained using a partially close ended item. Embarrassment was measured using a dichotomous item for both OTC and prescription contraceptives. Availability of and information about contraceptives were measured using 4-point Likert scales (1=excellent; 4=poor). Data Analysis. Descriptive statistics quantified where and what types of contraceptives were purchased. Chi-square tests determined if purchasing embarrassment varied by demographics as well as by contraceptive availability and information.

**RESULTS:** The most frequent places to purchase contraceptives were drug store/pharmacy (37.7%), discount store (24.1%), and from healthcare providers (20.4%). Most frequently purchased were pills (36.4%) and condoms (30.5%). Women never married were more embarrassed about OTC (82.8%) and prescription (92.5%) products

( $p < 0.001$ ). No differences in race, insurance, or rural/urban were observed. More people were embarrassed in purchasing prescriptions (65.9%) when good availability of contraceptives was reported ( $p = 0.010$ ). Embarrassment in purchasing OTC (37.3%) was associated with fair availability of information ( $p = 0.031$ ).

**CONCLUSIONS:** The most frequent places to purchase and types of contraceptives were consistent with expectations. However, purchasing embarrassment is an issue that requires further understanding, as pharmacists can assist their patients in appropriate use of contraceptive products.

## Critical Care

**17. Impact of prolonged morphine infusions in ICU patients with or without renal insufficiency.** Brian J. Kopp, Pharm.D.<sup>1</sup>, Brian L. Erstad, Pharm.D.<sup>2</sup>, Jill M. Schultz, Pharm.D.<sup>3</sup>; (1)University Medical Center, Tucson, Arizona; (2)The University of Arizona, Tucson, Arizona; (3)University Physicians Hospital, Tucson, Arizona, USA.

**OBJECTIVES:** Clinical practice guidelines for sustained analgesia in critically ill patients recommend alternative agents to morphine in patients with renal insufficiency due to metabolite accumulation concerns. However, this recommendation is based on a low grade of evidence due to the lack of studies in the ICU setting. The objectives of this study were to investigate guideline compliance and to compare duration of mechanical ventilation and ICU length of stay (LOS) in critically ill patients with/without renal insufficiency who received morphine.

**METHODS:** This was a one-year retrospective investigation of adult patients admitted to medical/surgical ICUs at an academic medical center. Patients were included if they received morphine by continuous IV infusion for at least 3 days. Patients were classified as having renal insufficiency or normal renal function according to RIFLE criteria.

**RESULTS:** Thirty-six patients met inclusion criteria. Baseline characteristics between groups were similar. Twenty-seven patients (9 with renal insufficiency) were included in the analysis after excluding patients with ICU stays greater than 21 days. Results are presented as median (interquartile range). Patients with renal insufficiency received 65 (31–100) vs. 64 (45–158) mg/day ( $p = 0.27$ ) of morphine in patients with normal renal function. No differences in duration of mechanical ventilation (10.5[8–13] vs. 8.5[4.5–12] days,  $p = 0.41$ ) or ICU LOS (15[12–17] vs. 12.3[6–15.5] days,  $p = 0.28$ ) were identified between patients with and without renal insufficiency, respectively. Most cases of renal insufficiency were temporary; only one patient had end-stage-renal disease.

**CONCLUSIONS:** Morphine continues to be used in patients with renal insufficiency despite metabolite-related concerns. While there were no significant differences in duration of mechanical ventilation or ICU LOS in patients with or without renal insufficiency who received morphine, the reversible insufficiency of most patients studied and sample size issues preclude a change in current guideline recommendations.

**18. Evaluation of blood glucose control with subcutaneous insulin in patients with recent critical illness.** April D. Miller, Pharm.D., Leslie McKenzie, Pharm.D. Candidate, Richard M. Schulz, Ph.D., P. Brandon Bookstaver, Pharm.D., Celeste N. Rudisill, Pharm.D.; South Carolina College of Pharmacy-USC Campus, Columbia, South Carolina, USA.

**OBJECTIVES:** Patients recovering from critical illness and transitioning to general hospital care often receive hyperglycemic care using insulin protocols designed for patients admitted directly to general wards. The objective of this study is to determine whether differences in blood glucose (BG) control and insulin requirements exist between these groups.

**METHODS:** Pharmacy records of adult inpatients receiving subcutaneous insulin using standardized protocols were used to identify 50 patients for two study groups: patients admitted to the intensive care unit (ICU) who received  $\geq 24$  hours of intravenous insulin therapy and subsequently transferred to the general ward (ICU group) and patients directly admitted to the general ward (non-ICU). Retrospective medical record review was used to collect BG readings and insulin doses administered. The primary endpoints of average daily BG and average daily insulin dose were compared between groups. Additional data compared include the number of blood glucose readings outside goal range ( $\leq 60$  or  $\geq 180$ mg/dL) and scheduled versus correction factor doses of insulin administered.

**RESULTS:** Average daily BG did not differ significantly between groups (ICU 173mg/dL; non-ICU 170mg/dL;  $p=0.83$ ). The ICU group received significantly larger average daily insulin doses than the non-ICU group (ICU 93 units; non-ICU 43 units;  $p<0.001$ ). More BG readings in the ICU group were outside goal range (ICU 310; non-ICU 242;  $p=0.02$ ), and ICU patients received more scheduled and correction factor doses of insulin.

**CONCLUSIONS:** Though no difference in average daily BG readings existed between the two groups, patients with recent critical illness required larger doses of insulin to maintain glycemic control similar to that of patients without recent critical illness. Future study is needed to elucidate more specific differences and develop specific protocols to improve glycemic control in this population.

## Dermatology

**19. Effect of topical insulin on cutaneous wound healing in non-diabetic and acute diabetic rats.** Sule Apikoglu-Rabus, Ph.D.<sup>1</sup>, Fikret V. Izzettin, Prof.<sup>1</sup>, Pinar Turan, Ph.D.<sup>2</sup>, Feriha Ercan, Prof.<sup>2</sup>; (1)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (2)Marmara University Faculty of Medicine, Histology-Embryology Department, Istanbul, Turkey.

**OBJECTIVES:** Diabetes is a condition known to impair normal course of wound healing even at its early stages; thus leading to chronic wounds. Insulin's role on protein synthesis, cell differentiation and growth suggests that this hormone could also play an essential role in wound healing regulation. This study aims to determine the effects of topical insulin administration on wound healing both in non-diabetic and acute diabetic rats.

**METHODS:** The study conducted on male Sprague-Dawley rats was carried on four groups: non-diabetic rats receiving topical insulin ( $n=7$ ); non-diabetic rats receiving topical water for injection ( $n=7$ ); diabetic rats receiving topical insulin ( $n=7$ ); diabetic rats receiving topical water for injection ( $n=7$ ). Two 0.6 mm round, full-thickness excision wounds were created on the dorsal thoracic area of each rat. Test animals received insulin (Humulin R® [regular] human insulin 100 IU/mL; in water for injection) and control rats received sterile water for injection until the end of experiment (day 15). Wound healing was assessed by "wound contraction rate," "complete epithelization time," and histological observations.

**RESULTS:** It was observed that topical insulin administration enhanced wound healing by shortening complete epithelization time both in the non-diabetic and acute diabetic groups (median 8 days vs. 11 days;  $p<0.05$  for both diabetic and non-diabetic groups).

**CONCLUSIONS:** This study revealed that topical insulin application to non-diabetic as well as acute diabetic cutaneous wounds accelerates wound healing in rats.

## Drug Information

**20. Extent of Information Desired in patients with major depression: what happens after hospital discharge?** Franciska A. Desplenter, Pharm.D.<sup>1</sup>, Gert Laekeman, Prof., Ph.D., Pharm.D.<sup>1</sup>, Koen Demyttenaere, Prof. M.D.<sup>1</sup>, Vza Psychiatri, Pharm.D.<sup>2</sup>, Steven Simoens, Prof. M.Sc.<sup>1</sup>; (1)Katholieke Universiteit Leuven, Leuven, Belgium; (2)Flemish Association of Hospital Pharmacists - Psychiatry, Eeklo, Belgium.

**OBJECTIVES:** This study aims to: (1) measure the extent of drug information desired by patients at discharge from a psychiatric hospital; (2) analyse the evolution over time of information desire following discharge; (3) compare information desire between study groups receiving differentiated, undifferentiated or usual information; and (4) rate patient satisfaction with drug information.

**METHODS:** Upon discharge, a control group received usual information about antidepressants, and two intervention groups received information that was either undifferentiated or differentiated according to the extent of information desired by the patient. 11 psychiatric hospitals in Flanders (Belgium) enrolled adult patients with major depression taking an antidepressant. The EID (Extent of Information Desired) questionnaire consists of 6 questions measuring patient information desire on a 5-point Likert scale (total score range: 6–30). EID was measured at hospital discharge, 1 month and 3 months following hospital discharge by telephone follow-up. Satisfaction with

drug information provided during hospital stay was measured on a 6-point Likert scale (score 0–5). The information desire was compared within and between study groups using General Linear Model, Repeated Measures ANOVA.

**RESULTS:** 99 patients were included during February 2007–July 2008. Eighty patients were eligible for analysis. (1) Mean score of information desire at hospital discharge was  $21.36 \pm 4.79$ . (2) Information desire decreased after hospital discharge: mean score was  $20.54 \pm 4.06$  after 1 month and  $19.4 \pm 3.92$  after 3 months. (3) There was a significant decrease in information desire over time ( $df=2$ ;  $F=9.892$ ;  $P \leq 0.001$ ). There were no significant differences between the study groups at any time point. (4) Mean score on satisfaction was  $3.28 \pm 1.51$ . No significant difference was observed between study groups.

**CONCLUSIONS:** Patients are rather satisfied with drug information received during hospital stay, independently from the amount of information received. Information desire decreases after hospital discharge in all study groups. Further investigation of the telephone contacts will be done.

## Ear Nose Throat

**21. Effects of topical verapamil administration on acute tympanic membrane perforation in guinea pigs.** Mert Eken, M.Sc.<sup>1</sup>, Fikret Vehbi Izzettin, Prof.<sup>1</sup>, Mehmet Eken, Ph.D.<sup>2</sup>, Mesut Sancar, Ph.D.<sup>1</sup>, Betül Okuyan, MSc.<sup>1</sup>; (1)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (2)2nd ENT, Kartal Training and Research Hospital, Istanbul, Turkey.

**OBJECTIVES:** This study aims to investigate the effects of topical verapamil on acute tympanic membrane perforation in guinea pigs.

**METHODS:** Tympanic membrane perforation was made in pars tensa of each ear (right and left ear) of 10 adult healthy guinea pigs. Topical verapamil (verapamil 1 mL; infused gel foam) was administered in the right ears of guinea pigs (treatment group) for 7 days. Saline solution infused gel foam was applied to the left ears of the guinea pigs (control group) for 7 days. The animals were examined with otomicroscopy in two days intervals during the study and histopathologically at the end of the study (day 14).

**RESULTS:** Histopathological examination revealed no significant differences between the two groups in respect to time to wound closing of the subjects' tympanic membranes (7 days) ( $p>0.05$ ). In addition, no statistically significant difference between the two groups in the development of tympanosclerosis was found ( $p>0.05$ ).

**CONCLUSIONS:** In our study, topical verapamil was not found to have a significant effect on acute tympanic membrane perforation in guinea pigs. In order to determine whether oral and/or topical calcium channel blockers have a significant effect on the development of tympanosclerosis, we believe, further studies are necessary.

## Education/Training

**22. Impact of a continuous professional development program on the counseling practices and attitudes of the pharmacists about emergency contraceptive pills.** Sule Apikoglu-Rabus, Ph.D., Fikret V. Izzettin, Prof.; Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey.

**OBJECTIVES:** In Turkey emergency contraceptive pills (ECP) can be purchased from the pharmacies without a prescription. This relatively new practice brings the pharmacists the responsibility of ECP counseling. The aim of this study was to assess the impact of a standard continuous professional development (CPD) program on reproductive health on the counseling practices and attitudes of the pharmacists about ECP.

**METHODS:** The survey tool was structured to question demography, professional experience, counseling practices about ECP and attitudes on ECP. Attitudes were measured by 18 items under four domains: reproductive health; information and availability; risk behavior and regulatory restrictions. A 5-point Likert scale ranging from "totally agree" to "totally disagree" was used for rating. Pharmacists registered at a professional web site ( $n=822$ ) were invited to fill in the questionnaire.

**RESULTS:** Among 624 pharmacists who took the survey, 127 (22%) of the pharmacists had attended to the CPD course on reproductive health (CPD Pharmacist) and 497 (88%) haven't attended to this course (No-

CPD Pharmacist). The CPD Pharmacists counseled more often about side-effects ( $p < 0.001$ ), mechanism of action ( $p = 0.001$ ), efficacy ( $p < 0.01$ ) and methods of contraception ( $p < 0.001$ ), when compared with No-CPD Pharmacists. In general, both groups showed positive attitudes towards all domains of the survey. A total of 76% of the CPD Pharmacists and 66% of the No-CPD Pharmacists showed a positive attitude towards the OTC availability of ECP ( $p < 0.05$ ). Both groups showed a negative attitude towards the items suggesting that ECP should be sold only to women and ECP should be sold on prescription only. The interesting finding is that 52% of the CPD Pharmacists and 60% of the No-CPD Pharmacists agreed that ECP should be sold only to those over 18 years of age.

**CONCLUSIONS:** CPD program on reproductive health has a favorable impact both on the counseling practices and the attitudes of pharmacists about ECP.

**23E. Safer pharmacy practice: a preliminary study of significant event analysis and peer feedback.** Nicholas Bradley, Ph.D.<sup>1</sup>, Ailsa Power, M.R.Pharm.S. Ph.D.<sup>2</sup>, Hannah Hesselgreaves, Ph.D.<sup>2</sup>, Fiona McMillan, MRPharmS<sup>2</sup>, Paul Bowie, Ph.D.<sup>2</sup>, Rose Marie Parr, MRPharmS, Ph.D.<sup>2</sup>; (1) Postgraduate Medicine, NHS Education for Scotland, Glasgow, United Kingdom; (2) Pharmacy Directorate, NHS Education for Scotland, Glasgow, United Kingdom.

**OBJECTIVES:** To investigate the content and quality of pharmacists' significant event analyses (SEAs) using a validated tool to provide independent, constructive feedback by 'peers'.

**METHODS:** Preliminary study involving content analysis of pharmacists' significant event reports and written feedback generated by pharmacists trained in provision of peer feedback using validated instrumentation. The content of reports and feedback letters were systematically coded and categorised. Data collection included the range and severity of significant events; reported reasons for the event; types of learning needs identified; action(s) taken; and learning issues raised by peer feedback.

**RESULTS:** 37 pharmacists submitted 43 SEA reports during the study. All events submitted were classified as having a negative impact on the quality and safety of patient care. Most events related to prescribing, dispensing, administration, communication and patient/relative-centered issues. Patients reportedly were harmed in 13% of cases. 63% of reported learning needs related to personal awareness/responsibilities and 58% of implemented change involved amending existing protocols or introducing new procedures. 70% of SEAs were deemed to be 'satisfactory' by peers. Effectiveness of providing a clear description of an event and change implementation were highlighted as key issues for improvement in those Significant Event Analyses (SEAs) judged 'unsatisfactory' by peers.

**CONCLUSIONS:** Findings demonstrate that Significant Event Analysis shows promise as a quality improvement method in demonstrating reflective learning and implementing change. SEA combined with independent peer feedback may have a key role to play in enhancing the quality and safety of pharmacy practices.

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**24. Educational interventions to curb the inappropriate use of acid-suppressive agents on a university hospital internal medicine service.** Amanda D. Osta, M.D.<sup>1</sup>, Vikas I. Parekh, M.D.<sup>1</sup>, Randolph E. Regal, Pharm.D.<sup>2</sup>; (1) The University of Michigan Health System, Ann Arbor, Michigan; (2) The University of Michigan Health System and College of Pharmacy, Ann Arbor, Michigan, USA.

**OBJECTIVES:** To measure the impact of three different levels of educational intervention on curbing the inappropriate prescribing of acid-suppressive medications (ASMs) on a University-based General Medicine Hospital Service.

**METHODS:** A retrospective chart review was performed on patients admitted to four different general medicine teams over a two month period in 2006. There was also a pre-intervention control group from the same two months in 2005. The 2006 interventions included: (A) Beginning of year lecture for all four 2006 teams; (B) additional reminder lecture at beginning of rotation month for two of the teams; and (C) a clinical pharmacist physically rounding with one of the two

intervention B teams. The parameters measured were: (1) percentage of patients receiving ASM during hospitalization, aka "use-percentage;" and (2) percentage of patients receiving ASMs inappropriately based upon current FDA labeling.

**RESULTS:** Intervention A did not statistically decrease the use-percentage versus the 2005 control (62% vs. 66%, respectively), but did decrease the inappropriateness from 59 to 37% ( $p < 0.001$ ). With the addition of Intervention B, there was a significantly reduced use-percentage of 53% ( $p = 0.025$ ) as well as reduced inappropriateness to 32% ( $p < 0.001$ ) compared to 2005, but no statistical difference between itself and the Intervention A group. When Intervention C was added to Interventions A and B, it helped decrease the use-percentage to 53% ( $p = 0.025$ ), and further decreased inappropriateness to 19% ( $p < 0.001$ ). When compared to the Intervention A group, Intervention C's inappropriateness rate decrease from 37% to 19% was significant ( $p = 0.007$ ).

**CONCLUSIONS:** Intern lectures were helpful in curbing inappropriate use of ASMs. However, ever after lectures, added benefit was seen when a clinical pharmacist rounded with the team.

**25. Impact of an Evidence Based Medicine elective course on student performance on Advanced Pharmacy Practice Experiences.** Aida R. Bickley, Pharm.D, Candidate,<sup>1</sup> Catherine E. McAbee, Pharm.D. Candidate,<sup>2</sup> P. Brandon Bookstaver, Pharm.D.<sup>2</sup>; (1) University of South Carolina College of Pharmacy, Columbia, SC; (2) South Carolina College of Pharmacy-USC Campus, Columbia, South Carolina, USA

**OBJECTIVES:** At the South Carolina College of Pharmacy (SCCP), an Evidence Based Medicine (EBM) elective is offered during the third professional year designed to teach the skill set required for critiquing the medical literature and applying it to patient care decisions. The objective of this study is to evaluate the impact and influence of an EBM course on student performance during Advanced Pharmacy Practice Experiences (APPE).

**METHODS:** This was a prospective, survey-based study evaluating students enrolled in the EBM course in 2007 and corresponding APPE clinical preceptors. The primary outcome was to determine the impact of the EBM course on APPE based on preceptor survey results comparing course enrollees' performance to students not enrolled. Secondary outcomes included survey results from course enrollees evaluating the influence of EBM on their APPE performance and ability to utilize the targeted skill set. ACPE-accredited schools of pharmacy were surveyed to evaluate the current status of EBM incorporation into pharmacy curriculums. Surveys were designed using the Dillman method with a standard rating scale of 1 through 5 (1=strongly agree, 5=strongly disagree). Descriptive statistics were applied for data analysis.

**RESULTS:** Survey response rates were 78.6% and 66.7% for students and preceptors respectively. The majority of preceptors (86.9%) agreed course enrollees possessed a broader and more detailed approach in applying EBM decisions to clinical practice compared to those not enrolled. Of student responders, 90.9% agreed the skill set learned in the EBM course was most valuable to their success on APPE. Of evaluable school of pharmacy surveys ( $n = 43$ ), 67.4% believed EBM should be incorporated to a greater degree into their curriculum.

**CONCLUSIONS:** The skill set acquired from an EBM course contributed strongly to the students' success on APPE performance. EBM practices and fundamentals should be a focus of incorporation into pharmacy curriculums.

**26. Problem based learning within UK pharmacy education: What is its value?** Tracey Sach, Ph.D.<sup>1</sup>, David J. Wright, B.Pharm., Ph.D.<sup>2</sup>, Jane Evans, M.Pharm., (Hons)<sup>1</sup>; (1) School of Chemical Sciences & Pharmacy, Norwich, United Kingdom; (2) University of East Anglia, Norwich, United Kingdom.

**INTRODUCTION:** Problem Based Learning (PBL) is a relatively new educational tool designed to bridge the gap between knowledge and the ability to apply this in clinical practice. Widely adopted within medical curricula its use within pharmacy education is limited. Four PBL scenarios are attempted yearly by all students for the first three years of the new pharmacy degree at the University of East Anglia.

**OBJECTIVES:** To determine student perceptions of the value of PBL within the pharmacy undergraduate curriculum.

**METHODS:** A questionnaire consisting mainly of likert scales was devised and based on the skills considered desirable within pharmacy graduates prior to their first substantial professional placement. A student led focus group confirmed content validity and identified the best method of dissemination. The piloted questionnaire was given to all pharmacy students by a final year pharmacy student during their sessions.

**RESULTS:** 201/329 (61.1%) students responded; demographically these were comparable to the pharmacy student population. 89.1% believed it was effective at improving their oral communication skills, 83.1% teamworking skills, 74.5% recognition of ethical dilemmas and 61.7% structured problem solving skills. 20.9% stated that they did not enjoy problem based learning and this was found to be related to whether they enjoyed working in teams ( $p < 0.001$ , Kruskal Wallis).

**CONCLUSIONS:** PBL was strongly perceived to be effective at the development of skills which will be relevant to the role of the pharmacist. The lack of enjoyment of reported by one fifth of respondents may reflect their preferred learning style, as in sharp contrast to didactic teaching methods is designed to develop a preference for active and therefore independent learning.

**27. Interdisciplinary student team training in geriatrics.** *Anne L. Hume, Pharm.D.,<sup>1</sup> Alicia Curtin, Ph.D., G.N.P.,<sup>2</sup> Philip G. Clark, Sc.D.<sup>1</sup>;* (1)University of Rhode Island, Kingston, RI; (2)Memorial Hospital of Rhode Island, Pawtucket, Rhode Island, USA.

**OBJECTIVES:** As part of the Rhode Island Geriatric Education Center, funded by the Health Resources and Services Administration (HRSA), a pilot model interdisciplinary student team training program was designed to produce students with knowledge and skills in geriatric clinical teamwork.

**METHODS:** During spring (and fall) 2008 semesters, an interdisciplinary program consisting of four monthly 1-hour seminars was offered, focusing on goals of the health care team, understanding conflict, communication style and leadership issues. These sessions are followed by a 3-hour patient assessment (in the geriatrics rotation of a medical residency). The resident selects an older patient based on criteria such as frailty, medical complexity, cognitive or functional impairment, and social or financial issues. The team prioritizes the patient's issues and creates a list of questions for him/her to provide further information. The medical resident, geriatrician, and (depending on the patient issues) the medical, pharmacy, nursing, or social work students are directly involved in assessing the patient. Remaining team members observe the patient assessment by video, if the patient has consented. The team reconvenes to develop a care plan. At the end of the interdisciplinary discussion, the team debriefs regarding participation on the team, what was effective, what was not effective, and how the team functioned as a whole.

**RESULTS:** The Hartford GITT team attitudes scale was used pre and post to assess students' attitudes about their experiences. Students and faculty overwhelmingly reported that learning from other disciplines was most helpful in participating on the interdisciplinary team. Also learning about communication and leadership styles was helpful in participating on interdisciplinary teams.

**CONCLUSIONS:** Exposing students from different health disciplines to training in teamwork is challenging especially in scheduling a student team program, but the attitudinal benefits suggest a potential for improving the care of complex older patients.

**28. Geriatric pharmacotherapy: an approach to active self-directed learning.** *Erica Estus, Pharm.D., C.G.P., Anne L. Hume, Pharm.D., FCCP, BCPS, Norma Owens, Pharm.D., FCCP, BCPS;* University of Rhode Island, Kingston, Rhode Island, USA.

**OBJECTIVES:** In fall 2007, an elective geriatric pharmacotherapy course was offered for the first time at the University of Rhode Island. A total of 21 P2 students enrolled, with 21 P3 students in the 2008 spring and 8 P3 students in the 2008 fall semesters. This course was designed to emphasize active, self-directed learning and to improve students' problem-solving skills for older patients with complex drug regimens.

**METHODS:** Students were introduced to tools for medication and functional assessment and how to apply the tools to the care of older adults. Five to ten medically complex patient cases were evaluated to

identify potential drug-related problems. Students presented their assessments and a written SOAP care plan that was systematically graded using a detailed rubric. Students gained experience in prioritizing problems and active learning about diseases and therapies not yet formally discussed in the core curriculum. Students also evaluated controversies in geriatrics and wrote brief papers supporting their arguments. Students also interacted with older adults in community, assisted living, or a nursing home setting and wrote reflections on their activities at the site visits. Students participated in an "Adopt-a-patient" program at an independent and assisted living facility.

**RESULTS:** Students were surveyed at the end of each semester. Assessment and discussion of complex patients as well as site visits and exploring long-term care careers were strengths of the course according to students, as well as discussions regarding controversies in geriatric practice. The adopt-a-patient program was valued by students because of the opportunity to talk with residents and perform assessments of their ability to manage drug regimens in the home.

**CONCLUSIONS:** The students' perceptions of aging improved through the semesters and gained significant skills in problem-solving and prioritizing problems. A follow-up survey will be given to the now P4 students completing their experiential rotations.

**29. Patient education and health promotion: a bridge between disease and illness.** *Daniela Scala, Pharmacist<sup>1</sup>, Maria D'Avino, Physician,<sup>2</sup> Santolo Cozzolino, Pharmacist,<sup>1</sup> Antonio Mancini, Pharmacist,<sup>1</sup> Barbara Andria, Pharmacist,<sup>1</sup> Giuseppe Caruso, Physician,<sup>2</sup> Domenico Caruso, Physician<sup>2</sup>;* (1)Centre of Biotechnologies, Cardarelli Hospital, Naples, Italy; (2)Centre for the diagnosis and therapy of arterial hypertension, Naples, Italy.

**OBJECTIVES:** Health promotion, according to the World Health Organization, is the process of enabling people to increase control over, and to improve, their health. This mandate should support the needs of individuals and communities for a healthier life, and open channels between the health sector and social, political, economic and physical environmental components. The Hypertension Working Group of Cardarelli Hospital in Naples, Italy developed a therapeutic education project "10annidivitaipiu" (a life ten year longer) to reduce blood pressure in hypertensive through a change of their lifestyle.

**METHODS:** Apart from the actions taken within the hospital setting, the HWG welcomed patients' proposals on activities outside the hospital to promote the whole person, rather than the disease, the "patient".

**RESULTS:** Visit to San Gennaro museum: patients, together with the health care providers, organized a visit to the museum to admire silver jewelry, paintings belonging to the Treasury of San Gennaro. Blog for "10annidivitaipiu" patients: patients organized and managed a devoted Web space inside the hospital website. It is a virtual meeting place where sharing documents, exchanging points of view, establishing meetings and initiatives, that can easily be upgraded or expanded over time with the contribution of all participants to meet the broad range of patient's needs and interests. "10annidivitaipiu" Calendar: consists of phrases and messages, ironic and serious, that patients collected during our educational meetings, directed to healthier lifestyles.

**CONCLUSIONS:** Health promotion is not something that is done on or to people; it is done by, with and for people either as individuals or as groups. The role of the health care providers must move increasingly in this direction, beyond their responsibility for providing clinical and curative services.

**30. The development of a therapeutic patient education project: the journey from the idea to the realization.** *Daniela Scala, Pharmacist,<sup>1</sup> Maria D'Avino, Physician,<sup>2</sup> Santolo Cozzolino, Pharmacist,<sup>1</sup> Antonio Mancini, Pharmacist,<sup>1</sup> Barbara Andria, Pharmacist,<sup>1</sup> Giuseppe Caruso, Physician,<sup>2</sup> Domenico Caruso, Physician,<sup>2</sup>;* (1)Centre of Biotechnologies, Cardarelli Hospital, Naples, Italy; (2)Centre for the Diagnosis and Therapy of Arterial Hypertension, Naples, Italy.

**OBJECTIVES:** The Hypertension Working Group of Cardarelli Hospital, Naples, Italy developed a therapeutic education program "dieciannidivitaipiu" (a life ten years longer) to reduce blood pressure in hypertensive through a change of their lifestyle.

**METHODS:** A Patient Information Leaflet on the management of hypertension was developed. Information is necessary but no sufficient

to improve clinical outcomes. An education pathway that involved patients actively was set up. Motivation is what makes people learn what they learn, and behave the way they do: where there is no motivation, there is no learning and no action. Sessions were set in a way that patients could easily talk about what they were learning, write reflectively about it, relate it to past experiences, and apply it to their daily lives.

**RESULTS:** The results of a randomized controlled study on 170 patients showed that our approach lowered significantly blood pressure and/or reduced drug therapy. A high percentage of drop outs and the cost were variables to consider. To overcome these limits the experiences was transferred from hospital to the community with the collaboration of the General Practitioners (GP) of Campania Region. Thanks to the Regional Scientific Research Grant GPs of one Campania Region's county were involved. To date 20 GPs and 700 patients were enlisted. Data are in progress and will be completed by the end of next January. A grant from the Italian Drug Agency will let enroll a bigger sample size (3500 patients) since all GPs of Campania Region could be involved.

**CONCLUSIONS:** This programme increases the options available to people to receive more control over their own health and over their environments, and to make choices conducive to health. Enabling people to learn throughout life, to prepare them for all of its stages and to cope with chronic illness and injuries is essential.

### 31. Comparison of student performance on multiple choice questions divided into three cognitive domains using Bloom's Taxonomy.

Zachary A. Stacy, Pharm.D., BCPS, Amy M. Tiemeier, Pharm.D., John M. Burke, Pharm.D.; St. Louis College of Pharmacy, St. Louis, Missouri, USA

**OBJECTIVES:** Multiple choice (MC) questions are often used to assess student performance because of ease of administration and grading, while written cases are used to assess higher levels of thinking. The use of MC questions that target higher order thinking in therapeutic problem-solving has not been evaluated. This prospective study was designed to evaluate student performance on MC questions in three cognitive domains.

**METHODS:** The study included pharmacy students enrolled in a therapeutics course. Students were assessed using three exams each consisting of 38 MC questions and a written patient case. All MC questions were prospectively classified into one of three cognitive domains based on Bloom's Taxonomy, including 15 recall (knowledge and comprehension), 15 application, and 8 analysis (analysis and synthesis) questions. The primary outcome was a comparison of student performance at each Bloom's level. The secondary outcome was the correlation of student performance in each Bloom's level relative to their performance on the patient case. An ANOVA test was used for the primary comparison and correlations were analyzed using the Pearson's Correlation Coefficient. All statistical analyses were performed using SAS, version 16.0. Continuous variables were reported as means  $\pm$  standard deviation.

**RESULTS:** The evaluation included 168 students. Overall MC and case average scores were 62.7% and 62.3%, respectively. A significant difference in student performance was observed between recall, application, and analysis domain averages (73.8%, 68.5% and 46.0%;  $p < 0.001$ ). A significant correlation between the recall domain and the case (0.44;  $p < 0.001$ ), application domain and the case (0.38;  $p < 0.001$ ), and analysis domain and the case (0.41;  $p < 0.001$ ) was observed.

**CONCLUSIONS:** Students perform significantly better on MC questions written at the recall level compared to the analysis level. Additionally, a significant correlation exists between scores on MC questions in all three cognitive domains and the patient case.

## Emergency Medicine

32. The impact of pharmacy education on the use of weight-based fosphenytoin dosing in the emergency department. April D. Miller, Pharm.D.,<sup>1</sup> Carrie S. Wylie, Pharm.D.,<sup>2</sup> Joseph Kohn, Pharm.D.<sup>2</sup>; (1)South Carolina College of Pharmacy-USC Campus, Columbia, SC; (2)Palmetto Health Richland, Columbia, South Carolina, USA.

**OBJECTIVES:** Physicians infrequently order weight-based loading doses of fosphenytoin in the emergency department (ED). As a result, lower than indicated weight-based doses are often administered. However,

patients receiving fosphenytoin have had recent seizures, have severe traumatic brain injury or are in status epilepticus. These non-weight-based doses likely result in suboptimal outcomes. Educational interventions and pre-defined order sets to encourage appropriate doses for other agents have demonstrated effectiveness in improving prescribing habits.

**METHODS:** A retrospective review of 50 patients receiving fosphenytoin loading doses was conducted. Data collected included patient weight, loading dose(s) administered, and post-infusion concentrations, if ordered. An educational intervention for ED residents on using weight-based fosphenytoin dosing of 15-20mg PE/kg and using post-infusion concentrations to ensure that patients are within goal range was conducted during a routine scheduled conference. A pre-defined order set encouraging weight-based dosing and collection of post-infusion concentrations was also explained and implemented. Medical records of the first 50 patients receiving fosphenytoin loading doses in the ED after the intervention were reviewed for the same data as the pre-intervention review.

**RESULTS:** The educational intervention led to an increase in average dose/kilogram for ED patients (pre-intervention 13mg PE/kg, post-intervention 14.8mg PE/kg;  $p = 0.053$ ). In addition, a statistically significant increase in the number of doses within the recommended dosing range of 15-20mg PE/kg was observed (pre-intervention 12 patients, post-intervention 31 patients;  $p < 0.001$ ). No difference in the number of appropriately collected post-infusion levels collected was observed.

**CONCLUSIONS:** Education on fosphenytoin dosing aimed at ED physician residents can be an effective tool for improving dosing accuracy of this agent. ED residents are reluctant to collect post-infusion concentrations and a greater emphasis on their importance is required to increase their routine use.

### 33. Factors associated with adverse drug events in a French emergency department.

Lucien Roulet, Fellow,<sup>1</sup> Jean-Benoit Hardouin, Ph.D.,<sup>2</sup> Florence Ollivier, Pharm.D.,<sup>3</sup> Gilles Potel, M.D., Ph.D.,<sup>4</sup> Françoise Ballereau, Pharm.D., Ph.D.,<sup>3</sup> Nathalie Asseray, M.D., Ph.D.<sup>1</sup>; (1)UPRES EA 38 26, Faculté de Médecine, Nantes, France; (2)EA 4572 Biostatistics, Clinical Research and Subjective Measures in Health Sciences, Faculté de Pharmacie, Nantes, France; (3)CHU, MEDQUAL, Nantes; (4)CHU, Emergency Department, Nantes, France

**BACKGROUND:** Adverse drug events (ADEs) are frequent causes of hospital admission. Little is known about factors associated with ADEs observed in emergency departments (ED).

**OBJECTIVES:** To investigate the characteristics of ED patients with ADEs and to identify some factors associated with ADE observation.

**METHODS:** We carried out a cross-sectional study with prospective data collection. During 6 months, at randomized time periods, all adult patients admitted in the ED of a French teaching hospital were included. Intentional drug poisonings were excluded. The main outcome was the observation of an ADE. Logistic regression models were fitted to identify factors associated with an ADE observation.

**RESULTS:** 465 patients were included for analysis. ADEs were observed in 102 of them (21.9%; 95% CI 18.8-23.6). Only one third of ADEs were identified by ED physicians. In univariate analysis, patients with ADEs were older ( $p < 0.0001$ ) and took more drugs ( $p < 0.0001$ ) than patients without ADEs. In multivariate analysis, the observation of an ADE was significantly more frequent in case of: (1) involuntary intoxication related admission (OR 5.50; CI 1.46-20.69); (2) poly pathology related admission (OR 3.68; CI 1.65-8.23); (3) endocrine or metabolic pathology related admission (OR 5.37; CI 1.59-18.09); (4) regular use of cardiovascular system drugs (OR 2.77; CI 1.24-6.15). Polymedication was statistically associated with ADEs observation only in patients discharged after ED examination (OR 1.39; CI 1.16-1.67). In hospitalized patients, ADEs frequency increased with regular use of musculo-skeletal system drugs (mainly NSAIDs) (OR 2.22; CI 1.06-4.64). Age, gender, self-medication, regular use of alimentary tract and metabolism drugs and regular use of nervous system drugs were not significantly associated with ADEs observation.

**CONCLUSIONS:** ADEs frequency in ED is high. Clinical pharmacist intervention allows to better identify the characteristics of patients likely to present ADEs.

## Endocrinology

**34E. Exenatide utilization and effectiveness in a health plan population.** *Rolin Wade, R.Ph., M.S.,<sup>1</sup> Brock Schroeder, Ph.D.,<sup>2</sup> Ralph Quimbo, M.A.,<sup>1</sup> Derek Misurski, Ph.D.,<sup>3</sup> Rosalind Fabunmi, Ph.D.,<sup>2</sup> Loretta Nielsen, Ph.D.,<sup>2</sup> Matthew Wintle, M.D.,<sup>2</sup>* (1)HealthCore, Inc., Wilmington, Delaware, USA; (2)Amylin Pharmaceuticals, Inc., San Diego, California, USA; (3)Eli Lilly and Company, Indianapolis, Indiana, USA.

Numerous clinical outcomes trials have demonstrated the benefits of achieving glycemic goals in patients with type 2 diabetes (T2D). In controlled clinical trials, the incretin mimetic exenatide improved glycemic control in patients with T2D; 34% to 46% of patients achieved HbA1c  $\leq$ 7% and mean HbA1c change from baseline was -0.8% to -0.9% (baseline HbA1c: 8.2% to 8.7%).

**OBJECTIVES:** To investigate the effects of exenatide in clinical practice. **METHODS:** This retrospective cohort study used a large, US commercial health plan claims database to describe baseline characteristics, comorbidities, concomitant therapies, and clinical effectiveness in patients initiated on exenatide.

**RESULTS:** A total of 4936 patients were identified having a new prescription claim for exenatide between May 1, 2005 and June 30, 2006 (first claim = index date), with  $\geq$ 12 months of pre- and post-index eligibility, and  $\geq$ 18 years old. Mean ( $\pm$ SD) age was 53.7  $\pm$  10.2 years (11.7%  $\geq$ 65y; 52% female). The 12-month mean (SE) medication possession ratio (MPR = days of supply/365 days) in patients with  $>$ 1 prescription claim was 66  $\pm$  30%. Most patients analyzed (94%) were treated with at least one other antidiabetic medication at initiation (100d pre-index to 15d post-index); 25% with 1 drug, 35% with 2 drugs, and 34% with  $\geq$ 3 drugs. The mean number of antidiabetic drugs (including exenatide) per patient was similar at initiation (3.08) and post-index (3.05). Clinical effectiveness was measured in all patients with an HbA1c  $>$ 7.0% at baseline ( $\leq$ 100d pre-index) and having both baseline and post-index (60–365d) HgA1c data available (n=201; mean baseline HbA1c = 8.9  $\pm$  1.5%). In this cohort, 31% achieved HgA1c  $\leq$ 7% in the post-index period and mean HgA1c change from baseline was -0.8%.

**CONCLUSIONS:** The mean change in HgA1c and percentage of patients achieving HgA1c  $\leq$ 7% in this real-world analysis mirrored results of controlled clinical trials. Furthermore, glycemic improvement was achieved without a further increase in concomitant antidiabetic drugs.

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**35. Occurrence of Hemoglobin A1c testing during inpatient hospitalization at Wellspan.** *Molly A. Walbrown, Pharm.D., CACP, CDE;* Wellspan Health/York Hospital, York, Pennsylvania, USA.

**OBJECTIVES:** According to the Joint Commission Certification for Inpatient Diabetes Mellitus (DM), all DM patients should have a hemoglobin A1c (HbA1c) drawn on hospital admission, unless a value has been obtained within the previous 60 days. At Wellspan Health (WSH), which includes Gettysburg (GH) and York (YH) Hospitals, the Inpatient DM Clinical Effectiveness Team (CET) serves as a quality initiative for glycemic control. Interim data revealed 44% of DM patients had a documented HbA1c. We hypothesize higher percentages of HbA1cs will be checked within 90 days of hospitalization, given the life span of red blood cells.

**METHODS:** From May to September 2008, 751 orders for oral diabetic agents and/or insulin products were identified from weekly pharmacy reports. This retrospective chart review was IRB approved and the following data collected: HbA1c value, DM type, and DM treatment. Statistical analyses were performed using SPSS 15 at the YH Research Center and included descriptive statistics, chi-square, and Mann-Whitney tests.

**RESULTS:** At WSH, 41% of DM patients have documented HbA1cs within 90 days of admission; 63% (N=52) at GH, compared to 38.3% (N=256) at YH (P<0.05). The mean HbA1c at WSH is 7.49 SD  $\pm$  2.14. Mean values at GH are 7.02 SD  $\pm$  0.18 (Range: 5.3–12%) compared to YH with 7.58 SD  $\pm$  0.14 (Range: 4–18.9%) P=NS. There is no difference in HbA1c testing between patients on insulin and those on DM medication. Of the 591 orders for short-acting insulin and sliding scale, 39% (N=232) of patients had HbA1cs. The majority have DM2 (N=172) and 5.2% (N=12) have DM1. Within this group, 20.7% (N=49) did not have the diagnosis of diabetes.

**CONCLUSIONS:** The occurrence of HbA1c testing within 90 days of hospitalization at WSH remains low. The DM CET will issue a statement regarding the importance of HbA1c testing to meet Joint Commission standards and indicate when testing is appropriate.

**36. Evaluation of prescribing patterns of sitagliptin based on estimated glomerular filtration rates in two multi specialty practices.** *M. Shawn McFarland, Pharm.D.,<sup>1</sup> Jeffery Tunney, Pharm.D.,<sup>1</sup> Chad Gentry, Pharm.D.,<sup>2</sup> Benjamin N. Gross, Pharm.D.,<sup>3</sup> L. Brian Cross, Pharm.D.,<sup>2</sup>* (1)Alvin C. York Veterans Administration, Murfreesboro, Tennessee, USA; (2)University of Tennessee/Holston Medical Group, Kingsport, Tennessee, USA; (3)University of Tennessee, Kingsport, Tennessee, USA

**OBJECTIVES:** The objective of this study was to evaluate the appropriateness of the prescribed dose of sitagliptin at the time of first initiation based on baseline glomerular filtration rate.

**METHODS:** This was a retrospective cohort analysis using data pulled from electronic medical records databases of two large multi-specialty medical practices assessing all patients prescribed sitagliptin between October 17, 2006 and June 5, 2008. Data was evaluated for creatinine clearance/glomerular filtration rate (GFR) at the time of initiation of sitagliptin, and the dose of sitagliptin prescribed. GFR was calculated using the Modification of Dosing in Renal Disease (MDRD) formula which estimates GFR using the serum creatinine, age, gender and ethnicity of the patient. Chi-Square statistics were used to estimate the association between GFR and dose of sitagliptin prescribed. Cochran-Armitage trend test was used to evaluate a discernible trend in proportions of the appropriate dose of sitagliptin and GFR.

**RESULTS:** A total of 624 patients (302 male patients and 322 female patients) were evaluated. Overall, 16% (101 of 624) of patients received inappropriate dosing of sitagliptin. Sixty-two percent of patients with a GFR  $<$ 30 ml/min received inappropriate dosing of sitagliptin (8 of 13 patients; p<0.0001). Fifty-three of 85 patients (62.34%) with a GFR between 30 and 50 ml/min received inappropriate dosing of sitagliptin (p<0.0001). Eight percent (40 of 526 patients) with a GFR  $>$ 50 ml/min received inappropriate dosing of sitagliptin. (p<0.0001). There was a strong association between the levels of GFR and the dosing of sitagliptin regardless of gender (p<0.0001).

**CONCLUSIONS:** Patients receiving sitagliptin should have baseline GFR measured prior to initiation of therapy. Patients with a GFR  $<$ 30 ml/min or between 30 and 50 ml/min are more likely to receive inappropriate initial dosing of sitagliptin.

**37. Assessment of quality of diabetes care for type 2 diabetics.** *Sule Apikoglu-Rabus, Ph.D.,<sup>1</sup> Mehmet Hursitoglu, Assist., Prof.,<sup>2</sup> Sami S. Bulgurlu, Ph.D.,<sup>3</sup> Akin Dayan, Ph.D.,<sup>3</sup> Nilcihan Yolcu, Ph.D.,<sup>3</sup> Nuray Gebologlu, R.N.,<sup>3</sup> Fikret V. Izzettin, Prof.,<sup>1</sup>* (1)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (2)Vakif Gureba Teaching and Research Hospital, Internal Medicine Department, Istanbul, Turkey; (3)Haydarpaşa Numune Teaching and Research Hospital, Internal Medicine Department, Istanbul, Turkey.

**OBJECTIVES:** Comorbidities and complications accompanying diabetes make quality health care essential for all type 2 diabetics. This study aimed to determine the quality of diabetes care provided to type 2 diabetics.

**METHODS:** The study was performed on 253 type 2 diabetes patients from the diabetes outpatient clinics of two hospitals. For the assessment of quality of diabetes care, data regarding the following quality indicators were collected: number of annual physician visits; annual number of blood lipid panel measurements; annual number of dilated eye exam; annual number of HbA1c measurements; annual number of blood pressure measurements; annual number of foot examinations; annual number of nephropathy controls; annual number of microalbuminuria measurements; the HbA1c, LDL-cholesterol and blood pressure levels.

**RESULTS:** Annual number of physician visits was  $\geq$ 3 in 79% of the patients. Blood pressure control was not performed in 11% and performed only once in 19% of the patients. As a result, only 16% of the patients reached to the blood pressure goal. During the past year, 26% of the patients didn't receive a foot examination; while 55% didn't receive a dilated eye exam; 3% didn't receive a blood lipid panel measurement; 4%

didn't receive a HbA1c measurement. Microalbuminuria measurement was not performed in 43% and serum creatinine and urea measurements were not performed in 13% of the patients. Glycemic control was good (HbA1c <7) in 51% and bad (HbA1c ≥9) in 18%. LDL cholesterol goal of <100 mg/dL was reached in 36% of the patients.

**CONCLUSIONS:** Quality of diabetes care was high when assessed through the indicators of "number of annual HbA1c, blood pressure and serum creatinine measurements; and number of annual foot examinations", while it failed to be high enough when assessed through the indicators "number of annual microalbuminuria testing and number of annual retinal examinations; HbA1c, blood pressure and LDL levels".

**38. Identifying comorbid depression among adults with diabetes in secondary databases.** *Marianne McCollum, Ph.D., Julia F. Slejko, B.S., William V. Padula, M.S.; University of Colorado Denver School of Pharmacy, Aurora, Colorado, USA*

**OBJECTIVES:** The prevalence of depression among people with diabetes is more than twice that of the general population. Comorbid diabetes and depression is associated with poor health outcomes and high costs. Identifying people with diabetes and depression in large datasets is essential in the conduct of health outcomes studies among people with diabetes. The objective of this study is to determine agreement between a two-question depression screen and diagnosis codes for major and minor depression among people with diabetes.

**METHODS:** Data were obtained from the 2005 Medical Expenditure Panel Survey (MEPS). Adults with diabetes were identified by patient self-report or ICD-9-CM code (250.\*). Diagnosed depression was identified by ICD-9-CM codes for major (296.\*) and minor (311.\*) depression. Depression diagnoses were compared with PHQ-2 scores, a validated screening tool for depression. A cutoff PHQ-2 score of 3 or greater was considered positive for depression (sensitivity = 83% for major depression). Kappa scores were calculated to determine degree of agreement between PHQ-2 scores and diagnosis codes and depression.

**RESULTS:** Of 33,961 respondents to the 2005 MEPS, 2,200 adults with diabetes were identified. PHQ-2 scores were available for 87% (1915/2200); 1524 were negative and 391 positive for depression. There was slight agreement between ICD-9 codes and PHQ-2 scores for major depression ( $\kappa=0.036$ ;  $p<0.001$ ). Kappa scores calculated comparing PHQ-2 scores and ICD-9 codes for minor depression indicated fair agreement between the two ( $\kappa=0.27$ ;  $p<0.001$ ).

**CONCLUSIONS:** Accurate identification of patients with diabetes and depression is required to avoid misclassification bias in cohort studies using secondary datasets. There was slight or fair agreement between diagnosis codes for major and minor depression and a 2-question screen for depression. Additional research is warranted to determine agreement between PHQ-2 scores and diagnosis codes coupled with use of antidepressant agents.

## Ethics in Pharmacy

**39E. A comparative study of the level of agreement with statements on pharmaceutical ethics between interns in France and Quebec.** *Jean-François Bussières, B.Pharm., M.Sc.,<sup>1</sup> Karin Scharr, D.Pharm.,<sup>1</sup> Sonia Prot-Labarthe, D.Pharm.,<sup>1</sup> Denis Lebel, B.Pharm., M.Sc.,<sup>1</sup> Olivier Bourdon, D.Pharm.,<sup>2</sup> (1)CHU Sainte-Justine, Montreal, Quebec, Canada; (2)APHP Hôpital Robert Debré, Paris, France.*

**OBJECTIVES:** Compare the level of agreement with statements related to pharmaceutical ethics between pharmacy interns in France and residents in Quebec.

**METHODS:** The study conducted between April 1 and May 25, 2008 focused on 16 general questions and 43 statements: training and studies, clinical research, marketing and advertising, evaluation and conclusive findings, delivery, pharmaceutical care, economic aspects, and deontology. A 4-choice Likert scale was used to measure the level of agreement/disagreement. The main result showed the difference between the interns and residents' level of agreement. The secondary results compared the level of agreement of (1) 1st-yr. interns in France with that of 1st-yr. residents in Quebec; and (2) the level of agreement of 1st- and 2nd-yr. interns in France with that of interns in the 3rd and 4th yrs. A  $\chi^2$  test and Fisher's exact test were used.

**RESULTS:** Usable data were gathered from 50 respondents in Quebec and 158 respondents in France. A statistically significant difference

( $p\leq 0.05$ ) was found in terms of the consolidated level of agreement/disagreement with 14 of the 43 statements by comparing the views of the residents in Quebec with those of the interns in France, particularly with respect to the statements about relations with the pharmaceutical industry ( $n=7$ ), the place of conclusive findings when it comes to natural health products ( $n=2$ ), deontology ( $n=2$ ) and patient relations ( $n=3$ ). A significant difference was noted for 10 of the 43 statements by comparing the views of 1st-yr. interns in France with 1st-yr. residents in Quebec. A significant difference was only observed for 4 statements between the 2 intern groups in France.

**CONCLUSIONS:** This study demonstrates that there is a difference in the level of agreement/disagreement between pharmacy interns in France and residents in Quebec.

Will be presented at the Canadian Society of Hospital Pharmacists Professional Practice Conference, Toronto, Ontario, Jan 31-Feb 4, 2009.

## Family Medicine

**40. Survey of physician knowledge regarding acetaminophen dosing, toxicity, and product recognition.** *Lori B. Hornsby, Pharm.D., Miranda Andrus, Pharm.D., Jessica Starr, Pharm.D.; Auburn University Harrison School of Pharmacy, Auburn, Alabama, USA*

**OBJECTIVES:** Acetaminophen is the most widely used analgesic in the US and although considered safe when taken within the maximum daily dose, unintentional acetaminophen overdose accounts for 30% to 57% of all acute liver failure (ALF) cases. The purpose of our study was to assess physician knowledge regarding acetaminophen dosing, toxicity, and recognition of acetaminophen-containing products.

**METHODS:** Resident and faculty physicians at three family medicine residency programs were asked to complete a 7-item questionnaire. Questions were designed to assess knowledge of acetaminophen dosing, toxicity, and product recognition and were formatted as multiple choice, yes/no, and true/false. Each item contained an answer choice of "unsure" to best assess actual knowledge.

**RESULTS:** Seventy-six physicians completed the survey. Only 76% were aware of the appropriate maximum daily dose (4 grams) with 7% choosing 6 grams and 5% answering "unsure". While 93% recognized Lortab<sup>®</sup> and 90% Percocet<sup>®</sup> as acetaminophen containing products, only 83% and 75% identified Lorcet<sup>®</sup> and Darvocet<sup>®</sup>. The majority could identify non acetaminophen containing products, however only 86% responded "no" as to OxyContin<sup>®</sup> containing acetaminophen. Knowledge of over-the-counter acetaminophen products was generally less accurate with more "unsure" responses. Ninety-eight percent recognized hepatotoxicity as the primary toxicity. While 72% did not feel the majority of acetaminophen overdoses were intentional and 76% agreed that the incidence of acetaminophen related ALF was increasing, only 32% felt these cases were likely to result in liver transplantation.

**CONCLUSIONS:** Many physicians are unaware of acetaminophen dosing and toxicity issues and demonstrate some difficulty with accurately identifying acetaminophen containing products. How this may contribute to unintentional acetaminophen overdose as a result of inappropriate prescribing and lack of patient education is not clear but should raise concern. These results also reinforce the importance of pharmacists providing appropriate counseling when dispensing acetaminophen products.

## Gastroenterology

**41. The role of lactobacillus in the prevention of antibiotic-associated diarrhea.** *Pramodini B. Kale-Pradhan, Pharm.D., Sheila M. Wilhelm, Pharm.D., BCPS, Harjot Jassal, Pharm.D. Candidate, Raymond Cha, Pharm.D.; Wayne State University, Detroit, Michigan*

**BACKGROUND:** Antibiotic-associated diarrhea (AAD) is a significant concern associated with antibiotic use. Probiotics' role in preventing AAD is controversial. There are a limited number of studies evaluating the efficacy of a *Lactobacillus* mono-regimen in preventing AAD.

**OBJECTIVES:** To evaluate the efficacy of a *Lactobacillus* probiotic mono-regimen in preventing AAD.

**METHODS:** The meta-analysis only included studies that met the following stringent criteria: randomized, blinded, placebo-controlled trials, published in English, evaluating *Lactobacillus* mono-regimens on

AAD incidence. Studies using non-*Lactobacillus* or combination probiotics were excluded. PubMed, Medline, and Cochrane Central Register of Controlled Trials were searched using the terms: Probiotic, *Lactobacillus*, and antibiotic-associated diarrhea. Quality of studies was assessed using the Jadad scoring system. Number of subjects, age, *Lactobacillus* regimen, follow-up period and occurrence of AAD was extracted by two investigators independently into standardized data collection form. Overall impact of *Lactobacillus* on AAD was compared to placebo using the random effects model (RevMan<sup>®</sup> Ver 5.0.15).

**RESULTS:** Ten studies, with a total of 1862 subjects (49.6% males), met all criteria. Six studies included subjects  $\geq 18$  years of age, while four included patients  $< 18$  (range: 2 weeks–14 years). Jadad scores ranged from 2–5 out of 5. The total *Lactobacillus* dosage ranged from  $2 \times 10^9$  CFUs to  $4 \times 10^{10}$  CFUs and was administered throughout the entire antibiotic treatment (3–14 days) for all subjects. The follow-up period varied from 0 to 49 days after the end of antimicrobial treatment. The combined risk ratio (RR) of developing AAD was significantly lower with *Lactobacillus* compared to placebo (RR 0.35, 95% CI: 0.19, 0.67).

**CONCLUSIONS:** Administration of a *Lactobacillus* mono-regimen as a prophylactic agent during antibiotic treatment reduced the risk of developing antibiotic-associated diarrhea compared to placebo. Further evaluations with standardized *Lactobacillus* regimens and classification of AAD are warranted.

**42. The effect of arginine and omega 3 fatty acids in critically ill and surgical patients.** Sheila M. Wilhelm, Pharm.D., BCPS, Mark Essak, Pharm.D., Candidate, Pramodini B. Kale-Pradhan, Pharm.D., Raymond Cha, Pharm.D.; Wayne State University, Detroit, Michigan, USA.

**BACKGROUND:** Immuno-nutrients may improve outcomes in critically ill and surgical patients. Supplementation with glutamine has been studied extensively. However, arginine and omega 3 fatty acids (w-3FA) have limited data.

**OBJECTIVES:** To determine if arginine and w-3FA improve infection rate, length of stay (LOS) and mortality in critically ill or surgical patients.

**METHODS:** Medline (1966–2008), EMBASE and Cochrane Library were searched by two investigators independently using the key words: immunonutrition, arginine, w-3FA. Bibliographies of recent review articles and systematic reviews were hand searched. English studies published in full were included in this meta-analysis if they met the following stringent criteria: controlled trials using arginine and w-3FA in combination (Impact) in adult critically ill or surgical patients dosed pre- or postoperatively with at least one of the following endpoints –LOS, mortality and infectious complications. Trials were excluded if they did not meet the inclusion criteria. Study quality was assessed using the Jadad scoring system. Impact of arginine and w-3FA was compared to placebo with respect to infection rate, LOS and mortality using the random effects model (RevMan<sup>®</sup> Ver 5.0.15).

**RESULTS:** Twenty two studies (n=2423, 62% males), met all criteria. Jadad scores ranged from 0–5 out of 5. Immunonutrition with arginine and w-3FA was administered either pre- or post-operatively or during ICU stay in 7, 6, and 9 studies, respectively. Infection rate (OR: 0.54, 95% CI 0.41, 0.7) and LOS (Mean difference: -2.08, 95% CI -2.91, -1.26) was significantly lower in patients receiving immunonutrition compared to control group. In a subgroup analysis, these differences were maintained in the pre- and post-operative populations, but were not significant in the critically ill population. Mortality was not significantly different between the two groups (OR: 1.05, 95% CI 0.73, 1.5).

**CONCLUSIONS:** Immunonutrition significantly decreases infection rates and LOS in surgical populations. The effect of immunonutrition is unclear in critically ill patients.

## Geriatrics

**43. A comprehensive pharmacist intervention to reduce morbidity in patients aged 80 years or older: A randomized, controlled trial.** Ulrika Gillespie, M.Sc., Pharm.,<sup>1</sup> Anna Allassaad, M.Sc., Pharm.<sup>2</sup>; (1)University of Uppsala, Uppsala, Sweden; (2)Hospital pharmacy, Uppsala university hospital, Stockholm, Sweden.

**BACKGROUND:** Although patients aged 80 years or older are often under-represented in scientific studies, they contribute more than other groups to the increasing costs of health care and drug usage.

**OBJECTIVES:** The aim of this study was to investigate the effectiveness of interventions carried out by ward-based pharmacists, in reducing morbidity and usage of hospital care for elderly patients.

**METHODS:** A randomized, controlled study of patients aged 80 years or older was conducted at the University Hospital of Uppsala, Sweden. Patients (400) were recruited consecutively between October 2005 and June 2006 and randomized into control (n=201) or intervention group (n=199). The interventions were performed by ward-based pharmacists and included medication reconciliation, drug review, patient education, drug monitoring, discharge counseling and communication with primary care. The control group received standard care without pharmacists' involvement. The primary outcome measure was the frequency of hospital visits (emergency department and re-admissions; in total and drug-related) during the 12-month follow-up period.

**RESULTS:** Three hundred and sixty eight patients were analyzed (182 intervention and 186 control). There was a 47% reduction in visits to the emergency department for the intervention group (quotient 0.35 vs. 0.66, estimate 0.53, 95% CI 0.37, 0.75) and a reduction of 16% in all visits to the hospital (quotient 1.88 vs. 2.24, estimate 0.84, 95% CI 0.72, 0.99). Drug-related re-admissions were reduced by 80% (quotient 0.06 vs. 0.32, estimate 0.20, 95% CI 0.1, 0.41) in the intervention group. The total cost/patient, after inclusion of the intervention costs, was \$267 lower than in the control group.

**CONCLUSIONS:** The results suggest that, if implemented on a population basis, adding pharmacists to health care teams, would lead to major reductions in drug-related morbidity and health-care costs.

**REGISTRATION:** [www.clinicaltrials.gov](http://www.clinicaltrials.gov); ID: NCT00661310.

**44. Is high dose statin therapy safe in the elderly?** Séverine Gupta, Pharm.D.,<sup>1</sup> Isabelle Peyron, Pharm.D.,<sup>1</sup> Christelle Laguillier, Pharm.D.,<sup>2</sup> Nadine Oboa, Pharm.D.,<sup>1</sup> Anna Sarfati, Pharm.D.<sup>1</sup>; (1)APHP Hôpital Charles Foix, Department of Pharmacy, Ivry Sur Seine, France; (2)APHP Hôpital Charles Foix, Department of Clinical Chemistry, Ivry Sur Seine, France.

**OBJECTIVES:** The aim of this study is to perform a one day survey of statin prescriptions in a French geriatric hospital and to analyze the blood lipid levels in patients receiving a statin.

**METHODS:** Patients who receive statin are selected and have laboratory test (Total cholesterol [TC], low-density lipoprotein cholesterol [LDL-C], and high-density lipoprotein cholesterol [HDL-C]).

**RESULTS:** 167 of 730 (22.8%) hospitalized patients received a statin. A blood lipid levels were performed in 136/167 patients: 88 female and 48 male, mean age  $81 \pm 10$  years; 20 patients were hospitalized in geriatric care units; 34 patients in re-education and re-adaptation units; and 82 were institutionalized patients. The laboratory test results showed: 74 (54%) patients had hypocholesterolemia (TC:  $117 \pm 20$  mg/dL, LDL-C:  $63 \pm 16$  mg/dL, HDL-C:  $35 \pm 10$  mg/dL), 60 (44%) patients had normocholesterolemia, and 3 (2%) patients had hypercholesterolemia. 43 patients of 136 received high dose statin therapy (rosuvastatin 5 mg/d (n=5) or 10 mg/d (n=3), atorvastatin 40 mg/d (n=31) or 80 mg/d (n=1), pravastatin 40 mg/d (n=1) and 31 of the 43 patients (72%) were hypocholesterolemic. Statin treatment was stopped in 8 hypocholesterolemic patients.

**CONCLUSIONS:** Statins are widely used in elderly patients but result frequently in hypocholesterolemia. Several studies have demonstrated an association between hypocholesterolemia and intracerebral hemorrhage, and hemorrhagic stroke risk increased with age. Low LDL-C and low HDL-C concentrations may be associated with an increased risk of infectious disease. Furthermore elderly patients may be more susceptible to adverse events when receiving high doses of statins because of polytherapy and reduced hepatic and renal function. Since studies with high dose of statin were not performed in elderly cohorts, what is the benefit/risk ratio of aggressive reduction in cholesterol levels in elderly patients?

## Health Services Research

**45E. Helping patients use their medicines more effectively: A pilot study of medicine use reviews in the UK.** James A. Desborough, M.Pharm., Ph.D., David J. Wright, BPharm, Ph.D., John Wood, B.Sc., M.Sc., Richard C Holland, B.A., B.M. Bch, Ph.D.; University of East Anglia, Norwich, United Kingdom.

**OBJECTIVES:** Medicine Use Reviews (MURs) were introduced in the UK in 2005. Pharmacies are reimbursed for having a face to face consultation with a patient with the aim of improving patient knowledge and use of medicines. However little is known about the ability of these reviews to achieve this. The aim of this pilot study was to provide estimates of the level of patient reported adherence and satisfaction following an MUR that could be used to power a RCT.

**METHODS:** Seven pharmacies across Norfolk, UK were asked to invite all patients they identified as suitable for an MUR to participate in this study. Consenting patients were randomised to receive an MUR (intervention) or usual care (control). A baseline questionnaire on adherence and satisfaction was given to all participants and completed prior to the MUR in intervention patients or post recruitment in control. One week later, a follow-up questionnaire was sent to all participants; this was similar to the baseline questionnaire with additional questions for intervention patients. Data was extracted from pharmacy records and interviews conducted with four patients to enrich questionnaire responses.

**RESULTS:** 410 patients received MURs in participating pharmacies during the data collection period, of which only 124 were invited to participate in the study and 72 (58%) agreed. For the primary outcomes at follow-up there was no change in adherence, but satisfaction scores improved in the intervention group (n=24) compared to control (N=30), mean score changed by 1.5 vs. 0.0 respectively (p=0.051, Mann Whitney U).

**CONCLUSIONS:** This pilot study has highlighted the potential recruitment difficulties of any further studies. It appears likely that this intervention needs to be developed if it is going to demonstrate any significant effects on patient behaviour.

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Presented at the British Pharmaceutical Conference, Manchester, UK, September 7–9, 2008.

**46. Identification of resources to provide appropriate language services for limited english proficient patients.** *Priti N. Patel, Pharm.D., BCPS, Emily M. Ambizas, Pharm.D.; St. John's University, Queens, New York, USA.*

**OBJECTIVES:** To determine resources available to help pharmacists provide better care for Limited English Proficient (LEP) patients.

**METHODS:** An online survey was distributed to various health professionals involved in the care of LEP patients. The survey tried to identify the respondents' profession, practice setting, frequency of encounters with LEP patients, need for language services in their respective states, resources utilized to improve care of LEP patients, and services offered to LEP patients. Follow-up telephone calls and emails were used to obtain more detailed information regarding the various resources and services identified.

**RESULTS:** Of the 57 respondents who identified their profession, 32 were pharmacists (56.1%). When including both pharmacists and non-pharmacists, most participants described their practice area as something other than pharmacy practice (44.6%). Fifty-one respondents (89.5%) believed there is a need within their state for language services for LEP patients. Most (91.1%) reported encountering LEP patients at their practice site, with the majority stating they encounter LEP patients on a daily basis (62.7%). Numerous languages of patients were identified, with Spanish being the most frequently encountered. Russian, Vietnamese, and Korean were among other common languages. Translation services, both oral interpretation and translation of labels and educational materials, were the most common method of providing appropriate language access services. The most common resources used by pharmacists included online websites (27.5%), general language translation dictionaries (29.4%), and health-related translation guides (25.5%). The majority of these resources encompassed general medical topics rather than pharmacy-specific material.

**CONCLUSIONS:** Pharmacists frequently encounter LEP patients and provision of appropriate language services is necessary to optimize patient care. Many resources that are being utilized to assist health care providers in caring for LEP patients were identified. Since little pharmacy-specific resources were identified, development of pharmacy-related materials will help pharmacists provide better care for LEP patients.

**47E. Pre- vs. post-National Coverage Determination blood utilization and hemoglobin values among Medicare patients treated with erythropoietic-stimulating agents for chemotherapy-induced anemia.**

*Tanya Burton, Ph.D.<sup>1</sup>, Kay Larholt, Sc.D.,<sup>2</sup> Elizabeth Apgar, M.P.H.,<sup>1</sup> Chris Pashos, Ph.D.,<sup>1</sup> Brahim Bookhart, M.B.A., M.P.H.,<sup>2</sup> Mitra Corral, M.S., M.P.H.,<sup>2</sup> Catherine T. Piech, M.B.A.,<sup>2</sup> R. Scott McKenzie, M.D.<sup>2</sup>; (1)Abt Bio-Pharma Solutions, Inc., Lexington, Massachusetts, USA; (2)Centocor Ortho Biotech Services, LLC, Bridgewater, New Jersey, USA.*

**OBJECTIVES:** In July 2007, CMS issued erythropoietic-stimulating agents (ESAs) coverage limitations for cancer pts with CIA through an National Coverage Determination (NCD). To understand hematologic outcomes in the Medicare population treated in Pre- and Post-NCD time period, data from the D.O.S.E. (Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies) registry, an ongoing prospective observational study, were analyzed.

**METHODS:** ESA-treated chemotherapy-induced anemia (CIA) pts were selected based on Medicare coverage, available baseline (BL) Hb value, and receipt of  $\geq 2$  ESA doses. Data were categorized based on date of initial ESA administration: Pre-NCD (4/06-4/07) and Post-NCD (10/07-5/08). BL demographics, Hb values during ESA treatment, and blood utilization patterns were analyzed.

**RESULTS:** 288 pts were identified (Pre-NCD – 230; Post-NCD – 58) from 41 sites. Age, gender, weight, and tumor type were similar among groups. ESA treatment duration was significantly greater in the pre-NCD group (70 vs. 54 days, p=0.0011). Differences in blood utilization and Hb values were observed between the Pre-NCD and Post-NCD populations (Table). A significantly greater proportion of pts required a blood transfusion and the number of units administered per study patient was significantly higher in the Post-NCD group. Hb levels were significantly lower at all time points of observation in the Post-NCD group.

Transfusion Outcomes	Pre-NCD	Post-NCD	p-value
% Pts Transfused	18.3%	32.8%	p=0.0157
Mean No. Units/ Study Patient	0.5	1.1	p=0.0089
<i>Hematologic Outcomes: Mean Hb (SD)</i>			
Baseline	10.6 (0.8)	9.6 (0.5)	<0.0001
Week 4	11.1 (1.3)	9.9 (1.1)	<0.0001
Week 8	11.2 (1.3)	10.4 (1.3)	0.013
Week 12	11.1 (1.3)	9.8 (1.2)	0.0002
Week 16	11.0 (1.1)	9.7 (0.2)	0.018

**CONCLUSIONS:** Greater blood utilization and lower Hb values were observed in Medicare CIA pts treated with ESAs during the Post-NCD compared to the Pre-NCD time period. The impact of the NCD on patient outcomes is important to providers and hospital systems and warrants further research.

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**48. Interest in and knowledgebase of practice based research networks (PBRNs): a survey of Maryland pharmacists.** *Heather B. Congdon, Pharm.D., CACP, CDE, Melissa Kim, Pharm.D. Candidate; University of Maryland School of Pharmacy, Rockville, Maryland, USA.*

**OBJECTIVES:** To assess the interest in and knowledgebase of PBRNs among Maryland pharmacists.

**METHODS:** A survey was created to assess the awareness of and interest in PBRN's among Maryland pharmacists. The survey also addressed potential factors affecting one's decision to join a PBRN and potential disease states and pharmacy practice issues to focus on, if one were created. The investigators met with the Maryland Pharmacy Coalition, which is comprised of 5 Maryland pharmacy associations, in order to gain their support of the survey. Each association contacted members via an email containing a cover letter and the survey. An email was also sent out with the same information to all University of Maryland School of Pharmacy preceptors.

**RESULTS:** 93 pharmacists completed the survey. 76.4% of respondents had little or no knowledge about PBRNs. 79.4% of respondents were definitely or probably interested in learning more about PBRNs. 58.7%

of respondents were definitely or probably interested in helping to develop a PBRN. 67.1% of respondents would definitely or probably participate in a PBRN. The 3 most common factors influencing one's decision to join a PBRN were time commitment (58.6%), improving outcomes through research (57.5%) and how research fits into daily work flow (57.5%). Potential disease states and practice issues that elicited the greatest response included (1) diabetes (66.3%); (2) hypertension (53.9%); and (3) cardiovascular disease (49.4%); and (i) patient counseling/education (74.2%); (ii) patient safety (70.8%); and (iii) patient compliance (69.7%), respectively.

**CONCLUSIONS:** Maryland pharmacists indicated their awareness of PBRNs is lacking but are interested in learning more. Next steps for this project include a continuing education opportunity providing information about PBRNs, and the formation of an interest group to facilitate creation of a statewide PBRN.

**49. Montenegro primary care physicians awareness of evidence based medicine—call for a clinical pharmacist intervention?** Ivana Ilickovic, M.Sc.,<sup>1</sup> Branislava Miljkovic, Ph.D.,<sup>2</sup> Sandra Vezmar, Ph.D.<sup>2</sup>; (1)Pharmaswiss, Podgorica, Yugoslavia; (2)School of pharmacy, University of Belgrade, Belgrade, Yugoslavia.

**OBJECTIVES:** In order to identify need for clinical pharmacist interventions which may contribute to better outcomes for patients with myocardial infarction and no heart failure, the primary care physicians' awareness and knowledge of evidence based medicine (EBM) were explored. The use of medicines information sources and the physicians' prescribing for the patients were investigated.

**METHODS:** Qualitative semi-structured interviews were performed with 8 non-pediatric physicians working in two out of 14 facilities of primary health centre of Podgorica, which were chosen by purposive, theoretically informed cluster sampling. The framework approach using iterative qualitative technique and constant comparison method were applied for analysis. Prophylactic drug therapy of myocardial infarction without heart failure (MI) was investigated due to the availability, explicitness, robustness of evidences and relevance for physicians' daily practice to enhance validity and reliability of answers.

**RESULTS:** Discrepancy between declared awareness and vague conceptualisation of EBM is revealed by qualitative interview. Misconception of research evidences, lack of retrieval and appraising skills, therapeutic conservatism, relying on shortcuts for interpretation of research studies were shown. Cognitive inputs stated by all interviewees were: cardiologists' prescription, pharma companies, uncritical internet searches and unsystematic clinical experience. Nevertheless information sources stated as valuable and influential were: continuous medical education (CME), opinion leaders and journals. Need for updating was not recognised and was prompted by erratic personal interest. Appropriate drug selection was revealed from one of the eight physicians while the choice of others revealed several "care gaps".

**CONCLUSIONS:** Physicians unawareness of skills needed to practice EBM is demonstrated by the study. Reliance on non evidence based information sources may have contributed to inappropriate medication choices. Revealed "care gaps" indicate that MI patients could benefit from interventions of a health care worker with appropriate training and skills for the use of EBM, such as clinical pharmacists.

**50E. Hypoglycemia and costs in patients newly initiated on exenatide or insulin glargine.** Rolin Wade, R.Ph., M.S.,<sup>1</sup> Loretta Nielsen, Ph.D.,<sup>2</sup> Rosalind Fabunmi, Ph.D.,<sup>2</sup> Ralph Quimbo, M.A.,<sup>1</sup> Brock Schroeder, Ph.D.,<sup>2</sup> Marjan Massoudi, Pharm.D.,<sup>2</sup> Derek Misurski, Ph.D.,<sup>3</sup> Matthew Wintle, M.D.<sup>2</sup>; (1)HealthCore, Inc., Wilmington, Delaware, USA; (2)Amylin Pharmaceuticals, Inc., San Diego, California, USA; (3)Eli Lilly and Company, Indianapolis, Indiana, USA

**BACKGROUND:** The incretin mimetic, exenatide (EX), and basal insulin glargine (IG) improves glycemic control in patients with type 2 diabetes (T2D).

**OBJECTIVES:** In this retrospective analysis using a US commercial health plan claims database, we describe one-year annualized hypoglycemia event rates (AHR) and associated costs in T2D patients initiating EX or insulin glargine (IG).

**METHODS:** Patients were  $\geq 18$ y with a pre-index T2D claim and an

initial prescription claim for EX (n=3,262) or IG (n=3,038) between May 1 2005 and June 30 2006;  $\geq 6$ mo pre-index (first claim=index date), and  $\geq 12$ mo post-index data. The EX cohort had no previous exposure to IG or other insulins and vice versa; no other insulin was started. Hypoglycemic events were identified by ICD-9 codes 250.3, 250.8, 251.0, 251.1, and 251.2.

**RESULTS:** For EX, age ( $\pm$ SD) was  $53 \pm 10$ y (9%  $\geq 65$ y); 54% female. For IG, age was  $56 \pm 12$ y (19%  $\geq 65$ y); 41% female. Hypoglycemic event rates were adjusted for the covariates of age, sex, pre-index Deyo-Charlson comorbidity index, number of pre-index hypoglycemia events, and sulfonylurea cotherapy, using a generalized linear model. Overall AHR was 1.8-fold higher for IG than for EX ( $0.117 \pm 0.007$  vs.  $0.065 \pm 0.011$ ;  $p < 0.0001$ ). By treatment location, AHR was 1.7-fold higher for IG for outpatient events, 2.8-fold higher for hospital events, and 5.0-fold higher for emergency room events, respectively ( $p < 0.0001$  for each). The associated median cost per hypoglycemic event across treatment groups was \$81 for outpatient (range \$5 to \$2,766; mean \$148), \$7,951 for the hospital (range \$43 to \$153,696; mean \$15,166), and \$633 for the emergency room (range \$90 to \$4,985; mean \$919).

**CONCLUSIONS:** The incidence of hypoglycemic events and the predicted associated costs were lower in T2D patients initiating EX than IG.

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## Hematology/Anticoagulation

**51. Impact of Proactive Interventions in Patients with a Rapid Increase in International Normalized Ratio While Receiving Warfarin Therapy in An Inpatient Setting.** Danny McNatty, Pharm.D., BCPS,<sup>1</sup> Karen L. Johnson, R.Ph.,<sup>2</sup> Carrington R. K. Raney, Pharm.D.,<sup>2</sup> Mary A. Gurney, Ph.D.<sup>1</sup>; (1)Midwestern University College of Pharmacy-Glendale, Glendale, AZ; (2)Banner Thunderbird Medical Center, Glendale, Arizona, USA

**OBJECTIVES:** To determine the effect of proactively providing recommendations for warfarin dosage adjustments to prescribers in patients with an INR increase of more than 0.5 within a 24-hour period.

**METHODS:** A retrospective chart review was completed for all patients receiving warfarin from January 2008 through June 2008. All patients with an INR increase of greater than 0.5 in any 24-hour period were included in the analysis. The intervention occurred irrespective of the relationship of the INR to the therapeutic range, with pharmacists recommending either a significant dosage reduction or holding the dose of warfarin when a rapid increase in an INR is identified. Patients were stratified based on acceptance or rejection of the intervention by prescribers. INR results 24 and 48 hours after the intervention were compared. The number of INRs exceeding 3.0 and 4.0 within both groups were evaluated using Pearson  $\chi^2$ . Negative outcomes such as transfusion requirements, intracranial hemorrhage, and other bleeding events were not evaluated during this preliminary study.

**RESULTS:** Of the 1079 inpatients who received warfarin, 326 (30%) had an INR increase of more than 0.5 in a 24-hour period during their admission. A total of 225 were included in the analysis (101 lost to follow-up) with 56% of the interventions being accepted and acted on by prescribers. Patients in whom the intervention was rejected were more likely to have subsequent INR values exceeding 3.0 (69% vs. 45.6%  $p < 0.001$ ) and 4.0 (30% vs. 21.6%,  $p = 0.150$ ) within 48 hours.

**CONCLUSIONS:** An INR increase of more than 0.5 in a 24-period may be a useful predictor for identifying those patients at risk for exceeding a therapeutic goal. A larger, prospective study is needed to determine whether this relatively simple and standardized intervention has the potential to reduce bleeding events and prolonged hospitalizations in this patient population.

**52E. Retrospective comparison of bivalirudin and argatroban in the management of heparin-induced thrombocytopenia.** Lee P. Skrupky, Pharm.D., Jennifer R. Smith, Pharm.D., Heather Arnold, Pharm.D., Eli N. Deal, Pharm.D., James M. Hollands, Pharm.D., Emily J. Martinez, Pharm.D., Scott T. Micek, Pharm.D.; Barnes-Jewish Hospital, Saint Louis, Missouri, USA

**OBJECTIVES:** Argatroban has been prospectively evaluated for heparin-induced thrombocytopenia (HIT), but bivalirudin has not and direct comparisons are lacking. The purpose of this study was to compare

outcomes achieved with bivalirudin versus argatroban in the treatment of patients with known or suspected HIT.

**METHODS:** This was a retrospective analysis of all patients admitted between January 2007 and July 2008 whom received either bivalirudin or argatroban for  $\geq 24$  hours for known or suspected HIT.

**RESULTS:** One-hundred ten patients were evaluated, 74 receiving bivalirudin and 36 receiving argatroban. Duration of use ranged from 24–621 hours. At the time of DTI initiation 75% of patients were in an ICU, with the majority (52%) being cardiothoracic surgery. The institution practice is for all cardiothoracic ICU patients with suspected HIT to receive bivalirudin, which accounted for the primary imbalance between groups. The average doses of bivalirudin and argatroban at the time of first reaching the therapeutic goal were 0.07 mg/kg/hr and 1.1 mcg/kg/min, respectively. The mean percentage of PTTs within the therapeutic range while on DTI therapy were similar for bivalirudin and argatroban (70% vs. 66%,  $p=0.43$ ). A greater percentage of PTTs were supratherapeutic while on argatroban versus bivalirudin (24% vs. 14%,  $p=0.047$ ). Median time to therapeutic goal was similar for bivalirudin (5.25 hr, IQR 4–12) and argatroban (6.75 hr, IQR 3–18),  $p=0.987$ . Rates of venous thromboembolism, diagnosed either before or after initiation of DTI, were similar for the bivalirudin and argatroban groups (57% vs. 53%,  $p=0.694$ ). Bleeding events were infrequent and occurred at similar percentages in both groups (14% vs. 8%,  $p=1.0$ ).

**CONCLUSIONS:** Bivalirudin and argatroban were similar with respect to achieving and maintaining therapeutic anticoagulation goals, clinical outcomes, and safety. This study suggests that bivalirudin represents an alternative in the management of HIT, but prospective studies are needed to establish both efficacy and safety.

Presented at The Society of Critical Care Medicine Annual Congress, Nashville, TN, January 31–February 4, 2009.

**53. Drug use evaluation of prothrombin complex concentrate (Factor IX complex concentrate).** Luis Mendarte, Pharm.D., Marta Munne, Pharm.D., Francesc X Nuvials, Phys.D., Jessika Gomez-Lopez, Technician, Jose B. Montoro, Ph.D., Jose Monterde, Ph.D.; Hospital Universitari Vall D'Hebron, Barcelona, Spain.

**BACKGROUND:** Massive hemorrhage is defined as 20% of blood loss or more. It is considered as an emergency treatment in medical therapy. In these situations blood volume restoration and haemostasis recovery is immediately needed. For haemostasis recovery several hemoderivates have been used: blood red cells, platelets, fresh frozen plasma, cryoprecipitate, factor IX complex concentrate and coagulation factors alone. Nonetheless there is lack of evidence about which agent should be chosen. Besides major surgery or trauma, patients who receive oral anticoagulants, vitamin K deficiency, digestive hemorrhage, hematologic cancers, and cardiac and cardiovascular surgery may benefit of treatment with factor IX complex concentrate.

**OBJECTIVES:** Prospective evaluation of factor IX complex concentrate use at a university hospital. Evaluate drug use efficiency, safety and survival at the end of the proceeding.

**METHODS:** Patients who received a FCC prescription from January to August 2008 were included. Demographic data, treatment indication, INR before and INR after treatment, hemoglobin (Hgb), hematocrit (Hct), admission diagnosis, indication diagnosis, dose, anticoagulant treatment, vitamin K, blood concentrates or other hemoderivates administration were collected.

**RESULTS:** 124 patients were treated with PCC, but 22 patients were excluded because data not available, therefore 102 patients were included. Mean age was 63.3; 66 men. Average dose was: 3.042 UI. Mean INR levels before and after PCC were 2.95 and 1.47 respectively. Mean difference ( $n=64$ ) before and after the administration was 1.73 (0.97–2.48)  $t = 4.58$   $p < 0.0001$ . 61.57% of patients survive at the end of the process. 34 patients present bleeding during cardiac surgery, 11 gastrointestinal bleeding, 37 major surgery and 14 cerebral bleeding. 34% of patients where receiving oral anticoagulants before the emergency bleeding. No thrombotic events where observed.

**CONCLUSIONS:** PPC quickly restores haemostasis and significantly reduced the INR. The use of PCC allows quickly surgical intervention and was considered safe.

**54. Venous thromboembolism prophylaxis study in hospitalized non-surgical patients.** Petra Jancar, Pharm.D.,<sup>1</sup> Tina Morgan, Pharm.D.,<sup>1</sup> Ales

Mrhar, Pharm.D.,<sup>2</sup> Mitja Kosnik, M.D.,<sup>1</sup> Mitja Lainscak, M.D.,<sup>2</sup>; (1)University Clinic Golnik, Golnik, Slovenia; (2)Faculty of pharmacy, University of Ljubljana, Ljubljana, Slovenia.

**OBJECTIVES:** Prevalence of venous thromboembolism (VTE) in hospitalized non-surgical patients is 5–20%, which can be substantially reduced by the use of low-molecular-weight heparins (LMWHs). In clinical practice, guidelines for LMWH use are not implemented appropriately. This study aimed to evaluate initiation, dose, and duration of LMWH treatment in non-surgical admissions to the university pulmonary clinic.

**METHODS:** In this prospective population study we screened all admissions to our hospital during a two month period ( $N=1067$ ). Surgical patients and patients receiving LMWHs as treatment were excluded; final sample included 750 patients (age  $72 \pm 14$  years, 55% men). Eligibility for VTE prophylaxis with LMWH was assessed by ACCP guidelines. Primary and secondary outcomes were LMWH prophylaxis in eligible patients and LMWH use according to guidelines (daily dose, length of treatment).

**RESULTS:** LMWH prophylaxis was indicated in 298 (34%) patients and 259 (87%) were actually treated. Adherence to guidelines was complete in 121 (47%) patients whilst in 51 (20%) and 87 (34%) patients either dose or treatment duration was inappropriate. VTE prophylaxis with LMWHs was prescribed to 28 (6%) patients without risk factors for VTE present. Of the patients receiving LMWHs, 11 (4%) patients (age  $78 \pm 8$  years, 64% men) developed bleeding; two received a higher dose than recommended and three were treated for too long. One patient developed VTE, and 2 (1%) patients developed thrombocytopenia.

**CONCLUSIONS:** VTE prophylaxis was indicated in 298/750 non-surgical admissions and LMWHs were initiated in 87% of patients. Inappropriate dose or treatment duration was detected in 53% of treated patients. The rate of patients receiving thromboprophylaxis was higher as compared to some recent studies. However, further improvement should be made in optimizing the therapy with LMWHs to prevent unnecessary exposure to increased risk of VTE or bleeding.

**55. Renal dysfunction is associated with reduced warfarin maintenance dose and increased INR instability.** Megan E. Kleinow, Pharm.D.,<sup>1</sup> Jennifer L. Clemente, Pharm.D.,<sup>1</sup> Candice L. Garwood, Pharm.D.,<sup>2</sup> Peter Whittaker, Ph.D.,<sup>3</sup>; (1)Detroit Medical Center, Detroit, Michigan, USA; (2)Wayne State University, Department of Pharmacy Practice, Detroit, Michigan, USA; (3)Wayne State University School of Medicine, Cardiovascular Research Institute and Dept of Emergency Medicine, Detroit, Michigan, USA.

**OBJECTIVES:** Despite identification of several clinical and genetic factors that influence patients' response to warfarin, approximately 35% to 45% of inter-patient dosing variability remains unaccounted for. The appreciation that renal dysfunction (RD) also affects hepatically-cleared drugs prompted us to hypothesize that RD influences warfarin dosing; resulting in lower maintenance doses. Furthermore, we speculated that the underlying disease process in RD could promote INR instability.

**METHODS:** Our retrospective chart-review examined 26 matched patients enrolled at a pharmacist-managed anticoagulation clinic. To maximize our ability to detect RD-related influences, we matched RD patients with controls based on parameters previously established to influence warfarin dose; target INR (2–3), gender, ethnicity, age, and body surface area (BSA). We calculated average weekly dose (WD) used to maintain target INR (assessment period 158–1,281 days). To evaluate INR stability, we determined: (1) percentage of clinic visits requiring any dose adjustment; (2) percentage of visits requiring WD change; (3) time between dose adjustments; and (4) INR standard deviation (SD).

**RESULTS:** Both groups were predominantly African American (92%); mean age 59 years and BSA 2.0 square meters. RD patients' eGFR was  $46 \pm 5$  vs.  $101 \pm 4$  mL/min in controls ( $P < 0.001$ ). RD patients required 18% lower WDs versus their matched control ( $38.9 \pm 2.9$  vs.  $47.5 \pm 3.5$  mg;  $P < 0.03$ , paired  $t$ -test). Furthermore, RD patients were unstable; indicated by greater proportion of visits requiring dose adjustment ( $42.7 \pm 3.4\%$  vs.  $28.3 \pm 2.8\%$ ;  $P < 0.004$ ), twice as many visits requiring WD changes ( $24.7 \pm 3.5\%$  vs.  $10.7 \pm 2.7\%$ ;  $P < 0.005$ ) and one month less between dose adjustments ( $45.0 \pm 6.5$  vs.  $77.9 \pm 7.7$  days;  $P < 0.004$ ). These differences were consistent with increased INR SD in RD patients ( $0.64 \pm 0.05$  vs.  $0.51 \pm 0.03$ ;  $P < 0.03$ ).

**CONCLUSIONS:** We propose that renal dysfunction contributes to

previously unaccounted for warfarin dose-response variability. In addition, INR instability requires more frequent and intensive management of RD patients and may also increase their risk for thrombosis and bleeding, potentially increasing healthcare utilization.

**56. Comparison of intravenous and subcutaneous heparin conversion methods.** Avinash S. Patil, M.D.,<sup>1</sup> Tracy Clapp, Pharm.D.,<sup>2</sup> Kan Gaston, Pharm.D.,<sup>2</sup> David Kuhl, Pharm.D.,<sup>3</sup> Eliza Rinehart, Pharm.D.,<sup>2</sup> Norman L. Meyer, M.D.<sup>1</sup>; (1)Department of Obstetrics & Gynecology, University of Tennessee Health Science Center, Memphis, Tennessee, USA; (2)Department of Pharmacy, The Regional Medical Center at Memphis, Memphis, Tennessee, USA; (3)School of Pharmacy, Union University, Jackson, Tennessee, USA.

**OBJECTIVES:** Two options exist for conversion to unfractionated heparin (UFH) for anticoagulation of venous thromboembolic events (VTE) during pregnancy: IV therapy followed by adjusted-dose subcutaneous UFH (IV→SC), or adjusted-dose subcutaneous UFH alone (SC only). Our goal was to determine if either approach provided an advantage for antepartum conversion to UFH.

**METHODS:** A 5-year retrospective chart review identified patients with VTE events requiring therapeutic anticoagulation antepartum, and subsequent conversion to UFH at 36 weeks gestational age. Patient demographics, UFH dosing regimens, and time to therapeutic levels were analyzed with appropriate statistical methods (*t*-test,  $\chi^2$ ).

**RESULTS:** Thirty-one gravidas were identified that met the inclusion criteria. Of these, 16 underwent IV→SC conversion, while 15 were converted with SC only. Characteristics were compared between the groups, including gestational age at admission ( $p=0.7080$ ) and discharge ( $p=0.9905$ ), age ( $p=0.0495$ ), ideal body weight ( $p=0.1008$ ), weight ( $p=0.6005$ ), and BMI ( $p=0.4399$ ). A 36% increase ( $p=0.0007$ ) between end-infusion and end-SC therapeutic doses was seen within the IV→SC group. Additionally, the end-SC therapeutic dose was 24% greater ( $p=0.0485$ ) than in the SC only group. The total time to complete conversion to UFH within the IV→SC group was  $74.5 \pm 44.6$  hours (infusion:  $32.1 \pm 33.4$  hours, SC:  $42.4 \pm 26.2$  hours), compared to  $41.0 \pm 27.1$  hours for the SC only group ( $p=0.0183$ ).

**CONCLUSIONS:** With the exception of age (IV→SC: 25 years; SC only: 28 years), the demographics were similar between both groups. Conversion to UFH by a SC only regimen allows the patient to reach therapeutic levels quicker with a lower dose of medication.

## Herbal/Complementary Medicine

**57. Effects of Nigella Sativa oil on cutaneous wound healing in rats.** Fikret V. Izzettin, Prof.,<sup>1</sup> Yasemin Varol, M.Sc.,<sup>1</sup> Sule Apikoglu-Rabus, Ph.D.,<sup>1</sup> Adile Cevikbas, Prof.<sup>2</sup>; (1)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (2)Marmara University Faculty of Pharmacy, Pharmaceutical Microbiology Department, Istanbul, Turkey.

**OBJECTIVES:** Due to its antiinflammatory, antioxidant, antibacterial and antifungal effects *Nigella Sativa* can be a beneficial agent for wound healing. The aim of the study was to assess the effects of *Nigella sativa* oil on cutaneous wound healing in rats.

**METHODS:** The study was conducted on female Wistar rats. Rats were randomized to the following five groups: rats receiving topical injectable water (n=6); rats receiving topical mupirocin (n=6); rats receiving topical sesame oil (n=6); rats receiving topical *Nigella sativa* oil (n=6); rats receiving both topical and intraperitoneal *Nigella sativa* oil (n=6). Two 0.6 mm round, full-thickness excision wounds were created on the dorsal thoracic area of each rat. Animals received test or control preparations until the end of experiment (day 15). Wound healing was assessed by "wound contraction rate" and "complete epithelization time".

**RESULTS:** Complete epithelization times for the rats receiving 'topical *Nigella sativa* oil' and 'both topical and intraperitoneal *Nigella sativa* oil' were found to be shorter than those observed for the control groups receiving 'topical injectable water', 'topical mupirocin' and 'topical sesame oil' ( $9.83 \pm 0.42$ ;  $9.5 \pm 0.34$ ;  $11.08 \pm 0.36$ ;  $11.83 \pm .46$  and  $11.17 \pm 0.46$  days respectively;  $p<0.05$ ). Rats receiving 'topical *Nigella sativa* oil' and those receiving 'both topical and intraperitoneal *Nigella sativa* oil' had higher wound closure rates than the control groups after the second day. Though not statistically significant, rats receiving 'both

topical and intraperitoneal *Nigella sativa* oil' had higher wound closure rates than those receiving only 'topical *Nigella sativa* oil' ( $p>0.05$ ).

**CONCLUSIONS:** The results suggest that topical *Nigella sativa* oil application either alone or in combination with systemic administration, accelerates cutaneous wound healing in rats.

## HIV/AIDS

**58. Assessment of HIV-infected patients: a response to the American Heart Association initiative to reduce cardiovascular risk.** Kelly Hester, Pharm.D., BCPS, Cara L. Leos, Pharm.D., BCPS; Auburn University Harrison School of Pharmacy, Auburn, Alabama, USA.

**PURPOSE:** The American Heart Association (AHA) recently reported that the Framingham cardiovascular (CV) risk calculation may underestimate the risk of coronary heart disease in the HIV population, especially smokers. Antiretroviral (ARV) therapy approximately confers a 1.7-fold increased risk of myocardial infarction (MI) with the highest risk in those treated with protease inhibitors (PIs). The risk of MI is not entirely attributed to lipid changes on ARV therapy. Three years ago, 81% of ARV-treated patients in an HIV clinic were without lipid monitoring for the duration of treatment, and 93% had an untreated indication for lipid lowering therapy. In light of this new initiative from the AHA, this study was designed to re-evaluate frequency of lipid monitoring in the same clinic.

**OBJECTIVES:** To evaluate frequency of lipid monitoring, CHD risk stratification (Framingham risk score), tobacco abuse, and exposure to protease inhibitors in an HIV population.

**METHODS:** Chart reviews were conducted on 102 patients evaluating CV risk factors, past and current ARV, and prescription medications. Framingham risk scores were calculated for patients with available lipid information.

**RESULTS:** Routine lipid monitoring was observed in 78% of patients. The CHD risk stratification (<10%, 10–20% and >20%) were 85%, 11%, and 3% respectively, including 2% with known CHD. Fifty percent of patients were currently on PIs and 37% were previously exposed to  $\geq 2$  PIs. Of the 42% who smoked, 17% had uncontrolled hypertension, 23% were on PIs, and 8% had uncontrolled LDL values.

**CONCLUSIONS:** Although 85% of this population is considered low risk by current standards, Framingham scoring may under-predict CV risk in the HIV population. While lipid monitoring with pharmacist intervention has significantly improved in this clinic, more aggressive CV risk reduction efforts (hypertension and smoking cessation) are warranted targeting PI-treated smokers as highlighted by the recent AHA initiative.

**59. Lipid lowering effects of rosuvastatin in HIV-infected patients on highly active antiretroviral therapy.** Humberto R. Jimenez, Pharm.D., BCPS,<sup>1</sup> Stephen Esker, Pharm.D.,<sup>2</sup> Alexander Ganetsky, Pharm.D.,<sup>3</sup> Jihad Slim, M.D.<sup>1</sup>; (1)Saint Michael's Medical Center, Newark, NJ; (2)Bristol-Myers Squibb Company, Plainsboro, New Jersey, USA.

**OBJECTIVES:** This study documented (1) the lipid-lowering effects of rosuvastatin in the HIV+ population, and (2) evaluated differences in rosuvastatin's efficacy among different antiretroviral (ART) regimens.

**METHODS:** Medical records of 83 HIV+ patients treated with rosuvastatin at the Peter Ho HIV Clinic between March 2004 and October 2008 were reviewed. Patients over 18 years of age, receiving ART, and rosuvastatin for at least 3 months were included in this analysis. Patients on concurrent antilipidemics were excluded. Patients' demographics, baseline CD4 count, viral load, and medications were documented. Lipid panel, including serum total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL), and triglycerides (TG) were analyzed.

**RESULTS:** Twenty five patients met the criteria. Statistical analyses compared baseline lipid panel with those at Week 12. Patients receiving rosuvastatin therapy experienced significantly lowered TC levels (256 vs. 213 mg/dL,  $p=0.013$ ), significantly lowered LDL levels (151 vs. 114 mg/dL,  $p=0.0035$ ), as well as significantly improved TC:HDL ratio (5.3 vs. 4.1,  $p=0.032$ ). 44% and 32% of patients were on a lopinavir/ritonavir or an efavirenz-based regimen. Patients on lopinavir/ritonavir had a greater reduction in TC than the efavirenz patients ( $P=0.0498$ ).

**CONCLUSIONS:** Although recent data questions the pharmacokinetic profile and lipid lowering effect of rosuvastatin in healthy volunteers

receiving ART, our study demonstrated therapeutic benefit of this agent in HIV+ patients receiving ART throughout a 6-month period. Further studies are needed to verify the value and safety of rosuvastatin in this population.

## Infectious Diseases

**60. The effect of desferrioxamine as supplement to cefotaxime in the treatment of spontaneous bacterial peritonitis.** Manal H. El Hamamsy, Ph.D., Nehal A., Mohamed R., Mohamed A. Abou-Seada, ElwakilAl-Azizi., M.D., Ph.D.; Faculty of Pharmacy, Ain Shams University, Cairo, Egypt.

**OBJECTIVES:** To assess the efficacy of the iron chelating agent Desferrioxamine supplemented to the antibiotic therapy in the treatment of Spontaneous Bacterial Peritonitis (SBP) in cirrhotic patients.

**METHODS:** thirty patients admitted in In-patient units of the Tropical disease department of Ain Shams University Hospitals and Tanta University Hospitals. during the period of October 2006 to October 2007 divided into two groups: Group I (n=15) with SBP and receiving Cefotaxime (1g IV every 12 hours) alone and Group II (n=15) with SBP receiving Cefotaxime (1g IV every 12 hours) with desferrioxamine (500mg IM twice daily). all patient were monitored for seven days, their vital organs were screened and their ascitic fluid was assessed completely including microbiological investigations.

**RESULTS:** The concomitant administration of Desferrioxamine with Cefotaxime significantly at ( $p < 0.001$ ) and ( $p < 0.01$ ) improved the therapeutic outcome and the cure rate after 5 days of treatment as compared to patients using cefotaxime only.

**CONCLUSIONS:** Desferrioxamine can improve the therapeutic outcome through reduction of the time required for complete cure (defined as resolution or disappearance of all signs and symptoms of SBP, detection of no bacteria in the peritoneal fluid, normalization of polymorphonuclear count) by preventing iron-induced organ damage and inhibiting bacterial growth.

**61. Steady-state pharmacokinetics and pharmacodynamics of piperacillin/tazobactam, administered by prolonged infusion, in hospitalized patients.** Katherine M. Shea, Pharm.D.,<sup>1</sup> S. Christian Cheatham, Pharm.D.,<sup>2</sup> David W. Smith, Pharm.D.,<sup>1</sup> Matthew F. Wack, M.D.,<sup>3</sup> Kevin M. Sowinski, Pharm.D.,<sup>4</sup> Michael B. Kays, Pharm.D.<sup>4</sup>; (1)Clarian Health Partners, Inc., Methodist Hospital, Indianapolis, IN; (2)St. Francis Hospitals and Health Centers, Beech Grove, IN; (3)Infectious Diseases of Indiana, Indianapolis, IN; (4)Purdue University School of Pharmacy, Indianapolis, Indiana, USA.

**OBJECTIVES:** Prolonging the infusion time is a strategy to optimize  $\beta$ -lactam pharmacokinetics/ pharmacodynamics (PK/PD). The objective of this study was to evaluate the steady-state PK/PD of piperacillin/tazobactam (P/T), administered by prolonged infusion, in hospitalized patients.

**METHODS:** Patients with a suspected or proven bacterial infection and an estimated CLcr  $\geq 40$  ml/min were enrolled. Patients received P/T 4.5 g IV q8h, infused over 4h. Serial blood samples were obtained after  $\geq 2$  days, and P/T concentrations were determined by HPLC. PK parameters were determined by noncompartmental methods. Using the PD target of 50% fT>MIC, Monte Carlo simulations (10,000 patients) were performed to calculate the cumulative fraction of response (CFR) for 7 gram-negative pathogens (MYSTIC 2004–2007, USA) and the probability of target attainment (PTA) at MICs ranging from 1 to 64  $\mu$ g/ml.

**RESULTS:** 13 patients were studied. Mean  $\pm$  SD age, weight, and CLcr were 53  $\pm$  13 yr, 80  $\pm$  14 kg, and 83  $\pm$  42 ml/min, respectively. P and T PK parameters (mean  $\pm$  SD) were as follows:

	$C_{max}$ ( $\mu$ g/ml)	$C_{min}$ ( $\mu$ g/ml)	$t_{1/2}$ (h)	CLs (L/h)	$V_{ss}$ (L)	$V\beta$ (L)
Piperacillin	108.2	27.6	2.1	8.6	22.1	21.8
	$\pm 31.7$	$\pm 26.3$	$\pm 1.2$	$\pm 3.0$	$\pm 4.0$	$\pm 5.1$
Tazobactam	21.7	4.4	2.5	6.5	20.3	21.7
	$\pm 7.8$	$\pm 3.1$	$\pm 1.2$	$\pm 2.4$	$\pm 9.2$	$\pm 7.8$

CFR was  $\geq 91.3\%$  for *E. coli*, *Citrobacter* species, and *S. marcescens*, 88.6% for *Enterobacter* species, 87% for *K. pneumoniae*, 85.5% for *P. aeruginosa*, and 52.8% for *Acinetobacter* species. PTA was 1.00, 0.81, and 0.12 at MICs  $\leq 16$ , 32, and 64  $\mu$ g/ml, respectively.

**CONCLUSIONS:** P/T 4.5 g q8h, infused over 4 h, provides excellent target attainment for organisms with MICs  $\leq 16$   $\mu$ g/ml in hospitalized patients. However, CFR was  $< 90\%$  for 4 of the 7 gram-negative pathogens evaluated.

**62. Comparative pharmacodynamics of intermittent and prolonged infusions of piperacillin/tazobactam using pharmacokinetic data from hospitalized patients.** Katherine M. Shea, Pharm.D.,<sup>1</sup> S. Christian Cheatham, Pharm.D.,<sup>2</sup> Matthew F. Wack, M.D.,<sup>3</sup> David W. Smith, Pharm.D.,<sup>1</sup> Kevin M. Sowinski, Pharm.D.,<sup>4</sup> Michael B. Kays, Pharm.D.<sup>4</sup>; (1)Clarian Health Partners, Inc., Methodist Hospital, Indianapolis, Indiana, USA; (2)St. Francis Hospitals and Health Centers, Beech Grove, Indiana, USA; (3)Infectious Diseases of Indiana, Indianapolis, Indiana, USA; (4)Purdue University School of Pharmacy, Indianapolis, Indiana, USA.

**OBJECTIVES:** To compare the pharmacodynamics (PD) of several dosing regimens of piperacillin/tazobactam (P/T) administered by intermittent infusion (II) and prolonged infusion (PI) using pharmacokinetic (PK) data from hospitalized patients.

**METHODS:** 13 patients with suspected or proven bacterial infections and estimated CLcr  $\geq 40$  ml/min were studied. Patients received P/T 4.5g IV q8h, infused over 4 hr, and serial blood samples were collected after  $\geq 2$  days. P/T concentrations were determined by HPLC, and PK parameters were determined by noncompartmental methods. Monte Carlo simulations (10,000 patients) were performed for 8 different P/T dosing regimens: 4 II regimens (0.5 hr infusion) and 4 PI regimens (4 hr infusion). The probability of target attainment (PTA) for 50% fT>MIC was calculated for each regimen at MICs ranging from 1 to 64  $\mu$ g/ml. Regimens were considered optimum if the PTA was  $\geq 90\%$ .

**RESULTS:** PK parameters for P (mean  $\pm$  SD) were as follows: CLs 8.6  $\pm$  3.0 L/h;  $t_{1/2}$  2.1  $\pm$  1.2 h;  $V\beta$  21.8  $\pm$  5.1 L. PTA (%) was as follows:

	4 $\mu$ g/ml	8 $\mu$ g/ml	16 $\mu$ g/ml	32 $\mu$ g/ml	64 $\mu$ g/ml
3.375 g II q6h	0.97	0.92	0.79	0.48	0.07.
4.5 g II q8h	0.93	0.86	0.71	0.43	0.10.
4.5 g II q6h	0.98	0.95	0.87	0.64	0.21.
3.375 g II q4h	0.99	0.99	0.94	0.73	0.19.
2.25 g PI q8h	1.00	1.00	0.81	0.12	0.00.
3.375 g PI q8h	1.00	1.00	0.98	0.51	0.02.
4.5 g PI q8h	1.00	1.00	1.00	0.81	0.12.
6.75 g PI q8h	1.00	1.00	1.00	0.98	0.51.

**CONCLUSIONS:** PI regimens of P/T provide optimum PD at lower daily doses compared to II regimens at MICs  $\leq 16$   $\mu$ g/ml. Only 6.75 g PI q8h was optimum at a MIC of 32  $\mu$ g/ml, but no regimen was optimum at an MIC of 64  $\mu$ g/ml.

**63E. Implications of phenotypic clustering on predicting future trends of antimicrobial resistance patterns.** Steven M. Smith, Pharm.D., John G. Gums, Pharm.D.; University of Florida, Gainesville, Florida, USA.

**OBJECTIVES:** Increasing resistance among bacteria has created a need to develop new methods for predicting future antimicrobial susceptibility patterns. This study intended to determine whether clustering similar resistance phenotypes is capable of redefining resistance tracking and predicting future resistance trends.

**METHODS:** We performed two experiments with data collected from hospitals participating in the Antibiotic Resistance Management (ARM) Program. *E. coli* isolate susceptibility data (n=9660 isolates) was collected from several hospitals between 2004 and 2007. Isolate data was grouped into five phenotypic clusters and analyzed over time. Secondly, *S. aureus* isolate data between 1992 and 2006 were analyzed. This data was grouped into 3 phenotypic clusters for analysis.

**RESULTS:** For *E. coli*, each of the 5 clusters showed distinct patterns of resistance with cluster 2 showing nearly 100% susceptibility to all drugs, whereas cluster 5 showed  $< 80\%$  susceptibility to all drugs except carbapenems and amikacin. Cluster 2 prevalence decreased from 55% in 2004 to 45% in 2007, whereas cluster 1 (resistance to early generation cephalosporins) prevalence doubled from 10% to 20% over the same time period. The prevalence of clusters 3, 4, and 5 did not change appreciably. For *S. aureus*, all 3 clusters showed susceptibility patterns greater than 50% over the entire time period. Cluster 1 prevalence diminished from nearly 100% in 1992 to 50% in 2006, whereas clusters 2 and 3 increased from 0% to 23% and 27%, respectively.

**CONCLUSIONS:** Using a bayesian mixture model, we were able to categorize patterns of antibiotic resistance into clusters and analyze them over time. This method may have implications for predicting future resistance patterns. This technique may be especially useful to antimicrobial stewardship committees for developing appropriate prescribing guidelines in anticipation of future resistance patterns with a goal of curtailing further deterioration of antimicrobial activity.

Presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)/46th Annual Meeting of the Infectious Diseases Society of America, Washington, DC, USA., October 25–28, 2008.

**64E. Outcomes associated with the implementation of a national antibiotic surveillance program.** Steven M. Smith, Pharm.D., John G. Gums, Pharm.D.; University of Florida, Gainesville, Florida, USA.

**OBJECTIVES:** The IDSA published guidelines in 2007 for development and implementation of institutional programs to reduce resistance and improve antimicrobial stewardship. The “Bugs and Drugs” Program, an initiative developed by the Antimicrobial Resistance Management (ARM) Program and VHA East Coast, tracks antibiotic use and susceptibility rates and develops recommendations for participating VHA institutions. The objective of this study is to document preliminary results of using this program to help curtail antibiotic resistance within a single institution.

**METHODS:** Recommendations were presented to Hunterdon Medical Center, a 178-bed non-profit community hospital, in the fall of 2006. Between February and August of 2007, the institution’s Antibiotic Subcommittee instituted changes consistent with the summary recommendations made by the program. Susceptibility data for 2006 and 2007 were collected and analyzed for changes in antimicrobial resistance semiannually.

**RESULTS:** Gram negative bacteria including *E. coli*, *K. pneumoniae*, and *P. aeruginosa* displayed a  $\geq 5\%$  increase in susceptibility for 56%, 87% and 78% of drugs, respectively, from 2006 to 2007. Susceptibility to *E. coli* decreased for 3 out of 16 (19%) drugs, whereas there was no decrease in susceptibility for *K. pneumoniae* and a 7% fall in susceptibility for cefepime against *P. aeruginosa*. Susceptibility to methicillin among isolates of *S. aureus* increased from 36% in 2005 to 44% in 2006 and 47% in 2007.

**CONCLUSIONS:** Partnerships between a national surveillance system and a hospital alliance can help antibiotic stewardship efforts in improving antibiotic use and decreasing antibiotic resistance within an institution. Following implementation of the program’s recommendations, there were significant improvements in antibiotic susceptibility among isolates of *E. coli*, *K. pneumoniae*, *P. aeruginosa* and *S. aureus*.

Presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)/46th Annual Meeting of the Infectious Diseases Society of America (ISDA), Washington, District of Columbia, USA, October 25–28, 2008.

**65. Use of antibiotic lock therapy in a treatment modality for catheter-related bloodstream infections.** P. Brandon Bookstaver, Pharm.D.,<sup>1</sup> Katherine R. Gerrald, Pharm.D.,<sup>2</sup> Robert R. Moran, Ph.D.<sup>3</sup>; (1)South Carolina College of Pharmacy-USC Campus, Columbia, SC; (2)Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina; (3)Health Sciences Research Core - University of South Carolina, Columbia, South Carolina, USA

**OBJECTIVES:** Catheter-related bloodstream infections (CRBSI) are a primary concern in patients with indwelling central venous catheters (CVC). Antibiotic lock therapy (ALT) may be considered as adjunctive therapy when catheter removal is not a favorable option. The objective of this study is to evaluate outcomes of ALT used for treatment of CRBSI.

**METHODS:** This was a retrospective study conducted at a tertiary medical center evaluating patients treated with ALT for CRBSI. Patients who received ALT for >24 hours in a treatment modality during the 24-month study period were screened for study inclusion. Patients with documented negative blood cultures prior to ALT initiation were excluded. The primary outcome was blood culture sterilization defined as negative peripheral blood and CVC cultures for 30 days post-ALT.

Secondary outcomes included clinical resolution, CVC salvage, and infectious sequelae. Antibiotic and pathogen-specific outcomes were also evaluated.  $\chi^2$  tests and student’s *t*-tests were used for analysis of categorical and continuous variables respectively, with a predetermined alpha of 0.1.

**RESULTS:** Twenty-six cases were included in data analysis. Patients ranged in age from 5 months to 82 years and the majority (76.7%) of patients had a CVC for total parenteral nutrition or chemotherapy. Antibiotics utilized in lock solutions included vancomycin (n=8), daptomycin (n=6), gentamicin (n=6), ethanol (n=1), and combination (n=5). Majority of CRBSI cases were caused by Staphylococcal species (59%). Blood culture sterilization was achieved in 69.2% of cases and sterilization with CVC retention was achieved in 11 cases (42.3%). Longer duration of ALT was significantly correlated with blood culture sterilization (OR=1.367, p=0.077). No infectious sequelae were attributed to CVC retention.

**CONCLUSIONS:** ALT used as an adjunct to systemic therapy for adequate duration in CRBSI can achieve catheter sterilization and CVC retention without infectious complications. ALT is an option for select patients, avoiding the risks associated with CVC replacement.

**66. Place of rapid diagnostic tests of pharyngitis in the practice of medicine in community in Pays de la Loire November 2006 to January 2007.** Marie Pajot, Pharm.D.,<sup>1</sup> Christophe Leux, M.D.,<sup>2</sup> Nathalie Asseray, M.D., Ph.D.,<sup>3</sup> Remy Senand, M.D.,<sup>4</sup> François Garnier, M.D.,<sup>5</sup> Gilles Potel, M.D., Ph.D.,<sup>3</sup> Pierre Lombrail, M.D., Ph.D.,<sup>6</sup> Françoise Ballereau, Pharm.D., Ph.D.<sup>7</sup>; (1)MEDQUAL, Nantes, France; (2)PIMESP, Nantes, France; (3)UPRES EA 38 26, Faculté de Médecine, Nantes; (4)Departments of General Medicine, Nantes, France; (5)Departments of General Medicine, Angers, France; (6)PIMESP, Nantes; (7)MEDQUAL, Nantes, France

**OBJECTIVES:** A strategy of management of pharyngitis based on the rapid diagnostic tests (RDT) of streptococci was proposed in France since 1996 to reduce the use of antibiotics. Since the availability of these tests in 2002, the french guidelines (AFSSAPS) advocate their use to limit the antimicrobial therapy to patients with symptomatic pharyngitis only if the presence of SGA is confirmed by RDT.

**METHODS:** During the winter of 2006–2007, a survey was conducted to evaluate if the use of RDT was applicable to general practice and if there was an impact on antibiotics prescription.

**RESULTS:** Data were collected from 525 patients, included for “sore throat”. Two hundred forty-three RDT was practiced. Patients for whom RDT was made were mostly patients with fever, patients with lymphadenopathy, patients with amygdale injury and patients were 3 to 15 years old. The 60 positive RDT patients systematically received an antibiotic. Despite the recommendations, 20 negative RDT patients received an antibiotic. When patients had pharyngitis symptoms, the frequency of antibiotic prescription was higher when the RDT was not used. Although over 75% of GP considered the RDT useful or very useful, less than 50% want to use them because they won’t be refunded anymore.

**CONCLUSIONS:** The use of RDT increased the number of patient who are appropriately treated for streptococcal pharyngitis. The guidelines on management of pharyngitis are applicable in general practice and relatively well respected.

**67. Linezolid compared to vancomycin for the treatment of osteomyelitis.** Ryan P. Moenster, Pharm.D.,<sup>1</sup> Patrick M. Finnegan, Pharm.D.,<sup>1</sup> Travis W. Linneman, Pharm.D.,<sup>1</sup> Rodney Lusk, M.D.<sup>2</sup>; (1)John Cochran VA Medical Center/St. Louis College of Pharmacy, St. Louis, Missouri, USA; (2)John Cochran VA Medical Center, St. Louis, Missouri, USA.

**OBJECTIVES:** Treating osteomyelitis (OM) requires long-term intravenous (IV) antibiotic therapy. Even with appropriate therapy, recurrence of infection is still as high as 50% within one year. Oral linezolid would be an attractive option for patients being treated for resistant gram-positive OM, however clinical data is limited and previous studies indicate questionable bone penetration.

**METHODS:** A retrospective, case-control study of all patients at a VA Medical Center between January 2000 and July 2006 who received linezolid for the treatment of a first case of OM was undertaken. Patients

must have had a diagnosis of OM, received at least 2 weeks of linezolid, and have had at least 1 follow-up visit 6 months after therapy. Each patient was then matched with 2 controls treated with at least 2 weeks of vancomycin. Matching criteria included site of OM, hardware involved, surgical therapy, and presence of comorbid conditions. The primary outcome was recurrence of infection within six months of discontinuation of initial therapy. Thrombocytopenia and documentation of peripheral or optic neuropathy were also evaluated. Fisher's exact test was utilized to compare rates of recurrence between groups.

**RESULTS:** Ten patients were found to have received at least 2 weeks of linezolid for a first incidence of OM. Fifty percent of patients receiving linezolid had a recurrence of infection compared to 47% in the vancomycin group ( $p=1.00$ ). Five patients on linezolid developed thrombocytopenia, while no cases were observed in the vancomycin group. No additional adverse effects were reported.

**CONCLUSIONS:** In a limited number of cases, no significant difference in recurrence of infection was observed. The 50% in both groups experiencing a recurrence of infection is consistent with previous data. Linezolid has demonstrated limited bone penetration, but the similar rates of recurrence in this analysis suggest further evaluation in the setting of OM may be warranted.

**68. Cefepime is not associated with increased mortality in pediatric cancer patients.** Jamie Frediani, B.S., Elisabeth E. Adderson, M.D., Patricia Flynn, M.D., M.S., Michael J. Herr, B.S., James M. Hoffman, Pharm.D., M.S., BCPS; St. Jude Children's Research Hospital, Memphis, Tennessee, USA.

**OBJECTIVES:** Recently, two systematic reviews suggested the risk of 30-day all-cause mortality is greater in patients treated with cefepime compared to those treated with other  $\beta$ -lactam antibiotics, particularly in neutropenic patients. These data prompted an ongoing FDA safety investigation of cefepime. Since 1987, our institution has had guidelines for antibiotic use in pediatric cancer patients. From 1989–2001, ceftazidime was recommended for empirical therapy of suspected bacterial infection; thereafter, cefepime was recommended. To determine the safety of cefepime, we compared outcomes of pediatric oncology patients treated with cefepime with contemporaneous patients treated with ceftazidime.

**METHODS:** Medical records of patients receiving either cefepime or ceftazidime from 2000–2002 were retrospectively reviewed. Recipients of stem cell transplants within the past year were excluded. Only the first episode of treatment was included; patients who received the alternate drug subsequently were also excluded.

**RESULTS:** 1106 courses of cefepime and ceftazidime were identified; 543 met the eligibility criteria (347 ceftazidime, 196 cefepime). The groups were similar in age, race, sex, underlying malignancy, and duration of antibiotic course and hospital days. Illness severity was similar with no difference in the frequency of neutropenia, ICU admission or the use of mechanical ventilation. There was a trend toward more frequent grade 3 hypotension ( $p=0.05$ ) and more microbiologically-confirmed infections ( $p=0.07$ ) in the cefepime group. There were 2 deaths in the cefepime group and 1 in the ceftazidime group within 30 days and 4 and 8 deaths, respectively, within 90 days ( $p>0.05$ ) of the start of treatment. Infection was the cause of death in 1 and 2 patients, respectively. There was no difference in the number of cefepime or ceftazidime adverse events.

**CONCLUSIONS:** All-cause mortality did not differ in pediatric cancer patients receiving either cefepime or ceftazidime. Cefepime remains a rational and safe choice for empirical antimicrobial therapy in this population.

## International Pharmacy Education Affiliations

**69E. Survey of US colleges/schools of pharmacy concerning international education and research relationships update: past, present and future.** Rosalie Sagraves, Pharm.D.,<sup>1</sup> Bruce Currie, Ph.D.,<sup>2</sup> Joseph Dean, Ph.D.<sup>3</sup>; (1)University of Illinois at Chicago, Naperville, Illinois; (2)University of California Davis, Davis, California; (3)Samford University, Birmingham, Alabama, USA.

**OBJECTIVES:** A survey of US pharmacy colleges/schools was undertaken in 2007 to illustrate their involvement with international

educational institutions, medical facilities, companies, etc. It was accomplished in association with the American Association of Colleges of Pharmacy (AACCP).

**METHODS:** Survey data were collected and analyzed using Survey Monkey. Then results were compared with applicable information obtained from a 2001 survey on this topic.

**RESULTS:** From 2001 survey results of 65 responding colleges/schools, 26 had one or more formal affiliations with 21 having informal affiliations. Data from 66 colleges/schools responding to the 2007 survey indicated that 28 had one or more formal affiliations with 21 having informal relationships with international universities, medical facilities and/or companies. The largest numbers of formal agreements (2007 survey) were for research ( $n=66$ ) and Pharm.D. clerkships/rotations ( $n=62$ ); greatest numbers of informal agreements were also for research ( $n=6$ ) and clerkships/rotations ( $n=7$ ). Other examples of engagement included clinical practice, observations, graduate student education, postdoctoral training, business partnerships, and faculty, student and practitioner exchanges. Examples of 2001 involvement included hosting students, residents, post-doctoral fellows and visiting scholars; fostering research collaborations; faculty serving as consultants, presenting lectures and speaking during international symposia. As noted in the 2007 survey, 26 colleges/schools planned to increase international affiliations, 4 planned to maintain relationships at current levels while none planned a decrease. US colleges/schools responded (2007 survey) that they benefited from international affiliations in research collaborations ( $n=23$ ), graduate student recruitment ( $n=15$ ), postdoctoral recruitment ( $n=8$ ), various student activities ( $n=15$ ) and Pharm.D. clerkship/rotation sites ( $n=19$ ).

**CONCLUSIONS:** International relationships provide opportunities for professional growth and scholarship for faculty and students. Countries globally are developing collaborations with US institutions for help in establishing Pharm.D. programs and expanding Ph.D. education as well as increasing research collaborations. An AACCP Global Pharmacy Education SIG has been established to foster international academic relationships.

Presented at the World Congress of Pharmacy and Pharmaceutical Sciences 2008, 68th International Congress of FIP, Basel, Switzerland, August 29–September 4, 2008; Abstract AS-O-006.

## Managed Care

**70. Prevalence of diabetes in a managed care organization and healthcare resource utilization in patients with diabetes and hemoglobin HbA1c above goal.** S. Scott Sutton, Pharm.D., Julie M. Sease, Pharm, D; South Carolina College of Pharmacy, Columbia, South Carolina, USA.

**OBJECTIVES:** To describe prevalence of diabetes and percentage of patients controlled within a managed care organization. To report rate of inpatient admissions and emergency department visits for poorly controlled patients in an effort to improve delivery of care.

**METHODS:** This was a retrospective observational analysis of patients with diabetes. Areas of interest were diagnosis, laboratory monitoring, therapeutic control, renal function screening, and identification of unique patients whose parameters did not meet national goal standards and may, therefore, represent a high risk population for frequent admissions or emergency department visits. This analysis identified a cohort of patients with diabetes by primary or secondary coded diagnosis (ICD-9) or through recorded laboratory result for hemoglobin A1c (HbA1c) in the medical chart.

**RESULTS:** There were 63,951 unique patients enrolled and 18,886 with an ICD-9 code for diabetes. Of these, 12% had heart failure, 90% had hypertension, 86% had lipid disorders, 32% had obesity, 26% had COPD, and 29% had depression. There were 16,581 patients that were tested for HbA1c (number of HbA1c values in 2007 was 45,371). Forty nine percent had an HbA1c less than 7%, 89% less than 9%, 11% greater than or equal to 9%, and 3% greater than or equal to 11%. Of patients with diabetes and HbA1c values greater than or equal to 9%, 2% had three or more emergency department visits, 1% had three or more inpatient admissions, and 1% of patients were re-admitted to the hospital within 30 days.

**CONCLUSIONS:** The high prevalence of diabetes within our institution presents challenges to optimal outcomes. The majority of patients were tested for HbA1c and approximately 50% had an HbA1c less than 7%.

We were able to identify patients not at goal in an effort to institute a system which would ensure appropriate follow-up to reduce emergency department visits, inpatient admissions, and ultimately improve care.

**71. Mortality, lipid monitoring, and therapeutic control of patients coded for myocardial infarction within the past five years and seen at least once in a primary care clinic.** Julie M. Sease, Pharm.D., S. Scott Sutton, Pharm.D.; South Carolina College of Pharmacy, Columbia, South Carolina, USA.

**OBJECTIVES:** To describe the mortality, lipid monitoring, and therapeutic control for patients coded for myocardial infarction (MI) in a managed care organization over a five year period.

**METHODS:** This was a retrospective observational analysis of patients coded for MI from 2003–2007. The areas of interest were diagnosis of myocardial infarction, laboratory monitoring of low-density lipoprotein cholesterol (LDL-C), therapeutic control, and mortality. Patients diagnosed with a MI in the past 5 years, as well as the percent of deceased patients during this period, were evaluated. Survivors were evaluated for LDL-C testing and LDL-C results less than or equal to 100 mg/dL, greater than 100 mg/dL, and greater than 150 mg/dL.

**RESULTS:** There were 54,180 patients with a diagnosis of myocardial infarction over the 5 year period. Of these patients, 19,641 (36%) died. Of the 34,539 surviving patients, 91% were seen in the primary care clinic at least once. Ninety percent of surviving patients had a LDL-C monitored and 73% were less than 100 mg/dL, 27% were greater than 100 mg/dL, and 5% were greater than 150 mg/dL.

**CONCLUSIONS:** The high prevalence of MI within our institution presents challenges to ensuring optimal outcomes. There was a high mortality rate over a 5 year period. The majority of survivors were followed at least once in a primary care clinic. However, 3,250 patients were not seen in a clinic and lost to follow-up. Even though the majority of patients had an LDL-C less than 100 mg/dL, 27% were not at goal. Given the high mortality rate following MI, opportunity exists for healthcare providers to improve the care of patients with a history of myocardial infarction. Patients that have not had a follow-up appointment or are not at LDL-C goal would be a set of patients likely to benefit from optimal medical treatment.

## Medication Safety

**72. Administration of medicines to older patients with dysphagia—is it optimal?** Jennifer C. Kelly, M.Sc., B.A.(Hons), R.G.N., Dip.N., Dip.N.Ed., David J. Wright, Ph.D., B.Pharm.(Hons), PGCHE; University of East Anglia, Norwich, Norfolk, United Kingdom.

**OBJECTIVES:** To identify the frequency and type of errors nurses make when administering medications to patients with dysphagia in acute general hospitals.

**METHODS:** Using undisguised direct observation 8 medicine administration rounds were observed on a stroke ward and elderly care ward at each of 4 hospitals in Eastern England between March 1 and June 30 2008. Nurses were observed administering oral medicines to patients with and without dysphagia, including those with enteral tubes and data was collected on medicine preparation and administration. The nurses were each given a questionnaire asking about education received on administering medicines to dysphagic patients.

**RESULTS:** In the 65 drug rounds observed (including the pilot) 2129 potential drug administrations were observed to 622 patients, 210 (33.8%) of whom were dysphagic. The error rate was calculated using the equation Total number of drug errors observed = (Observed errors X 100) divided by Total Opportunities for Error. When normalised this gave a frequency of medicine administration errors for dysphagic patients of 45.3% compared with 35.1% for non-dysphagics (Chi-squared=20.5 (P<0.0001)). Errors were classified using an 11-point system based on the American Society of Hospital Pharmacy's system. Time errors (602) were the most frequent followed by medicine preparation errors (69) and omissions (39). Of the 54 nurse questionnaires returned, 43 nurses identified problems administering medicines to patients with swallowing difficulties.

**CONCLUSIONS:** Medicine administration error rate is greater in dysphagic patients than the general in-patient population due to the complexities of preparing and administering their medicines. Further research is to be carried out to identify if the use of individualized

medicine administration guides can decrease this error rate.

**73E. Educational needs arising from patient safety incident reports related to the use of medicines.** Rose Marie Parr, Ph.D., Hannah Hesselgreaves, Ph.D., Anne Watson, M.Sc. M.Ed.; NHS Education for Scotland, Glasgow, Scotland.

**OBJECTIVES:** This study aimed to investigate the educational needs of healthcare staff based on analysis of medication incidents, staff views on these and review of existing educational programmes in order to propose an educational framework.

**METHODS:** A three stage, mixed methodology was used – analysis of medication incident reports in order to describe common medication errors to generate themes which were presented to three mixed focus groups of healthcare staff, to qualitatively explore how these key areas could be addressed educationally. Structured telephone interviews with programme leads within higher education and NHS in-service training was then undertaken to ascertain the extent to which patient safety generally, and using medicines safely, existed in current education systems.

**RESULTS:** The key areas in the medicine chain, the main drug groups and the types of errors were identified and summarized from the incident reports. The focus groups presented with these results were able to highlight educational needs under four broad themes - doctors' training (focus was on prescribing, (particularly prescribing and preparation of IV medicines) and consistent handwriting protocols; nurses' training (issues included skill mix, as well as their inadequate pharmacology and practical knowledge of drugs); the pharmacists' contribution (particularly the practical use of drugs and checking procedures); and education and training delivery (more exposure to clinical experiences, resourcing limitations, and variability in access to training were considerations in implementing training). The current curriculum content in higher education institutions and in-service training programmes does not directly and formally address the factors raised in patient safety incident data.

**CONCLUSIONS:** Patient safety data can inform areas for education and training across professional groups. A strategy is proposed to consider interventions for medical, nursing and pharmacy education, including formal training, local level improvement cycles, and other small-scale changes to influence attitudes about practices that contribute to patient safety.

Presented at the American Medical Education Europe (AMEE) Conference in Prague, Aug, 30–Sept 3, 2008.

**74E. Identifying, understanding, and overcoming barriers to medication error reporting in hospitals in Nova Scotia, Canada.** Nicole R. Hartnell, M.Sc.<sup>1</sup>, Neil J MacKinnon, Ph.D., FCSHP,<sup>1</sup> Ingrid Sketris, Pharm.D., M.P.A. (HSA),<sup>1</sup> Steven M. Smith, Ph.D.<sup>2</sup>; (1) Dalhousie University, Halifax, Nova Scotia Canada; (2) St. Mary's University, Halifax, Nova Scotia Canada.

**OBJECTIVES:** The purpose of this research was to enhance the understanding about barriers to medication error reporting in health care organizations. The objectives were to: (1) Identify barriers and incentives to medication error reporting; (2) Understand why barriers exist; and (3) Explore how some hospitals have successfully broken down barriers.

**METHODS:** Focus groups (with physicians, pharmacists, and nurses), in-depth interviews (with risk managers), and safety-specific physical artifacts (like error reporting policies and incident report forms) were used to complete a comparative case study analysis of medication error reporting beliefs and practices at four community hospitals in Nova Scotia, Canada. Audio tapes were transcribed verbatim and analyzed for thematic content using the template style of analysis. The development and analysis of this study were guided by Safety Culture Theory.

**RESULTS:** Thematic analysis of the transcripts identified incentives for and barriers to medication error reporting, as well as actions that participants felt could positively facilitate reporting. Incentives were thematized into two categories: patient protection and provider protection. Barriers were classified into four categories: reporter burden, professional identity, information gap, and cultural deficiencies. Positive facilitators were classified into three categories: reducing reporter burden, closing the communication gap, and educating for success.

Participants indicated they would report medication errors more frequently if reporting were made less time and work intensive, if they were adequately educated on all aspects of the reporting process, and if they received timely feedback.

**CONCLUSIONS:** The results of this study may lead to a better understanding of not only the barriers to medication error reporting, but why these barriers exist and what can be done to successfully break them down. These results could be used by hospitals to encourage reporting of medication errors and ultimately make organizational changes leading to a reduction in the incidence of medication errors and an improvement in patient safety.

Presented at the 24th International Conference on Pharmacoeconomics & Therapeutic Risk Management, Copenhagen, Denmark, August 17–20, 2008.

**75. Latent opportunities for errors in medication orders in four health authorities.** Neil J. MacKinnon, B.Sc.(Pharm), M.Sc., Ph.D.,<sup>1</sup> Rumi Pattar, B.Sc.(Pharm), Pharm.D.,<sup>2</sup> Rita Nigam, Ph.D.,<sup>1</sup> Vaneeta K. Grover, M.Sc.,<sup>1</sup> Tiffany T. Nguyen, B.Sc.<sup>1</sup>; (1)Dalhousie University, Halifax, NS, Canada; (2)University of British Columbia, Vancouver, British Columbia Canada.

**OBJECTIVES:** One of the latent opportunities for medication errors in prescribing is use of potentially dangerous abbreviations and dose designations. Little is known about the frequency and potential consequences of errors related to misinterpretation of medication order information in Canada. The objective was to validate a subset of Canadian consensus-approved safety indicators for medication-use systems in four Atlantic health authorities.

**METHODS:** Five medication-use safety indicators selected from a list of 20 such indicators derived using the Delphi technique were prospectively tested for feasibility, reliability and validity in four health authorities. Medications and abbreviations chosen for testing were based on the Institute for Safe Medication Practice's lists of high-alert medications, error-prone abbreviations and dose designation.

**RESULTS:** Over the three-month data collection period, 7113 medication orders were reviewed in each participating health authority. Seventy-seven percent of medication orders had at least one latent opportunity for error according to the composite indicator. Most latent opportunities were related to route of administration and dose unit. Clinical clerks and nurses generated the most latent opportunities, while pharmacists and nurse practitioners generated the least. The percentage of medication orders containing at least one latent opportunity for error was high for all sites. Latent opportunities for error were mostly due to use of "U or u" for units and "SC or SQ" for subcutaneously.

**CONCLUSIONS:** The safety indicators described in this study are feasible and reliable performance measures of safety during medication prescribing. These performance measures will allow organizations to evaluate the frequency and types of potentially dangerous medication abbreviations and dose designations and also, to target selected healthcare providers for further education.

**76. Drug-related hospital admissions: prospective analysis of 3904 patients.** Chuenjid Kongkaew, M.Sc.,<sup>1</sup> Peter Noyce, Ph.D.,<sup>1</sup> Steven Williams, B.Pharm.,<sup>1</sup> David Metcalfe, B.Sc.,<sup>2</sup> Jaydeep Mandal, M.D.,<sup>3</sup> Darren M. Ashcroft, Ph.D.<sup>1</sup>; (1)School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester, United Kingdom; (2)Wrightington, Wigan and Leigh NHS Trust, Wigan, United Kingdom; (3)University Hospital of South Manchester NHS Trust, Manchester, United Kingdom.

**OBJECTIVES:** To determine the current burden of drug-related hospitalisations involving adverse drug reactions, adverse drug events, non-compliance to medication and medication errors.

**METHODS:** Prospective observational study involving 3904 patients aged >16 years admitted to two acute hospital medical admission units and assessed for cause of admission. The main outcome measures were the prevalence of admissions due to specific drug-related problems, preventability, and identification of drugs most commonly involved in drug-related hospital admissions.

**RESULTS:** There were 585 drug-related admissions, providing a prevalence rate of 15.0%, with the drug-related problem directly leading to the admission in 80.5% of cases. Adverse drug events were associated with 554 admissions (14.2%), of which 390 admissions (70.4%) were

classified as due to adverse drug reactions (ADRs) using the ADR definition proposed by the WHO. 191 admissions were associated with non-compliance to medication, in terms of overdose of medication (75.9%) or due to the patient not taking recommended medication (24.1%). Only 19 admissions (0.5%) were due to prescribing, administering or dispensing the wrong drug. Of the drug-related admissions seen, 45.3% were judged to be preventable. The drugs most commonly implicated were diuretics, anticoagulants, antiplatelet drugs and analgesics.

**CONCLUSIONS:** The burden of drug-related hospital admissions is high, accounting for considerable morbidity. Future research should focus on targeting interventions towards specific drug groups which are likely to achieve the greatest impact.

**77. Assessing anticoagulation knowledge in patients new to warfarin therapy.** Amanda R. McFee, Pharm.D.,<sup>1</sup> Kelly M. Rudd, Pharm.D., BCPS,<sup>1</sup> Darren M. Triller, Pharm.D.<sup>2</sup>; (1)Bassett Healthcare, Cooperstown, New York, USA; (2)IPRO, Albany, New York, USA.

**OBJECTIVES:** Warfarin is highly efficacious in the treatment and prevention of thromboembolic disorders. However, anticoagulation control has been a long-standing challenge, as patients' lack of knowledge of warfarin therapy is a predictor of non-compliance and compromised patient safety. The primary endpoint of this study was to determine if there is a difference in patients' knowledge of warfarin between two groups—those counseled by pharmacists versus that of "usual care."

**METHODS:** This was a prospective, randomized study which consisted of 40 inpatients receiving warfarin for any diagnosis, with no previous use of warfarin, whom were subdivided into one of two groups. Patients received either formal education by a pharmacist or counseling by "usual care." Prior to discharge, the Oral Anticoagulation Knowledge (OAK) test, a pre-validated tool used to measure warfarin knowledge was administered to evaluate outcomes. Further warfarin education was provided post-test if necessary. Statistics were based on a power of 90% with a p-value of 0.05 to assess for a difference of 10% in OAK scores between the two groups.

**RESULTS:** The primary outcome was determined using the Wilcoxon Rank Sums Test due to non-normality in the distribution of the OAK test scores. The Pharmacist counseled group (N=20) scored significantly higher on the OAK test than the Usual Care group (N=20): 74% vs. 55%, respectively (p=0.0037).

**CONCLUSIONS:** A formalized inpatient warfarin education program involving a pharmacist may play a critical role in allowing patients to attain a larger spectrum of initial warfarin knowledge than those educated by "usual care." This may improve compliance and subsequently increase patient safety associated with oral anticoagulation.

**78. Attitudes of hospital pharmacists to reporting medication errors: insights from focus groups.** Steven D. Williams, B.Pharm., Darren M. Ashcroft, Ph.D.; School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester, United Kingdom.

**OBJECTIVES:** The attitude of doctors and nurses to reporting errors has been well studied. The aim of this study was to explore the attitudes of hospital pharmacists to reporting medication errors.

**METHODS:** Three focus group discussions involving 15 hospital pharmacists, of different grades and experience, were held in three hospitals. Groups were asked about the general process of reporting errors and any benefits and barriers to reporting. The transcripts from the focus groups were fully transcribed and subject to thematic analysis.

**RESULTS:** There was strong agreement between among the pharmacists that detecting medication errors was a key role of a pharmacist's job. However, it was felt errors were "endemic" and, as a consequence, pharmacists only generally reported errors that were serious enough to cause patient harm. Individual pharmacists appeared to have different personal thresholds for reporting medication errors also depending on type (individual versus system errors), frequency of error and working relationship with the practitioner involved. Error reporting forms were generally considered to be "beauracatic" and took too long to complete. There was a belief that simpler forms, possibly electronic, and specific to medication errors would be more successfully completed.

Groups differed on their willingness to report errors within pharmacy

but universally acknowledged a fear of being treated as a “traitor” by doctors and nurses, if they reported errors in certain clinical areas.

There were contrasting views regarding any positive outcomes following investigations into an error but a general acceptance that reporting needed to improve for the benefit of patients.

**CONCLUSIONS:** The results suggest that a number of cultural factors act as barriers to reporting medication errors by hospital pharmacists including knowledge of what to report, fears of reporting, effort required and perception of limited outcomes. Future research should examine the development and deployment of interventions to improve reporting.

**79E. Examining patient safety climate in the hospital pharmacy setting: a cross sectional survey.** *Steven D. Williams, B.Pharm, Darren M. Ashcroft, Ph.D.; School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester, United Kingdom.*

**OBJECTIVES:** To explore the prevailing patient safety climate amongst hospital pharmacy staff.

**METHODS:** A modified version of the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture was completed by hospital pharmacy staff working at nine hospitals in the. The questionnaire consisted of forty questions with a five point Likert scale and focussed on employee perception of department safety ethos & systems, communication and feedback about errors.

**RESULTS:** Responses were received from 256 pharmacy staff (48% response rate). Overall 77% of respondents (61.5% to 93.2% across the nine hospitals) agreed or strongly agreed that their department was actively working to improve patient safety, whilst 65.7% (52.9% to 90.9%) agreed or strongly agreed that systems within their departments were good at preventing errors. However, 23% (4.6–40%) agreed or strongly agreed that “it is just by chance that more serious mistakes don’t happen around here” and 20% (4.5–40%) said that they were never or rarely given feedback about changes put in place after an error. In total 18.9% (12–40.9%) of respondents agreed or strongly agreed that “staff worried that mistakes were kept on their personnel file”.

**CONCLUSIONS:** The vast majority of pharmacy staff believed their departments were striving to improve patient safety and that their systems were good at preventing errors. However the results also suggest that not enough feedback is given to staff about medication errors and supports the notion that a fear of blame and potential disciplinary action might still be a factor in the reporting of medication errors.

There was considerable variation in responses between different hospitals. Repetitive safety climate assessment could provide a way for individual pharmacy departments to track their progress in cultural transformation particularly after the implementation of a safety program. Presented at British Pharmaceutical Conference Manchester England Sept 2008.

**80. Monoclonal antibodies in clinical trials: where reconstitute them for a safety use?** *Elodie Ostojski, Resident, Berenice Des Champs, Pharmacist, Christophe Berneron, Pharmacist, Beatrice Thielemans, Pharmacist; University hospital, Lille, France.*

The use of monoclonal antibodies (mAb) in therapeutic is in constant advance, developed in several clinical trials. Today, very few data is available on their toxicity and their handling precautions. Only the *Food and Drug Administration* classified mAb in five categories: A, B, C, D and X, according to the risk levels for pregnant women or wishing the future.

**OBJECTIVES:** The objective thus is to assess current clinical trials containing mAb within our hospital and on their recommendations of handling defined by protocols.

**METHODS:** For that purpose, we made a request within our IT software (PharmEssais<sup>®</sup>) for the clinical trials management.

**RESULTS:** We found 69 clinical trials and 24 different antibodies, among which 19 in 3 main units: 8 in the Haematology ward, 7 in rheumatology and 4 in medicine inner. Among 24 mAb, only 1 is ready-to-use, the others are reconstituted. Sixteen are reconstituted in the service by nursing staff, 2 are of class C and 14 not classified. Two are reconstituted in the centralized unit of anticancer drugs preparation: 1 class C, 1 class D. The mAb reconstituted under laminar air flow are in class B (1) or not classified (3). The last one mAb, used in nuclear medicine, is in class D.

**CONCLUSIONS:** We noticed a trivialization of the mAb by nurses, probably due to wrong information about their possible toxicity during the setting up of the clinical studies. Until the preparations can be realized by the pharmacy, it is essential to sensitize nurses on the rules of protection of medicines handling and toxicity, with the promoter approval. In this purpose, information sheets are being built and will be distributed in the inquiring and relevant units.

## Nephrology

**81. Serum zinc concentrations in patients on maintenance hemodialysis and its relationship with anemia, parathyroid hormone concentrations and pruritus severity.** *Simin Dashti-Khavidaki, Assistant Professor, Hossein Khalili, Associate Professor, Maryam Vahedi, Pharm.D.; Tehran University of Medical Sciences, Tehran, Iran.*

**OBJECTIVES:** This study was designed to find any possible correlation between serum zinc concentration and anemia, intact parathyroid hormone (iPTH) concentration and pruritus severity in HD patients.

**METHODS:** During a case-control study, the serum Zn concentration of patients on maintenance HD was compared with those of the healthy controls and with the cut-off point of 70 µg/dL as the risk of Zn deficiency. Complete blood count, serum iron, total iron binding capacity, ferritin and iPTH were measured for all patients. Transferin saturation (TSAT) was calculated. Pruritus severity was assessed using Pauli-Magnus method.

**RESULTS:** The mean serum Zn concentration in patients on maintenance HD was significantly lower than that of the control group; however, it was not different with the cut-off point of 70 µg/dL. The results showed no correlation between serum Zn concentration and hematologic indices of the HD patients. The results showed significant positive correlation between serum Zn concentration and erythropoietin daily dose. The findings revealed no correlation between serum Zn concentration and PTH level or pruritus severity in HD patients.

**CONCLUSIONS:** The results of this study showed that zinc concentrations were lower in HD patients compared to controls, however, the effects of routine supplementation of zinc to control anemia, serum PTH level or pruritus severity are yet doubtful.

**82. The evaluation of gabapentin therapy for pruritus in the Iranian hemodialysis patients.** *Seyed Mojtaba Sohrevardi, Pharm.D., BCPS,<sup>1</sup> Jalal Azmandian, M.D., nephrologist<sup>2</sup>; (1)Faculty of pharmacy, yazd medical university, Yazd, Iran; (2)Faculty of medicine, Kerman, Iran.*

**OBJECTIVES:** Uremic pruritus has a major impact on the quality of life in patients. The exact mechanism of uremic pruritus is unknown and most of our treatments are ineffective. It has been suggested that activity of the nervous system plays an impact role in the mechanism of uremic pruritus. It has been demonstrated that uremic patients on hemodialysis develop abnormal innervation. In this study we used the gabapentine for treatment of persistent pruritus.

**METHODS:** From the hemodialysis unit in shafa hospital (Kerman, Iran), we enrolled 20 patients who had long history of pruritus. In this double-blind, placebo-controlled study, patients were asked to record the severity of their pruritus based on visual analogue scale from 0 to 10. Patients were assigned to receive 1 week of gabapentine (100mg/d) or placebo randomly. Between the two phases there was a 1 week washout period.

**RESULTS:** All 20 patients completed the study. The mean pruritus score before the study was  $8.3 \pm 1.06SD$  (range: 7–10). After placebo administration, the mean score decreased to  $6.73 \pm 1.7$  (range: 7–9;  $p=0.005$ ). Gabapentine could decrease the mean score pruritus to  $4.58 \pm 1.58$  (range: 0–10;  $p=0.005$ ). None of the patients was forced to drop out of the study due to adverse effects. Plasma level of P, Ca, HCT, Sr Cr and albumin were not different in the treatment phases.

**CONCLUSIONS:** The neuropathic hypothesis is the basis of therapeutic approach for gabapentine advantage for pruritus treatment. Our study shows that gabapentine is safe and effective to treat uremic pruritus in hemodialysis patients.

## Neurology

**83E. Effect of caffeine and choline on short-term memory.** *Jamie L. Kearns, Pharm.D., Vincent J. Giannetti, Ph.D., David A. Johnson, Ph.D.; Duquesne University, Pittsburgh, Pennsylvania, USA*

**OBJECTIVES:** To determine whether the administration of caffeine and/or choline increases short-term memory and recall.

**METHODS:** Using a nonrandomized controlled trial design, each subject served as their own control. Subjects who were between the ages of 40 to 64 years of age and without any pre-existing cognitive or memory problems were given once weekly appointments at a specified room in the school of pharmacy building. At each appointment the subject was given either placebo, 100 mg caffeine, 2 grams of choline, or caffeine/choline combination capsules. Forty-five minutes after oral administration of the capsules their short-term memory and recall were tested using digit span (forward and backward) and digit symbol tests. A total of 22 subjects completed the study.

**RESULTS:** A two-way ANOVA with repeated measures of the digit span scores revealed a p value of 0.13 for the combination of caffeine and choline. Given this n value, there was a trend toward an increase in memory function and an 87% probability that the combination therapy allowed subjects to remember more digits.

**CONCLUSIONS:** In conclusion, there is not yet enough evidence to recommend caffeine and choline as a preventative treatment for mild cognitive impairment, however further research is still warranted in this field. Given the trend of increasing memory function with this intervention, it is probable that a larger n or daily administration of the caffeine and choline will prove to be significant.

This abstract is also submitted to ASCPT for a poster presentation.

## Neurosurgery

**84. Evaluating venous thromboembolism prophylaxis in neurosurgical patients with craniotomy.** *Biljana Popovic, Pharm.D., BCPS, BCNSOP,<sup>1</sup> Sheila M. Wilhelm, Pharm.D., BCPS,<sup>2</sup> Bhattacharya Pratik, M.D.,<sup>1</sup> Asmita Patel, Pharm.D., Student,<sup>2</sup> Megha Parikh, Pharm.D., Student,<sup>2</sup> Lee Anthony, M.D.,<sup>1</sup> Guthikonda Murali, M.D.<sup>1</sup>;* (1)Harper University Hospital, Detroit, Michigan; (2)Wayne State University, Detroit, Michigan, USA.

**OBJECTIVES:** There is currently insufficient evidence regarding effective pharmacologic venous thromboembolism (VTE) prophylaxis in neurosurgery patients with craniotomy. The goal of this study was to evaluate current practices for VTE prophylaxis in neurosurgery patients with craniotomy and risk factor profiles of patients developing VTE.

**METHODS:** Patients aged 18 to 89 years admitted for a craniotomy under the neurosurgical service at Harper University Hospital, Detroit between October 2006 and September 2007 were included in the study. A retrospective chart review was conducted. The variables collected included demographics, reason for craniotomy, occurrence of VTE, presence of VTE risk factors (heart failure, severe infection, malignancy, history of prior VTE, etc.). VTE prophylactic regimens used, including number of doses ordered and numbers of doses missed were recorded. Associations between VTE risk factors and occurrence of VTE was analyzed using SPSS 16.0.

**RESULTS:** 140 patients (83 females and 57 males) with mean age of 48.3 years were included. All patients received intermittent pneumatic compression (IPC) in addition to pharmacologic prophylaxis for VTE. 108 patients received unfractionated heparin (UFH) 5000 units subcutaneously every 8 hours, 29 patients received UFH 5000 units subcutaneously every 12 hours, 3 patients received fondaparinux 2.5mg subcutaneously daily. The most prevalent VTE risk factors were malignancy (68.6%), body mass index (BMI) >30 (35.7%), severe infection (26.4%) and age >60 (21.4%). Ten patients had prior history of VTE. Nine patients developed deep vein thrombosis (DVT) and none developed pulmonary embolism (PE). Of these 9 patients, 6 patients had malignancy, 4 patients had BMI >30 and 4 patients had severe infection. Three patients had prior VTE which was statistically significant (Fisher's exact test, p value 0.018).

**CONCLUSIONS:** Neurosurgical patients with craniotomy are at increased risk for developing VTE and require close surveillance in addition to adequate VTE prophylaxis.

## Oncology

**85. Nucleic acid purine based tamoxifen-purine analogues as potential anticancer agents.** *Shashikant Phadtare, Ph.D., Nageswara Kode, Ph.D.;* College of Pharmacy, Xavier University of Louisiana, New Orleans, Louisiana, USA.

**OBJECTIVES:** We hypothesized that purine nucleic acid base incorporated tamoxifen(TAM) analogues may provide new agents that may exhibit a stronger affinity to form a DNA-ligand complex and thus may exhibit improved anticancer activity and less toxicity against breast cancer cell lines. In this study, the chemical synthesis of TAM-purine analogues Z-(4'-chloromethyl but-2'-ene)2,6-dichloropurine and E-(4'-chloromethyl but-2'-ene)2,6-dichloropurine, and their in vitro anticancer activity in several breast cancer cell lines will be presented.

**METHODS:** TAM-purine analogues Z-(4'-chloromethyl but-2'-ene)2,6-dichloropurine and E-(4'-chloromethyl but-2'-ene)2,6-dichloropurine were obtained by the reaction of 2,6-dichloropurine with Z and E-1,4-dichlorobutene. These compounds were evaluated for cytotoxic activity against a panel NCI-H460 (lung), MCF7 (breast) and SF-268 (CNS) cancer cell lines. The 'active' compounds, which reduced growth of cancer cells to ca. 32% or less, have been evaluated in a full panel of 60 human cancer cell lines over a 5-log dose range at the National Cancer Institute.

**RESULTS:** Compound Z-(4'-chloromethyl but-2'-ene)2,6-dichloropurine exhibited significant activity against several breast cancer MCF 7, HS 578T, T-47D (GI50 0.81, 0.33, 1.99 uM) cell lines. The E-(4'-chloromethyl but-2'-ene)2,6-dichloropurine in this series exhibited no significant inhibitory effects in a wide range of cancer cell lines.

**CONCLUSIONS:** It is apparent from this study that the incorporation of a 2,6-dichloropurine base in a Z-butene isomer, similar to Z-Tamoxifen (cis-isomer), led to the compound Z-(4'-chloromethyl but-2'-ene)2,6-dichloropurine with significant anticancer activity against several breast cell lines. The E-(4'-chloromethyl but-2'-ene)2,6-dichloropurine isomer similar to E-Tamoxifen (trans-isomer) exhibited no significant inhibitory effects in a wide range of cancer cell lines.

## Pain Management/Analgesia

**86. Opiophobic factors that may contribute to inadequate pain management.** *Mark H. McKenzie, B.S., Candidate,<sup>1</sup> Michael W. McKenzie, Ph.D.,<sup>2</sup> Lynda C. McKenzie, M.Ed.,<sup>2</sup> Carole Kimberlin, Ph.D.;* (1)University of Florida, Gainesville, Florida; (2)University of Florida College of Pharmacy, Gainesville, Florida, USA.

**OBJECTIVES:** This project's purpose was to compare attitudes by physicians, pharmacists, pharmacy students, and medical students toward pain and the use of opioid analgesics, and evaluate if this information indicated a significant degree of opiophobia. In addition, the data was analyzed to determine if the gender of physicians and pharmacists in Florida affected the degree of opiophobia.

**METHODS:** A survey instrument reported in the *Southern Medical Journal* in 2000 was adapted for this project. Institutional Review Board approval was obtained prior to distributing the survey to 179 pharmacy students and 153 medical students at the University of Florida. The survey was also administered to 403 pharmacists and to 200 physicians in Florida. The survey asked respondents to indicate strongly agree to strongly disagree across a seven-point Likert scale.  $\chi^2$  analysis, logistic regression, pair-wise comparisons, and one-way analysis of variance were tests applied to the data.

**RESULTS:** Statistical differences among the respondents indicated varying degrees of opiophobia on the majority of statements. No one group of respondents displayed a consistently better set of attitudes than other groups. A majority of respondents felt that most patients having chronic pain were under-medicated with narcotic medications. Despite this understanding, a substantial percentage of respondents demonstrated inadequate knowledge of pain and its treatment, an inappropriate fear of patient addiction to opioids, an apprehension of drug regulatory agencies, and reluctance to prescribe/recommend opioids for pain.

**CONCLUSIONS:** Consequently, the respondents displayed attitudes of opiophobia, which can significantly hinder patients' relief from chronic pain. The analysis revealed that gender was not a statistically significant factor in attitudes toward pain and the use of narcotic analgesics. Therefore, patients are at risk for inadequate pain management with narcotics whether they receive care from male or female physicians or pharmacists.

## Pediatrics

**87. Factors influencing pharmacists' perceived knowledge of pediatric topics.** Paul J. Munzenberger, M.S., Pharm.D.,<sup>1</sup> Victoria Tutag Lehr, Pharm.D.,<sup>1</sup> Stephanie Baringhaus, Pharm.D.,<sup>2</sup> Ronald Thomas, Ph.D.<sup>3</sup>; (1)Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan; (2)Wayne State University, Detroit, Michigan; (3)Department of Pediatrics, Children's Hospital of Michigan, Detroit, Michigan, USA

**OBJECTIVES:** To determine: (1) pharmacists' perceived knowledge of pediatric topics; (2) identify educational needs based on gaps in knowledge.

**METHODS:** A questionnaire exploring responder demographics, training and perceived knowledge regarding 38 selected pediatric topics was distributed to pharmacists practicing in a variety of settings. Data were examined using cross-tabulations. Differences in proportions were interpreted using Fisher's Exact  $\chi^2$  test. Differences were considered statistically significant at a p-value  $\leq 0.05$ .

**RESULTS:** Ninety-five of 400 completed or partially completed questionnaires were returned from community, hospital and home care sites. In general, responders believed they had the knowledge and expertise to make recommendations for the frequently occurring conditions (e.g., coughs, colds, diaper rash, head lice, etc.) but not for the less familiar (cancer, SIDS, apnea, etc.). Formal pediatric training was the most influential responder characteristic with a higher proportion with training believing they have the knowledge and expertise to make recommendations.

**CONCLUSIONS:** Additional training is necessary for pharmacists making recommendations to caregivers on the selection and use of products intended for children. Pharmacy curricula and continuing education programs need to address these gaps in pharmacy education.

## Pharmacoeconomics/Outcomes

**88. Economic evaluation of a pharmacy led disease and medicine management programme for patients with COPD.** Maher Al-Khdour, B.Sc., M.Sc., Ph.D.,<sup>1</sup> Ashley Murray, Ph.D.,<sup>2</sup> Grainne Crealey, Ph.D.,<sup>2</sup> James McElroy, Professor, FCPP<sup>3</sup>; (1)Queen's University Belfast and Al-Quds University, Jerusalem, Israel; (2)Royal Victoria Hospital, Belfast, United Kingdom; (3)Queen's University Belfast, Belfast, United Kingdom.

**OBJECTIVES:** To undertake a cost-utility analysis of a pharmacy-led education and self-management programme for Chronic Obstructive Pulmonary Disease (COPD) compared with usual care.

**METHODS:** Patients were randomly allocated to either the intervention group (n=64) or usual care (n=63). The intervention was an education and self-management programme involving face-to-face and telephone contacts with the pharmacist over a 12 month period, information booklets, advice on breathing techniques and a course of medication to take in the event of an exacerbation. Quantities of healthcare resource usage over the study period were combined with unit costs (£2007 Sterling). The EQ-5D<sup>1</sup> was administered at baseline, 6 and 12 months for the calculation of quality-adjusted life-years (QALYs). The incremental cost effectiveness ratio (ICER) was calculated and a cost-effectiveness acceptability curve (CEAC) constructed to establish the probability of the intervention being cost-effective for different values of the NHS' willingness to pay (WTP) per QALY.

**RESULTS:** The intervention was associated with a mean cost saving of £671.54 and a mean QALY gain of 0.056. The ICER was -£11,992 indicating that intervention dominates usual care and is highly cost-effective. Assuming an implicit threshold of £20,000 per QALY, the probability of the intervention being cost-effective was greater than 90%. Sensitivity analyses were performed to assess the impact of variation in key parameters on the dominance of the intervention. These analyses included varying the gain in hospital bed days and QALYs achieved by the intervention and varying programme costs. The impact of adjusting for differences in baseline utility and performing multiple imputation for missing data was also explored. The conclusions were robust to such analyses.

**CONCLUSIONS:** The education and self-management programme was found to be highly cost-effective compared to usual care.

<sup>1</sup>EuroQol Group. Euroqol—a new facility for the measurement of health-related quality of life. Health Policy 1990;16:199–208.

**89. Effectiveness of amlodipine/valsartan single-pill combination therapy in primary care.** Joseph E. Biskupiak, Ph.D., M.B.A.,<sup>1</sup> Diana I Brixner, Ph.D., R.Ph.,<sup>1</sup> Drew Griffin Levy, Ph.D.,<sup>2</sup> Robert Hilkert, M.D.<sup>2</sup>; (1)University of Utah College of Pharmacy, Salt Lake City, Utah, USA; (2)Novartis Pharmaceutical Corporation, East Hanover, New Jersey, USA.

**OBJECTIVES:** Based on NHANES survey, blood pressure (BP) control rates in hypertensive individuals is about 36%. The purpose of this retrospective study was to examine the "real-world" effectiveness on BP outcomes for the recently approved single-pill combination (SPC) of a calcium channel blocker (CCB) and an angiotensin receptor blocker (ARB), amlodipine/valsartan (A/V) and to provide a descriptive analysis of the clinical characteristics of patients being treated with this combination.

**METHODS:** A retrospective review of an electronic medical record (GEEMR) database containing the ambulatory health records of US patients was conducted. Patients with a physician order for one of the four dosages of A/V SPC (5/160 mg, 5/320, 10/160, 10/320) prior to April 2008 were included in the study. Demographics, clinical characteristics (co-morbidities, previous antihypertensive medications) and BP readings prior to and up to 3 subsequent office visits (approximately 30, 60 and 90 days post-index) were recorded. The mean change in systolic and diastolic BPs and percent patients attaining BP goal (BP <140/90 mmHg) were recorded.

**RESULTS:** 2849 patients (51.6% female, mean age 59.8 years) receiving A/V SPC therapy were identified. Ninety percent of patients had received prior antihypertensive medications. Co-morbidities included: dyslipidemia, 55.3%; diabetes, 26.5%; coronary vascular disease, 20.6%; coronary artery disease, 11.3%; and renal impairment, 9.6%. Proportion of the population achieving BP goal was 42.0% at Visit 1, 44.7% at Visit 2 and 43.2% at Visit 3. Mean change in BP (SBP/DBP) at Visit 3 for each dosage was: -13.6/-6.2, 5/160; -13.3/-7.48, 5/320; -11.0/-7.4, 10/160; -16.4/-6.7, 10/320.

**CONCLUSIONS:** Treatment of hypertension with amlodipine/valsartan SPC therapy in usual care settings is able to achieve additional reductions in BP. The BP control rates achieved are numerically greater than those reported in NHANES survey. These results demonstrate the "real world" effectiveness of a CCB/ARB single-pill combination therapy in managing hypertensive patients.

**90. Authentication of drugs at the point of dispensing protects patients.** Steven RA Simoens, M.Sc., Ph.D.,<sup>1</sup> Jan Saevens, M.Sc.<sup>2</sup>; (1)Katholieke Universiteit Leuven, Leuven, Belgium; (2)Association Pharmaceutique Belge, Brussels, Belgium.

**OBJECTIVES:** Authentication processes based on mass serialization technology have been developed to secure the drug supply to patients. This paper aims to assess the reliability, effectiveness and costs of the AegateProtect™ service, a drug authentication system implemented in Belgian and Greek community pharmacy.

**METHODS:** A prospective analysis assessed the reliability of the service in a sample of Belgian community pharmacists by means of a mystery shopper audit. A retrospective analysis evaluated the effectiveness of the service in Belgian and Greek community pharmacies in terms of the number of scans relating to authentic, recalled, expired, and suspicious products. Also, the costs of providing the service were calculated for a hypothetical country covering 10,000 pharmacies and five pharmacy software providers.

**RESULTS:** The AegateProtect™ service attained a sample reliability of 100% (95% confidence interval: 99.8% to 100%) in Belgium. Out of 219,897 scans tested in Belgium during June–August 2008, the service identified 211,544 authentic products (96.20% of scans); 1,639 recalled products (0.75%); 6,630 products that may be recalled (3.01%); and 84 expired products (0.04%). No suspicious products were identified. Extrapolated to the national level, the AegateProtect™ service would be expected to identify 1,854,421 recalled, expired and suspicious packs. Similar results were observed in Greece. For a hypothetical country, total costs would comprise start-up costs of 3 million Euro over the first two years and annual running costs rising to 3.6 million Euro.

**CONCLUSIONS:** The AegateProtect™ service is reliable, cheap and effective in identifying authentic, recalled, expired and suspicious drugs in community pharmacy at the dispensing point in Belgium and Greece. Policy makers in other countries need to consider enacting the necessary

legislation to introduce drug authentication processes based on mass serialization technology in community pharmacy.

**91. Costs of cardiovascular disease associated with the use of sunitinib and sorafenib in renal-cell carcinoma.** *Rex W. Force, Pharm.D., FCCP, BCPS,<sup>1</sup> Kjel A. Johnson, Pharm.D.<sup>2</sup>; (1)Departments of Family Medicine and Pharmacy Practice, Idaho State University and improveRX, LLC, Pocatello, Idaho, USA; (2)ICORE Healthcare, LLC, Orlando, Florida, USA.*

**OBJECTIVES:** Sunitinib and sorafenib have been shown to prolong survival in renal-cell carcinoma (RCC). Toxicity with these agents occurs in the cardiovascular system. The objective was to perform an exploratory analysis of the utilization and costs associated with cardiovascular disease (CVD) in patients receiving sunitinib or sorafenib for RCC.

**METHODS:** A retrospective analysis of paid medical and pharmacy claims was performed over a one-year period. Claims with ICD-9 codes for CVD were quantified and the mean (+/- SD) per-patient costs determined. Claims and charges were captured in the outpatient, inpatient, laboratory, and other (ER, SNF) settings. Total CVD-associated costs were calculated. T-tests and chi-square analyses were used to compare the groups.

**RESULTS:** 464 patients received sunitinib (n=239) or sorafenib (n=225). More patients on sunitinib than sorafenib had an ICD-9 code for CVD (93% vs. 79%, p<0.01) during the study period. More sunitinib patients had a CVD claim for office, outpatient hospital, laboratory, and other services compared with patients receiving sorafenib (p<0.01 for all comparisons). The percentages of patients with a claim for inpatient hospital services were not different between the two drugs. Mean per-patient outpatient office CVD charges were greater for sunitinib than sorafenib (\$6,371 ± \$21,413 vs. \$704 ± \$1,128, p<0.01). Inpatient hospital charges were greater for sunitinib than sorafenib (\$19,308 ± \$34,553 vs. \$8,613 ± \$18,782, p<0.01). Similarly, outpatient hospital charges were greater for sunitinib than sorafenib (\$12,250 ± \$35,819 vs. \$3,539 ± \$11,221, p<0.01). Mean per-patient laboratory and other charges were not different between the groups. The mean per-patient total CVD-associated costs were \$25,633 (± 47,962) for sunitinib and \$7,727 (± \$20,723) for sorafenib (p<0.01).

**CONCLUSIONS:** Although costs were variable in this exploratory analysis of a non-randomized cohort, patients receiving sunitinib had significantly higher utilization rates and costs associated with CVD when compared with patients receiving sorafenib.

## Pharmacoepidemiology

**92E. Recombinant activated factor VII utilization patterns and thromboembolic event incidence in critically ill intensive care unit patients.** *Gretchen M. Brophy, Pharm.D., James R. Robles, Ph.D.; VCU Medical College of Virginia, Richmond, Virginia, USA.*

**OBJECTIVES:** There are limited data available on the use and safety of recombinant activated Factor VII (rFVIIa) in non-hemophilic, critically ill patients admitted to US intensive care units (ICU). The objectives of this study were to identify rFVIIa utilization patterns and the incidence of events in critically ill ICU patients across a spectrum of US hospitals.

**METHODS:** Hospital and patient data were retrieved from a pre-existing ICU.

**RESULTS:** rFVIIa was given to 1,459 patients of 3,343,211 ICU patients identified in the database. Fifty-nine percent of the rFVIIa patients were male; 77% of patients were admitted during 2004 and 2005. The most frequent primary diagnosis codes were cirrhosis (6.4%) and ICH (5.3%). The median (IQR) dose of was 4.8 mg (2.4, 7.2) and 82% of patients received only one dose. The incidence of events was 3.8% during hospitalization, with acute MI being the most common event. The median ICU LOS was 7 days. Mortality was 36%; 51% of these patients expired in the ICU. 44% percent of survivors were discharged directly to home.

**CONCLUSIONS:** The use of increased substantially in 2004, consistent with the timing of published evidence supporting its use in an ICU population. Patients diagnosed with cirrhosis or ICH most commonly received rFVIIa, and the majority received one dose. The incidence of events in patients receiving rFVIIa in the clinical setting was 3.8%. This is the first, large scale study describing rFVIIa utilization patterns and

adverse events in non-hemophilic ICU patients.

Presented at the SCCM 38th Annual Critical Care Congress, Nashville, Tennessee, USA, February 2, 2009.

**93. Medication adherence and the use of different sources of medicine information.** *Jurgita Dauksiene, Ph.D. student, Raimundas Radziunas, Assoc. Prof., Jonas Grincevicius, Ph.D.; Kaunas Medical University, Kaunas, Lithuania.*

**OBJECTIVES:** To assess self-reported adherence among pharmacy clients, their most often used sources of medicine information and to evaluate if the used number of sources of medicine information is related to medication adherence.

**METHODS:** The data were collected by way of questionnaires. Standard individual 45-item validated questionnaires were developed and used to assess adherence and non-adherence. It was distributed to the all pharmacy customers who entered our chosen pharmacies in Lithuania.

**RESULTS:** Of the 162 participating pharmacy patients 36.42% considered themselves partly or complete non-adherent. The average of common use sources of information about medication was 3.52 for adherent respondents and 2.78 for non adherent respondents. The number of sources of medicine information was significantly related to medication adherence (p<0.05). Patients listed pharmacist (65.58%) and primary care physicians (88.13%) the most often sources of medicine information. Other mentioned sources were "TV" (44.44%), "patient information leaflets" (40.13%), "drug promotion leaflets" (38.27%), "press" (35.19%), "books" (18.23%), "internet" (1.85%). Less educated patients were significantly more likely (p<0.05) to list family members or friends as sources of medicine information. Full of suggestion finding was that majority of our respondents (73.14%) don't envisage the difference between patient information leaflets and drug promotion leaflets.

**CONCLUSIONS:** The problem of medication non-adherence exists among pharmacy clients. Primary care physicians and pharmacist are the most often mentioned sources of medicine information but not the only ones. Internet is still not very common source of medicine information among pharmacy clients in Lithuania. The number of sources of medicine information was significantly related to medication adherence. It is recommended to engage our patients to use more sources of medicine information.

**94. Who carries meticillin resistant *Staphylococcus aureus* (MRSA) in the community?** *Sonia Thibaut, Ph.D.,<sup>1</sup> Jocelyne Caillon, Pharm.D., Ph.D.,<sup>2</sup> Nathalie Asseray, M.D., Ph.D.,<sup>2</sup> Didier Lepelletier, M.D., Ph.D.,<sup>2</sup> Pierre Lombrail, M.D., Ph.D.,<sup>1</sup> Gilles Potel, M.D, Ph.D.,<sup>2</sup> Françoise Ballereau, Pharm.D., Ph.D.<sup>1</sup>; (1)MedQual, Nantes, France; (2)UPRES EA 38 26, Faculté de Médecine, Nantes, France.*

**OBJECTIVES:** To improve the care (prevention of transmission and antibiotherapy) of MRSA carrier in community, it was first necessary to better know this population. The aim was to determine the characteristics of patients carrying MRSA and to describe the various resistance phenotypes.

**METHODS:** An epidemiologic, prospective and multicentric survey was realised in the Pays de la Loire Region. 64 of the 175 private laboratories of the Region sent their results. The collection was carried out over a 15-month period (from June 2005 to September 2006).

**RESULTS:** 313 patients were included; for each of them risk factors were determined according to the literature data (e.g., invasive procedure, previous hospitalisation, chronic pulmonary disease).

The average age of the patients was 65 ±25 years old. The frequency of the resistance to meticillin was 15% (552/3667 *S. aureus* strains). The most frequent sampling sites were pus (41.2%), urine (38.3%). 36 patients had none of risk factors. We have compared the both populations: carrying MRSA without risk factors (WRF) or carrying MRSA with at least one risk factor (RF). The patients carrying MRSA WRF were younger than the RF patients (p<0.0001). The WRF patients were often more infected than the RF ones (most often colonized) (p<0.001). MRSA encountered among RF patients showed a resistance to ofloxacin in 81.1% of cases whereas only 50% of MRSA among WRF were ofloxacin-resistant (p<0.001). 36.1% of MRSA among WRF were resistant to fusidic acid versus 14.6% of the MRSA among RF patients (p<0.01). *S. aureus* strains resistant only to meticillin are emerging in the community.

**CONCLUSIONS:** On the basis of these results, we can alert general practitioners. Community infection could be related to MRSA in young people without risk factors. A bacteriologic sample is necessary before therapeutic decision.

**95. Prophylaxis of venous thromboembolism in orthopaedic surgery: impact of regional guidelines.** *Francesca Venturini, Pharm.D., M.S., Andrea Scalvi, M.D., Valeria Biasi, M.Stat., Giovanna Scroccaro, Pharm.D.; Azienda Ospedaliera di Verona, Verona, Italy.*

**OBJECTIVES:** Venous thromboembolism (VTE) is known to be a major cause of morbidity and mortality among hospitalized patients. Several authors suggest that VTE prophylaxis is not implemented according to Evidence Based Medicine, with wide variability among hospitals and type of surgery. The primary objective of the study is to evaluate the impact of regional guidelines on VTE prophylaxis in orthopaedic surgery, with particular focus on the appropriateness of prescribing of low molecular weight heparins (LMWHs, patient eligibility, dose, schedule, duration). Secondary objectives included the patient self-reported adherence on at home prophylaxis.

**METHODS:** This is a prospective pre-post intervention study. Data utilization on VTE prophylaxis in orthopaedic surgery will be collected before and after the implementation of regional guidelines in 21 hospitals in the Veneto Region, Italy. Guidelines dissemination will be considered the intervention. This paper describes the results of the pre-intervention prophylaxis utilization.

**RESULTS:** Twenty-four orthopaedic wards participated in the project, accounting for 2084 patients (50% women, 41.6% over 65 years old). Surgery is mainly performed during hospitalization (72.2%, n=1504) than day surgery (27.8%, n=580). Most frequent interventions were: total hip replacement (9.1%), knee arthroscopy (7.6%), total knee replacement (6.5%). Overall, 76.9% of the sample underwent DVT prophylaxis, mainly with LMWH. Compared to existing national and international guidelines, 936 patients underwent an intervention on which no clear indication on DVT prophylaxis is present. Of them 51% (n=480) received a prophylactic treatment. Self-reported adherence was high: 85.6% of the interviewed patients reported to have taken the drugs for the whole prescribed period.

**CONCLUSIONS:** Several areas in orthopaedic surgery need indications on whether and how DVT prophylaxis should be performed. Wide variability is present in Italian hospitals. Next step of the project will involve a literature search on surgery interventions for which no clear evidence is reported in national and international guidelines.

## Pharmacogenomics/Pharmacogenetics

**96. Genetic and clinical determinants of warfarin dose requirements in African Americans.** *Larisa H. Cavallari, Pharm.D., Kathryn M. Momary, Pharm.D., Shital R. Patel, M.S., Nancy L. Shapiro, Pharm.D., Edith A. Nutescu, Pharm.D., Marlos A.G. Viana, Ph.D.; University of Illinois at Chicago College of Pharmacy, Chicago, Illinois, USA.*

SNP	Genotype	n	Warfarin dose (mg)	p value
3673	AA	3	35 (24–36)	<0.01
	AG	32	35 (27–43)	
	GG	171	43 (33–56)	
6853	CC	14	36 (28–46)	0.14
	GC	70	40 (32–50)	
	GG	120	43 (33–60)	
861	AA	2	27 (26–27)	0.16
	CA	20	43 (33–55)	
	CC	183	40 (33–55)	
5808	GG or TG	16	35 (28–37)	0.01
	TT	189	42 (33–56)	
6484	AA	3	35 (24–36)	<0.01
	GA	35	35 (26–43)	
	GG	168	43 (34–57)	
9041	GG	50	37 (30–47)	0.08
	AA or AG	156	42 (33–56)	

**OBJECTIVES:** We previously showed that cytochrome P450 2C9 (C) genotype, age, and body surface area (BSA) explained about 30% of the variability in warfarin dose requirements in African-Americans. We sought to determine whether vitamin K epoxide reductase complex-1 (C) genotype provided additional contributions to warfarin response in this ethnic group.

**METHODS:** Genetic samples and data were collected from 206 African Americans, by self-report, who were on a stable dose of warfarin, defined as the same dose for  $\geq 3$  consecutive clinic visits. The VKORC1 G3673A, G5808A, A6484G, G6853C, A9041G, and A861C genotypes and CYP2C9 \*2, \*3, and \*5 alleles were determined by PCR and pyrosequencing methods.

**RESULTS:** All genotypes were in Hardy Weinberg equilibrium. The VKORC1 G3673A, T5808G, and G6484A genotypes were associated with median (IQR) weekly warfarin dose requirements (table), while A9041G tended to be associated. Other factors potentially associated with warfarin dose by univariate analysis were age, BSA, heart failure, hypertension, use of amiodarone, aspirin, phenytoin or carbamazepine; and CYP2C9 genotype. Multivariate regression analysis revealed that the G3673A and G9041A genotypes, CYP2C9 genotype, and the clinical factors listed above jointly explained 41% of the variability in warfarin dose requirements.

**CONCLUSIONS:** Our data suggest that consideration of multiple clinical and genetic factors, including VKORC1 and CYP2C9 genotypes, may be useful in predicting warfarin dose requirements among African-Americans. However, a substantial portion of variability remains unexplained by our model, and may be due to other genetic or dietary factors.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**97. Pharmacokinetics and dosing of desirudin in moderate renal impairment using Monte Carlo simulation.** *Joseph S. Bertino Jr., Pharm.D., Anne N. Nafziger, M.D., Ph.D.; Bertino Consulting, Schenectady, New York, USA.*

Desirudin is a renally eliminated parenteral direct thrombin inhibitor approved to prevent venous thromboembolism. The labeled dose is 15 mg twice daily as a subcutaneous injection. Guidelines suggest dosage adjustment to 5 mg twice daily with aPTT monitoring in patients with moderate renal impairment (creatinine clearance, CrCl, 31–60 mL/min), but few data exist to support this recommendation.

**OBJECTIVES:** The purpose of this study was to determine if dosing adjustment and aPTT monitoring are needed in moderate renal impairment.

**METHODS:** Individual plasma concentration vs. time data from 10 adults with moderate renal impairment and 12 adults with normal renal function (CrCl >90 mL/min) were obtained from data on file with the manufacturer. Following determination of pharmacokinetic parameters, steady state  $C_{max}$  of desirudin 15mg twice daily subcutaneously in both groups were simulated using WinNonlin v5.2 with derivation of means and standard deviations. Using these data, Monte Carlo simulation (MCS; n=5000 patients) for the renally impaired group was performed using Crystal Ball v7.1 to describe an overall distribution of  $C_{max}$ . Desirudin concentration vs. aPTT data were available for 28 adults (16 normal, 12 moderate renal impairment). Exposure response relationships (square root desirudin concentration vs. aPTT ratio, a validated biomarker) were evaluated for both renal groups.

**RESULTS:** Median steady state  $C_{max}$  values (~2h post dose) were similar in subjects with normal (35 nmol/L) and moderate renal impairment (42 nmol/L). The square root of desirudin  $C_{max}$  to aPTT ratios were similar in both groups ( $r^2=0.76$  for each). Using MCS, median  $C_{max}$  in moderate renal impairment was 40.4 nmol/L with 90% of subjects being below a  $C_{max}$  of 81 nmol/L, the IC<sub>50</sub> of thrombin.

**CONCLUSIONS:** Because  $C_{max}$  and exposure response relationships are similar in both renal function groups, these data support the use of desirudin 15 mg q12h without routine aPTT monitoring in patients with moderate renal impairment.

**98. Salazar-Corcoran equation versus Cockcroft–Gault formula in antimicrobial dosing in obese patients.** *Teena Abraham, B.S., M.S., Pharm.D., BCPS, Steven D. Colby, M.D., Natalya Goldshteyn, M.D., Larry Bernstein, M.D., Nasser Saad, B.S., Pharm.D., Lamya Bakoss, B.S., R.Ph., Eric Balmir, B.S., R.Ph., M.S., Fabienne Vastey, B.S., Pharm.D.; New York Methodist Hospital, Brooklyn, New York, USA*

**OBJECTIVES:** The Cockcroft–Gault formula (CG) remains the predominant equation used to estimate glomerular filtration rate (GFR). It has been recognized as being biased in obese patients. Although few

prospective validations have been done, several retrospective studies using Salazar-Corcoran (SC) equation which incorporates fat free mass has demonstrated less bias compared to CG equation. The objective of this study was to compare the accuracy and precision of estimators of true GFR, using SC equation and a modified CG formula, in obese patients receiving vancomycin.

**METHODS:** This was a prospective, double-blinded, randomized study. Patients actively treated with vancomycin were allocated to either a CG or SC equation arm. Using desired peaks and trough, predictive pharmacokinetic values for vancomycin were calculated in each group, recorded and compared to serum concentration levels at steady state. Geometric regression analysis was used to determine correlation between CrCl estimated by CG and SC formula. A p-value <0.05 was considered statistical significant.

**RESULTS:** A total of 48 out of 88 patients were enrolled. The outcomes of both groups compared were considered equal and the correlation coefficients remained above 0.916,  $p < 0.001$  in all subgroups except when the predicted trough of CG was compared to the measured trough ( $r = 0.881$ ,  $p < 0.001$ ). However, no differences were found in patients with a body mass index (BMI)  $> 25 \text{ kg/m}^2$  when the predicted trough of SC was compared to the measured trough ( $r = 0.691$ ,  $p = 0.064$ ) or when the predicted trough using CG was compared to the measured trough ( $r = 0.695$ ,  $p = 0.664$ ).

**CONCLUSIONS:** Although we hypothesized that SC equation would be the better overall predictor in estimating GFR in obese patients, a larger sample size is necessary to accurately predict CrCl when compared to measured serum concentrations in this subset of patients.

**99E. Influence of plasma exchange on the disposition of the fourth generation cephalosporin cefepime.** *Rami B. Ibrahim, Pharm.D.,<sup>1</sup> Simon M. Cronin, Pharm.D.,<sup>2</sup> Chin Liu, Pharm.D.,<sup>2</sup> Raymond Cha, Pharm.D.,<sup>3</sup> Paul Swerdlow, M.D.,<sup>4</sup> Tomoco Avila, R.N.,<sup>5</sup> Stephen T. Smith, M.S.,<sup>2</sup> Richard Lewis, M.D.,<sup>6</sup> David J. Edwards, Pharm.D.<sup>3</sup>;* (1) Karmanos Cancer Institute and Eugene Applebaum College of Pharmacy and the School of Medicine, Wayne State University, Detroit, Michigan, USA; (2) Karmanos Cancer Institute and Eugene Applebaum College of Pharmacy, Wayne State University, Detroit, Michigan, USA; (3) Eugene Applebaum College of Pharmacy, Wayne State University, Detroit, Michigan, USA; (4) Karmanos Cancer Institute and the School of Medicine, Wayne State University, Detroit, Michigan, USA; (5) Karmanos Cancer Institute, Detroit, Michigan, USA; (6) School of Medicine, Wayne State University, Detroit, Michigan, USA.

**OBJECTIVES:** Cefepime, a fourth generation cephalosporin, is widely used in hematology and solid tumors patients. This same group may require plasma exchange (PE) for various indications not the least of which are chemotherapy- or cancer-induced thrombotic thrombocytopenic purpura, idiopathic thrombocytopenic purpura, and blood group incompatibility. To date, no pharmacokinetic evaluation has been conducted assessing cefepime's disposition during PE.

**METHODS:** A 2g IV cefepime single dose was given to participants undergoing therapeutic PE. Two hours from cefepime dose administration, serum plasma concentration was measured. PE was then instituted and cefepime plasmapheresate concentration was measured at the completion of the PE session. Cefepime levels were measured using HPLC. The percentage (%) removed by PE was calculated as: amount removed/2g dose.

**RESULTS:** Ten adult patients were analyzed: male/female = 6/4; median age (range): 52 years (33–67); and median weight (range): 82.85 Kg (47–120). PE indications were: myasthenia gravis (n=3); transverse myelitis (n=2); multiple sclerosis (n=1); chronic inflammatory demyelinating polyneuropathy (n=1); idiopathic thrombocytopenic purpura (n=1); thrombotic thrombocytopenic purpura (n=1); and humoral rejection post cadaveric renal allograft (n=1). All patients except one had a creatinine clearance  $> 60 \text{ ml/min}$ . One patient was excluded from the pharmacokinetic analysis owing to loss of venous access during PE. For the remaining 9 patients, total plasma volume removed was 3.5 L (range: 2.5–3.5) and duration of PE was 120 minutes (range: 94–209). The cefepime % removed by PE was 3.7% (range: 2.1–6.7). A strong correlation was found between cefepime plasma concentration prior to PE and the amount of drug removed ( $r = 0.96$ ,  $r^2 = 0.92$ ).

**CONCLUSIONS:** The above results suggest that, under the studied

conditions, cefepime removal by PE is clinically insignificant (~4% of a 2g dose).

Presented at the Joint Hematology/Oncology Pharmacy Association (HOPA) and International Society of Oncology Pharmacy Practitioner (ISOPP) Meeting, Anaheim, CA, June 17–21, 2008.

**100. Clinical utility of the Child-Pugh score to determine hepatic dose adjustments of selected antimicrobials.** *Gina M. DeSevo, Pharm.D., Michael A. Wynd, Pharm.D., Arpi G. Kuyumjian, Pharm.D., Cristina E. Cicogna, M.D.;* Hackensack University Medical Center, Hackensack, New Jersey, USA.

**OBJECTIVES:** In the clinical setting, dosing of hepatically eliminated antimicrobials is complicated by the difficulty of accurately quantifying hepatic drug clearance (HDC). The objective of this study was to assess the clinical feasibility of utilizing the Child-Pugh score (CPS) to adjust drug dosages based on patient specific information from the medical record.

**METHODS:** Over a 1 month observation period, inpatients  $\geq 18$  years old, receiving  $\geq 2$  doses of tigecycline, caspofungin, or voriconazole were evaluated to determine if the elements necessary to calculate a CPS were available on day 1 of antimicrobial therapy for neurological and abdominal examinations (exam) and within 24 hours for bilirubin, albumin, and prothrombin time (PT). Data collection included patient demographics, medical history, antimicrobial indication and dosing regimen, and non-HDC-related factors that may alter the CPS. Patients with incomplete data on day 1 of therapy were re-evaluated daily to determine if a CPS could be calculated at any point during antimicrobial therapy.

**RESULTS:** At initiation of therapy, complete data was available to calculate the CPS in 11 of 27 occurrences (41%). Two, 9, and 0 patients were Child-Pugh class A, B, and C, respectively. In all 11 of these occurrences, at least 1 non-HDC-related factor was present and dosing regimens in 0 of 11 occurrences were in accordance with CPS-based U.S. product labeling recommendations. When the CPS could not be calculated PT, bilirubin, albumin, neurology exam, and abdominal exam were not documented 63, 44, 38, 38, and 19% of the time, respectively. For the 16 occurrences in which initial data was incomplete, 50% subsequently had sufficient data to calculate a CPS.

**CONCLUSIONS:** Required elements of the CPS are frequently not documented. When the CPS can be calculated, numerous confounding factors are also present. Thus, the CPS has limited clinical applicability for determining hepatic dose adjustments.

**101E. Pharmacokinetic study of omeprazole Multi-Unit Pellet System (Losec MUPS®) versus extemporaneous bicarbonate formulation in patients with cerebral palsy and mental retardation.** *Koen Bousserly, Pharm., Ph.D.,<sup>1</sup> Julie De Smet, Pharm.,<sup>1</sup> Myriam Van Winckel, M.D., Ph.D.,<sup>2</sup> Pieter De Cock, Pharm.,<sup>3</sup> Peter De Paep, M.D., Ph.D.,<sup>4</sup> Jean-Paul Remon, Pharm., Ph.D.,<sup>1</sup> Jan Van Bocxlaer, Pharm., Ph.D.<sup>1</sup>;* (1) Ghent University, Faculty of Pharmaceutical Sciences, Ghent, Belgium; (2) Ghent University Hospital, Paediatric Gastroenterology Dpt, Ghent, Belgium; (3) Ghent University Hospital, Hospital Pharmacy Dpt., Ghent, Belgium; (4) Ghent University, Heymans Institute of Pharmacology, Ghent, Belgium.

**OBJECTIVES:** In patients with tube feeding, the proton pump inhibitor omeprazole is often used off-label as an extemporaneous formulation (8.4% bicarbonate suspension). Few pharmacokinetic data on the use of this suspension are available. This study aims to compare the pharmacokinetics of omeprazole extemporaneous formulation with omeprazole MUPS®.

**METHODS:** The study population consisted of 10 patients (7 female, age 7–26 yrs) with cerebral palsy and mental retardation treated with omeprazole because of oesophagitis grade B–D. In a randomized cross-over design, their standard omeprazole dose (20 or 40 mg) was administered for a 14 day-period as MUPS (Losec®) followed by a 14-day period as a 8.4% bicarbonate suspension or vice versa. All doses were administered through a gastrostomy tube in accordance to local guidelines. On day 15 and day 29 venous blood samples were drawn pre-dose, and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8 hours post-dose. Omeprazole plasma levels were determined by hydrophilic interaction chromatography with tandem mass spectrometry (HILIC-MS/MS).

**RESULTS:** In all patients, time till peak plasma level ( $T_{max}$ ) was shorter with suspension (range 0.5–1h) versus MUPS (range 1–6h). In 7/10 patients Area Under the Curve (AUC) and peak plasma levels ( $C_{max}$ ) were at least doubled after administration of suspension (AUC 372–34,653  $\mu\text{g}\cdot\text{h}\cdot\text{L}^{-1}$ ;  $C_{max}$  570–5,619  $\mu\text{g}/\text{L}$ ) compared to MUPS (AUC 47–9,036  $\mu\text{g}\cdot\text{h}\cdot\text{L}^{-1}$ ;  $C_{max}$  18–2,109  $\mu\text{g}/\text{L}$ ), with large interpatient variation. In 3/10 patients however, administration of MUPS resulted in higher AUC and  $C_{max}$  (AUC 138–613  $\mu\text{g}\cdot\text{h}\cdot\text{L}^{-1}$ ;  $C_{max}$  157–533  $\mu\text{g}/\text{L}$ ) compared to suspension (AUC 54–497  $\mu\text{g}\cdot\text{h}\cdot\text{L}^{-1}$ ;  $C_{max}$  66–378  $\mu\text{g}/\text{L}$ ).

**CONCLUSIONS:** Even though interindividual variability in omeprazole-pharmacokinetics is substantial, the 8.4 % bicarbonate suspension shows a consistently shorter  $T_{max}$  compared to MUPS, with bio-availability being better for suspension in 7/10 patients.

Presented at the 11th biannual congress of the European Society for developmental perinatal and paediatric pharmacology, Rotterdam, The Netherlands, June 4–7, 2008

**102. Steady state pharmacokinetics of oral voriconazole and its primary metabolite (UK121-265) pre and post autologous peripheral stem cell transplantation.** Jarrett R. Amsden, Pharm.D.,<sup>1</sup> Scott A. McConnell, Pharm.D.,<sup>2</sup> Paul O. Gubbins, Pharm.D.,<sup>3</sup> Elias J. Anaissie, M.D.<sup>3</sup>; (1)Butler University, Indianapolis, Indiana, USA; (2)Cubist Pharmaceuticals, Lexington, Massachusetts, USA; (3)University of Arkansas for Medical Sciences, Little Rock, Arkansas, USA.

**OBJECTIVES:** Diarrhea, mucositis and vomiting often complicates oral voriconazole (VCZ) therapy in peripheral stem cell transplant (PSCT) recipients. This study was performed to characterize VCZ and UK121-265 pharmacokinetics in adult autologous PSCT recipients receiving oral VCZ.

**METHODS:** In this open label pharmacokinetic study patients received an oral loading dose (VCZ 400 mg q 12h) on day 1, followed by oral maintenance dosing (VCZ 200 mg q 12h) on days 2–17. Serial blood sampling occurred on days 3 and 12 prior to dosing and 0.5, 1, 1.5, 2, 3, 4, 6, 8 and 12 hrs post-dose. VCZ and UK121-265 plasma concentrations were measured via HPLC. Weight adjusted noncompartmental pharmacokinetic data were generated using WinNonlin (Pharsight Inc), and parametric and nonparametric statistical comparisons were made using NCSS (Kaysville, Utah, USA).

**RESULTS:** 10 patients (6 males) completed both pharmacokinetic sampling periods. Mean age and weight were 66 yrs. and 76 kg, respectively. VCZ and UK121-265 pharmacokinetic values exhibited significant interpatient variability.

Parameter	VCZ			UK121-265		
	Day		p-value	Day		p-value
	3	12		3	12	
$T_{1/2}$ (hr)	8.7	7.83	0.58	30.9	9.4	0.01
$T_{max}$ (hr)	2.5	2.8	0.50	3.8	2.5	0.68
$C_{max}$ (ng/mL)	3158	3351	0.63	3174	2227.5	0.005
$AUC_{0-12}$ (mg hr/L)	24.4	25.2	0.82	30.5	21.3	0.02
$C_{min}$ (ng/mL)	1357.9	1598.3	0.26	2118	1282.1	0.007
$CL_{ss}$ (mg hr/L/kg)	0.19	0.24	0.91	—	—	—
$Vd_{ss}$ (L/kg)	1.5	1.5	0.87	—	—	—

**CONCLUSIONS:** VCZ and UK121-265 interpatient pharmacokinetic values vary significantly in PSCT recipients. VCZ pharmacokinetic values are not significantly altered following PSCT. However, UK121-265 pharmacokinetic values are significantly altered following PSCT.

**103. Comparison of the modification of diet in renal disease study equation to the Cockcroft-Gault equation for estimation of vancomycin troughs.** Eric Greenberg, Pharm.D., Nasser Saad, Pharm.D., Teena Abraham, Pharm.D., Matt Briggs, Ph.D.; New York Methodist Hospital, Brooklyn, New York, USA

**OBJECTIVES:** To determine if the Modification of Diet in Renal Disease (sMDRD) 4 variable equation is a better estimator of vancomycin trough levels when used in place of the Cockcroft-Gault (CG) equation in hospitalized patients  $\geq 65$  years old.

**METHODS:** The sMDRD equation was compared to the IBW-CG equation. Patient data was retrospectively reviewed and entered into the CG and sMDRD equations and vancomycin pharmacokinetic equations for determination of predicted trough. The predicted trough was compared to the measured trough. Serum creatinine (SCr) values were

adjusted up to 1mg/dl. Inclusion criteria: patients  $\geq 65$  years old who received  $\geq 3$  doses of vancomycin with at least 1 trough level at steady state, GFR  $\geq 15$  ml/min (sMDRD), stable SCr (change in SCr  $\geq 0.4$ mg/dl in 2 weeks) and BMI  $< 30$ . Exclusion criteria: concurrent vasoconstrictor use, radiocontrast media given in the previous 48 hours, neuromuscular/muscle wasting diseases and diabetic ketoacidosis.

**RESULTS:** The mean and median ages were 79.8 and 80.5 years respectively (range 66–97 years). The mean CG and sMDRD (BSA corrected to 1.73) estimations were 2.56 L/hr (range 1.1–4.2 L/hr) and 3.79 L/hr (range 2.4–5.8 L/hr) respectively. The mean and median BMI was 22.8 kg/m<sup>2</sup> and 23.5 kg/m<sup>2</sup> respectively (range 13.3–28.2 kg/m<sup>2</sup>). The mean and median CG predicted troughs were 15.2  $\mu\text{g}/\text{ml}$  and 12.7  $\mu\text{g}/\text{ml}$  respectively (range 5.3–35.9  $\mu\text{g}/\text{ml}$ ). The mean and median sMDRD predicted trough (BSA & Bias corrected) were 15.2  $\mu\text{g}/\text{ml}$  and 15.1mcg/ml respectively (range 7.5–31.3  $\mu\text{g}/\text{ml}$ ). The mean and median measured trough was 15.8  $\mu\text{g}/\text{ml}$  and 14.4  $\mu\text{g}/\text{ml}$  respectively (range 5.7–34.7  $\mu\text{g}/\text{ml}$ ). The CG and sMDRD were not statistically significantly different from each other ( $p=0.48$ ) or from the measured trough ( $p=0.29$ ).

**CONCLUSIONS:** Our study shows promise in using the sMDRD for dosage adjustment, although due to our small retrospective study, we cannot recommend so at this time.

**104. Protamine dosing in cardiopulmonary bypass procedures: is there a best practice?** Eric L. Chernin, B.S., Pharmacy, David W. Jungst, Pharm.D.; Sarasota Memorial Hospital, Sarasota, Florida, USA.

**OBJECTIVES:** Our objective is to evaluate differences in activated clotting times after protamine administration in cardiopulmonary bypass procedures. Cardiopulmonary bypass procedures require the administration of large doses of heparin in order to ensure adequate anticoagulation over the course of the bypass pump run. The degree of anticoagulation is monitored perioperatively using activated clotting times (ACT). In general, heparin doses of 3–4 mg/kg are administered in order to achieve ACTs in the 460–600s range. Heparin levels are not performed perioperatively, and heparin/protamine titration curves are not generally employed here. Protamine is known to have anticoagulant properties of its own, though weaker than heparin. Recent studies using thromboelastography have indicated that even small amounts of excess protamine may have an anticoagulant effect.

**METHODS:** Common practice in this institution is to reverse heparin at the end of the bypass pump run with an empirical protamine dose of 1–1.3 mg per mg of administered heparin. More recently, a newer group of anesthesiologists at this institution have begun using a significantly lower protamine dose, and routinely administer a standard protamine 250 mg dose to all cardiopulmonary bypass procedures patients. A retrospective review of all cardiopulmonary bypass procedures performed during a 3-month period was performed in order to ascertain whether there are significant differences in post-protamine ACT measurements between the two different protamine dosing regimens used at our institution.

**RESULTS:** No differences in outcomes between the two groups has been noted. Detailed evaluation is in progress.

**CONCLUSIONS:** Good practice would suggest that using the smallest effective dose of protamine should be the practice standard.

## Psychiatry

**105. CIMS: Concordance In a Mental health Setting.** Debi Bhattacharya, Ph.D.,<sup>1</sup> Rebecca Inglis, M.Pharm.,<sup>1</sup> Ansuya Solanki, M.Pharm.,<sup>1</sup> Savaan Nathwani, M.Pharm.,<sup>1</sup> John Hunter, M.Sc., Dip.EBP;<sup>2</sup> (1)University of East Anglia, Norfolk, United Kingdom; (2)Norfolk and Waveney Mental Health NHS Foundation Trust, Norfolk, United Kingdom.

**OBJECTIVES:** Patients and prescribers within the mental health setting were surveyed in order to determine attitude towards concordance and identify any differences between patient and prescriber attitudes.

**METHODS:** Post informed consent, the Leeds Attitude Towards Concordance (LATC) questionnaire was administered to patients with affective disorder or functional psychosis and all prescribers of the mental health trust. LATC score ranges from 0 (very negative attitude towards concordance) to 36 (very positive attitude).

**RESULTS:** Patient and prescriber consent rate was 19%, (24 from 127 eligible patients) and 61% (69 of 113 prescribers) respectively. The

median (IQ) LATC score for prescribers was 24 (22, 28) compared to 28 (23, 31) for patients ( $p=0.054$ ). Particular statements of disagreement between prescriber and patient were 'consultation between prescriber and patient should be viewed as a negotiation between equals', 'the best use of medicines is that which is compatible with what the patient wants and is capable of achieving', 'just as prescribing is an experiment for the prescriber, so too is medication taking for the patient'. In all cases, the prescriber had a more negative attitude towards these statements.

**CONCLUSIONS:** Accepting the small sample size and that this study has been conducted within one mental health trust and therefore the results may not be generalized, there was an overall positive attitude towards concordance reported by both patient and prescriber. This is consistent with studies involving different healthcare professionals and general medicine rather than mental health. There are, however, specific areas in which patients and prescribers differ, which suggests that prescribers in the mental health field are not yet wishing to embrace the concept of concordance.

## Pulmonary

**106. Design and validation of a Medication Assessment Tool (MAT) to evaluate the quality of medication use based on international guidelines of asthma management in children aged from 5 to 12 years.**

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**OBJECTIVES:** Asthma is the commonest causes of morbidity and mortality in childhood. In 2005, the updated BTS/SIGN and GINA guidelines for asthma management were published. Development of the MAT in asthmatic children provides an opportunity to assess the management of asthma in children by using audit criteria based on the recommendations of the guidelines.

**METHODS:** The recommendations related to the long-term management in asthmatic children of the BTS/SIGN and GINA guidelines were identified and the corresponding criteria were created. These criteria were put into an assessment tool to generate the draft MAT. Two phases of pilot study of the MAT were undertaken and subjected to examination by a specialist practitioner focus group. The data from the field-testing analysed in terms of applicability and adherence to each criterion and overall adherence to the MAT. The MAT was modified according to the results of the pilot study and the feedback of focus group.

**RESULTS:** Thirty criteria were included in draft 1 MAT. Based on the comments of focus group and the results of the pilot studies, three criteria in draft 1 MAT were deleted and one new criterion was added. The results of the second phase pilot study field-testing showed high overall adherence of 70.0% (95% CI: 58.7–81.3) to the guidelines. Three criteria in the MAT draft 2 were deleted due to the high percentage of insufficient data in case notes. Therefore, the final MAT comprising 25 criteria was produced.

**CONCLUSIONS:** The findings of this study showed high utility of the MAT criteria as a means of identifying gaps in guideline implementation and quantifying overall guideline adherence. However, further study in assessment for the use of oral steroids and exercise-induced asthma and wider implementation of this MAT is required.

**107. A prospective assessment of therapeutic efficacy and immune effects of levofloxacin and ofloxacin in multiple-drug resistant tuberculosis.** Philip M. Clark, Assist. Prof.,<sup>1</sup> Sule Apikoglu-Rabus, Ph.D.,<sup>2</sup> Bayram Kiran, Assist. Prof.,<sup>3</sup> Turan Karagoz, Associate, Prof.,<sup>4</sup> Fikret V. Izzettin, Prof.,<sup>2</sup>; (1)Yeditepe University Department of Pharmacy, Istanbul, Turkey; (2)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (3)Istanbul University, Istanbul Medical Faculty, Department of Microbiology Virology and Basic Immunology, Istanbul, Turkey; (4)Sureyyapasa Center for Chest Diseases and Thoracic Surgery, Istanbul, Turkey.

**OBJECTIVES:** Multi-drug resistant tuberculosis impairing the effectiveness of standard treatments may contribute to increased mortality. High failure and relapse rates are recorded when standard regimens are used for multi-drug resistant tuberculosis. The aim of this study was to comparatively assess the effectiveness of levofloxacin and ofloxacin in the treatment of multi-drug resistant tuberculosis; and to determine the immunological effects of treatment regimens including either levofloxacin or ofloxacin.

**METHODS:** The study was conducted among multi-drug resistant tuberculosis patients ( $n=40$ ) who were randomized to receive either levofloxacin ( $n=18$ ), or ofloxacin ( $n=22$ ) as part of their regimen. The outcomes of MDR-TB treatment was were recorded as cure, failure, default or death. The immune profile covering a range of immune markers including CD45 (total lymphocyte), CD3 (total T-lymphocyte), CD4, CD8 and CD4/CD8 ratios were assessed for 14 patients from each group both before and two months after the commencement of treatment.

**RESULTS:** Cure rates were 86.4% for the ofloxacin and 72.2% for the levofloxacin groups. Both groups had similar cure, treatment failure, treatment default and death rates ( $p>0.05$ ; for all). When the pooled data from both groups were analyzed, CD45, CD3/CD4, CD19, CD3/CD25 (activated T cell), CD3/HLA-DR, HLA-DR and CD4/CD8 levels were found to increase in response to treatment while the CD3/CD8 level was found to decrease ( $p<0.05$ ; for all).

**CONCLUSIONS:** The results suggest that ofloxacin and levofloxacin as a part of multi-drug resistant tuberculosis treatment demonstrate similar cure rates and multi-drug resistant tuberculosis drug regimens including levofloxacin or ofloxacin may have positive immunomodulatory properties.

**108E. Impact of uncontrolled asthma on school attendance and social functioning among pediatric patients.** Bonnie Dean, Ph.D.,<sup>1</sup> Brian Calimlim, M.S.,<sup>1</sup> Daniel Aguilar, M.P.H.,<sup>1</sup> Patricia Sacco, M.P.H.,<sup>2</sup> Riant Maykut, M.D.,<sup>2</sup> David Tinkelman, M.D.<sup>3</sup>; (1)Cerner LifeSciences, Beverly Hills, California, USA; (2)Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA; (3)National Jewish Medical and Research Center, Denver, Colorado, USA.

**OBJECTIVES:** The burden of uncontrolled pediatric asthma on school attendance and social functioning has not been extensively studied.

**METHODS:** Adult caregivers of children aged 6–12 years with moderate to severe asthma were surveyed, and asked about the child's symptoms, activity limitation, social functioning, and school attendance. Children were classified with uncontrolled asthma (UA) if their caregiver reported  $>2$  days/wk with symptoms, awakened by symptoms 1 night/wk, activity limitation, or rescue inhaler use  $>5$  times/wk. School attendance and social functioning were compared for UA vs. controlled asthma (CA) using the chi-square test.

**RESULTS:** 473 caregivers completed the survey; 360 were caregivers of children with UA and 113 were for children with CA. Children with UA had a significantly greater number of absences (5.5 vs. 2.2 days;  $P<.001$ ) during the previous year and were more likely than CA controls to miss school-related activities (14.7 vs. 0%) and visit the health office (17.5 vs. 0.9%;  $P<0.001$ ). Impaired social functioning was also associated with UA; more children with UA avoided social activities.

**CONCLUSIONS:** Uncontrolled asthma was associated with a significant reduction in school attendance and social functioning. Further research is needed to understand how this affects their quality of life and development.

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**109E. Demographic and Clinical Factors Associated with Poor Asthma Control in Patients With Severe or Difficult-to-Treat Asthma.** Tmirah Haselkorn, Ph.D.,<sup>1</sup> James E. Fish, M.D.,<sup>2</sup> Larry Borish, M.D.,<sup>3</sup> David R. Mink, M.D.,<sup>4</sup> Hubert Chen, M.D., M.P.H.,<sup>5</sup> Sally E. Wenzel, M.D.<sup>6</sup>; (1)EpiMetric Inc, Sunnyvale, California, USA; (2)Genentech Inc, South San Francisco, California, USA; (3)University of Virginia Health Systems, Charlottesville, Virginia, USA; (4)ICON Clinical Research, San Francisco, California, USA; (5)University of California-San Francisco, San Francisco, California, USA; (6)University of Pittsburgh, Pittsburgh,

Pennsylvania, USA.

**OBJECTIVES:** Despite clinical guidelines and different treatment options, asthma remains poorly controlled for many patients. Management of asthma symptoms can be improved by identifying factors associated with poor asthma control.

**METHODS:** Baseline data from n=3,107 adult patients (≥18 years) with severe or difficult-to-treat asthma in the TENOR study were analyzed. Asthma control was measured using the ATAQ instrument. Variables associated with poor asthma control were assessed with a proportional odds model. A range of demographic and clinical measures were included as covariates.

**RESULTS:** Younger age ( $OR_{[per\ 10\ years]}=1.33$ , 95% CI 1.27–1.40), higher body mass index ( $OR_{[per\ 5\ units]}=1.13$ , 95% CI 1.08–1.18), and being female ( $OR=1.82$ , 95% CI 1.59, 2.13) were associated with an increased risk of poor asthma control. Patients classified as severe by GINA criteria had a nearly four-fold risk of poor asthma control compared to patients classified as mild ( $OR=3.91$ , 95% CI 2.57–5.96). An increased risk of poor asthma control was also observed in patients with comorbidities, such as allergic rhinitis ( $OR: 1.45$ , 95% CI 1.11–1.89) and bronchitis, emphysema, or COPD ( $OR=1.51$ , 95% CI 1.32–1.74). Patients with poor control were more likely to be seen by pulmonologists than allergists ( $OR=1.40$ , 95% CI 1.20–1.63).

**CONCLUSIONS:** Poor asthma control is associated with identifiable clinical and demographic characteristics in patients with severe or difficult-to-treat asthma. Increased awareness and evaluation of comorbidities, particularly among patients seen by pulmonologists, may improve asthma control in these patients.

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## Substance Abuse/Toxicology

**110. An observational study of intentional drug overdoses in a Singapore hospital.** *Ian Wee, M.Pharm.(Clin.Pharm.),<sup>1</sup> Chai Ling Ong, B.Sc.(Pharm) (Hons),<sup>2</sup> Charlene Ong, B.Sc.(Pharm) (Hons)<sup>1</sup>; (1)Changi General Hospital, Singapore, Singapore; (2)National Heart Centre, Singapore, Singapore.*

**OBJECTIVES:** To determine the profile of patients admitted to an acute care hospital following an intentional drug overdose (IDO), and the clinical outcomes of IDO cases.

**METHODS:** All patients discharged with an ICD-9-CM code of 960 to 979 over a 6-month study period were identified. Subjects were excluded if their drug overdoses were considered unintentional. The medical records of eligible subjects were reviewed to extract data on patient demographics, concomitant psychiatric conditions (if any), details of drug overdose, treatment administered, and clinical outcomes.

**RESULTS:** A total of 247 patients were initially identified, of which 225 patients were eligible for review. There were a similar number of married and unmarried patients but females outnumbered males by almost 2.5-fold. Most patients were Chinese, between 21 to 30 years of age, had no known pre-existing psychiatric conditions, and were committing an IDO for the first time. Where an underlying psychiatric condition was present, depression (66.2%) was the most frequent diagnosis. The most common drugs associated with IDOs were paracetamol (acetaminophen) and benzodiazepines, accounting for 30.4% and 16.9% of all cases, respectively. The majority of patients received medical attention within 8 hours of the IDO attempt and only 2.2% had to be admitted to intensive care. Most patients (85.4%) were reviewed by a psychiatrist during their admission and more than half required outpatient psychiatric follow-up treatment. Approximately 90% of the patients were discharged within 5 days of admission.

**CONCLUSIONS:** Intentional drug overdoses seen at this Singapore hospital usually involved young Chinese females with no prior history of psychiatric disease consuming drugs that were relatively easily available. Often, these patients also needed frequent psychiatric follow-up following their attempted IDO. Methods of identifying high-risk patients may be useful in minimising the incidence of IDOs in the community.

## Transplant/Immunology

**111. Review and revision of the clinical practice of G-CSF treatment in patients undergoing autologous and allogeneic hematopoietic stem cell transplantation at UCSD.** *Meghana Trivedi, Pharm.D., Ph.D, Sue Corringham, R.N., Sam Martinez, Pharm.D., Edward D. Ball, M.D., Katherine Medley, Pharm.D.;* University of California, San Diego, La Jolla, California.

**OBJECTIVES:** There is no consensus on the optimal use of G-CSF after hematopoietic stem cell transplantation (HSCT). The practice at UCSD has been unique, in that the G-CSF treatment has depended upon the number of CD34+ cells infused. The goal of this study was to evaluate outcomes in relation to the G-CSF use in patients undergoing autologous and allogeneic HSCT.

**METHODS:** We performed a 5-year retrospective analysis of data in autologous and allogeneic HSCT patients (N=440). The groups were for autologous HSCT patients: (1)  $<5 \times 10^6$  CD34+ cells/kg and G-CSF; (2)  $\geq 5 \times 10^6$  CD34+ cells/kg and no G-CSF; and (3)  $\geq 5 \times 10^6$  CD34+ cells/kg and G-CSF; and for the allogeneic HSCT patients; (4)  $\geq 5 \times 10^6$  CD34+ cells/kg and G-CSF; and (5)  $<5 \times 10^6$  CD34+ cells/kg and G-CSF. Time to neutrophil engraftment (TTNE), time to platelet engraftment (TTPE), and length of post-transplant hospital stay (PTHS) were compared.

**RESULTS:** Median TTNE and PTHS were significantly shorter in groups 1 and 3, compared to group 2. There was no significant difference in TTNE and PTHS between groups 1 and 3, suggesting that number of CD34+ cells did not influence these parameters if G-CSF was used. Median TTPE was significantly longer in group 1 compared to groups 2 and 3. There was no significant difference in TTPE between groups 2 and 3, indicating that G-CSF use did not influence TTPE. TTNE, TTPE, and PTHS were not significantly different in groups 4 and 5, suggesting that the number of CD34+ cells did not affect these outcomes when allogeneic HSCT patients were given G-CSF.

**CONCLUSIONS:** Regardless of the number of CD34+ cells infused, G-CSF accelerated neutrophil recovery and shortened the hospital stay. Based on this analysis, the practice at our institution has been revised to use G-CSF in all autologous transplant patients. The allogeneic HSCT patients continue to receive G-CSF.

**112. Psychometric reevaluation of the Immunosuppressant Therapy Adherence Scale among solid-organ transplant recipients.** *Marie A. Chisholm-Burns, Pharm.D., M.P.H.,<sup>1</sup> Scott E. Wilks, Ph.D.,<sup>2</sup> Christina A. Spivey, Ph.D.<sup>1</sup>;* (1)The University of Arizona College of Pharmacy, Tucson, Arizona, USA; (2)Louisiana State University School of Social Work, Baton Rouge, Louisiana, USA.

**OBJECTIVES:** The objective of this study was to conduct a psychometric reevaluation of the Immunosuppressant Therapy Adherence Scale (ITAS), a self-report measure of immunosuppressant therapy (IST) adherence targeted to solid-organ transplant recipients.

**METHODS:** Mailed questionnaires were used to collect data from 141 transplant recipients. A factor analysis of the ITAS was conducted. Validity was examined via Pearson's Product Moment correlations ( $r$ ) to theoretically tied measures of social support and resilience. Cronbach's and split-half alpha coefficients determined internal consistency.

**RESULTS:** The response rate was 72.3%. The aggregate mean on ITAS summed scores was 11.0 (SD=1.7). The single IST adherence factor had an eigenvalue of 2.92 and accounted for 73% of the scale items' variance. Component loadings for ITAS items were high ( $\geq 0.80$ ). Zero-order correlations among scale items were moderately strong ( $\geq 0.57$ ) and significant ( $p < 0.01$ ). ITAS summed scores were significantly associated with measures of social support and resilience ( $r = \geq 0.20$ ,  $p < 0.05$ ). Cronbach's  $\alpha$  was 0.87. The Guttman split-half coefficient was 0.90.

**CONCLUSIONS:** This reevaluation provides needed confirmation that the ITAS is a valid and reliable measure of IST adherence. The ITAS may be useful as an IST adherence measure in the outpatient transplant clinic setting as it is easy to administer, brief, and less expensive than many other adherence measures.

**113. Social support and immunosuppressant therapy adherence among adult renal transplant recipients.** *Marie A. Chisholm-Burns, Pharm.D., M.P.H.,<sup>1</sup> Christina A. Spivey, Ph.D.,<sup>1</sup> Scott E. Wilks, Ph.D.<sup>2</sup>;* (1)The University of Arizona College of Pharmacy, Tucson, Arizona; (2)Louisiana State University School of Social Work, Baton Rouge, Louisiana, USA.

**OBJECTIVES:** Non-adherence to immunosuppressant therapy is a serious concern among renal transplant recipients. To design and implement effective interventions to improve adherence, it is necessary to first develop a better understanding of modifiable risk factors such as poor social support and their associations with medication non-adherence. The purpose of the study was to assess the relationship between social support and immunosuppressant therapy adherence among adult renal transplant recipients.

**METHODS:** Mailed questionnaires were used to collect data from 82 recipients, and included the Immunosuppressant Therapy Adherence Scale (ITAS) and Modified Social Support Survey (MSSS-5). The correlation between ITAS and MSSS-5 summary scores was assessed using the correlation coefficient (*r*). Analyses of the following relationships were conducted using correlation coefficients: (1) ITAS summary score and individual items of the MSSS-5; and (2) MSSS-5 summary score and individual items of the ITAS. A hierarchical regression was conducted, and odds ratios were calculated.

**RESULTS:** The response rate was 74%. The relationship between social support and adherence was significant ( $r=0.214$ ,  $p<0.05$ ). Two MSSS-5 items (affectionate support and instrumental support pertaining to household functions) were related to ITAS summary score ( $p<0.05$ ), and one ITAS item (forgetfulness) was related to the MSSS-5 summary score ( $p<0.05$ ). The regression model (all MSSS-5 items) accounted for 24% of the variation in ITAS summary scores.

**CONCLUSIONS:** The findings suggest that strategies utilizing social support to address forgetfulness as well as strategies to improve affectionate support and instrumental support related to daily household functions may be useful adherence intervention tools.

**114E. In vitro dissolution of mycophenolate mofetil: differences observed between innovator and generic formulations.** Emmanuel Scheubel, M.D., Laurent Adamy, Ph.D.; F. Hoffmann-La Roche Ltd, Basel, Sweden.

**OBJECTIVES:** Mycophenolate mofetil (MMF) is an immunosuppressive agent indicated for the prophylaxis of acute rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. It's a Biopharmaceutics Classification System class II substance that has a strong pH-dependent solubility profile. Consequently, differences in solid-state properties, formulation and/or manufacturing processes of MMF can lead to disparities in bioavailability between brands of the same drug. This study was conducted to compare the in vitro dissolution profile of the original MMF innovator brand (CellCept®, Roche) with available generic products.

**METHODS:** Two representative batches of CellCept® 500 mg tablets and 14 different generic formulations were tested using different dissolution testing scenarios simulating conditions in the proximal gastrointestinal tract. These scenarios took into account stomach and/or small intestine media composition, surface tension, pH, increased buffer capacity and osmolarity after food intake.

**RESULTS:** Eight of the generic formulations tested passed the quality control dissolution test (pH 1.1) according to specification  $Q=75\%$  after 5 min (i.e., all single units  $>80\%$  dissolved), and 12 passed the specification  $Q=85\%$  after 15 min (i.e., all single units  $>90\%$  dissolved). This suggests an almost homogenous dissolution rate in an acidic environment between formulations. However, at pH 4.5, large variations in in vitro dissolution performance between generic formulations were observed (extremes resulting in more than 60% dissolved difference after 30 mins). Marked variability was seen among the different generic formulations and between the various generic formulations and the innovator brand, CellCept®.

**CONCLUSIONS:** In conclusion, important differences exist between the different generic formulations with regard to in vitro performance. As MMF is required for life-long use, changes in drug performance as a result of switching between formulations may have serious clinical consequences (e.g., organ rejection). Therefore, clinical testing is necessary to evaluate the pharmacokinetics and the impact on clinical safety of a switch between brands.

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**115. Effect of genetic polymorphism of MRP2 and UGT2B7 on gastrointestinal symptom rating scale in kidney transplant recipients**

taking mycophenolic acid. Jaewook Yang, Ph.D., Pharm.D.,<sup>1</sup> Puay-hoon Lee, B.S.,<sup>2</sup> Vera Pravica, M.D., Ph.D.,<sup>3</sup> Ian V. Hutchinson, Ph.D.,<sup>4</sup> Tariq Shah, M.D.,<sup>5</sup> David I. Min, Pharm.D.,<sup>6</sup>; (1)Western University of Health Sciences, College of Pharmacy and National Institute of Transplantation, Los Angeles, California, USA; (2)Singapore General Hospital, Singapore, Singapore; (3)USC/National Institute of Transplantation, Los Angeles, California, USA; (4)USC School of Pharmacy, Los Angeles, California, USA; (5)St. Vincent Medical Center and National Institute of Transplantation, Los Angeles, California, USA; (6)Western University of Health Sciences, College of Pharmacy and National Institute of Transplantation, Los Angeles, California, USA.

**OBJECTIVES:** To determine the relationship between single nucleotide polymorphisms in MRP2 and UGT2B7 and the incidence and severity of the GI symptoms in patients receiving MPA.

**METHODS:** Genotypes of MRP2 C-24T and UGT2B7 C802T were determined and the incidence and severity of GI symptoms were assessed using the validated Gastrointestinal Symptom Rating Scale (GSRS) at baseline, 2 weeks, 1 month, 3 months and 6 months post transplant. The mean overall GSRS score and subscale for diarrhea were compared by the Student *t* test and linear regression was performed to determine the predictors of GI symptoms.

**RESULTS:** Sixty seven renal transplant recipients were included in the study. The overall GSRS score was not significantly different between heterozygous variant MRP2 C-24T and homozygous wild type ( $23.5 \pm 4.5$  vs.  $26.7 \pm 9.9$   $p=0.07$ ). However the GSRS subscale score for diarrhea was significantly lower in heterozygous variant MRP2 C-24T compared to the homozygous wild type ( $3.5 \pm 0.9$  vs.  $5.1 \pm 3.3$ ,  $p=0.04$ ). For the UGT2B7 C802T, the overall mean GSRS score ( $29.2 \pm 9.3$  vs.  $24.0 \pm 8.2$ ,  $p=0.02$ ) and diarrhea subscale score ( $4.1 \pm 1.9$  vs.  $5.7 \pm 4.1$ ,  $p=0.04$ ) were significantly different between the variant (CT+TT) and the homozygous wild type (CC). There were however no difference in the scores between patients receiving either MMF or enteric coated mycophenolic acid (EC-MPA); and patients receiving the different calcineurin inhibitors. When the genotypes for MRP2 and UGT2B7 are considered together, the variant MRP2 C-24T and UGT2B7 C802T had significantly lower overall GSRS ( $22.5 \pm 4.3$  vs.  $30.1 \pm 10.1$ ,  $p=0.008$ ) and diarrhea subscale score compared to the wild type ( $3.4 \pm 0.7$  vs.  $6.2 \pm 4.4$ ,  $p=0.015$ ).

**CONCLUSIONS:** This study demonstrates that among patients receiving MPA, those with MRP2 C-24T and UGT2B7 C802T variant genotypes are potentially protected from the GI side effects regardless of the formulation administered.

## Urology

**116. Effect of multiple doses of the cytochrome CYP3A4 inhibitor ketoconazole on the single-dose pharmacokinetics of the highly selective alpha-1A-adrenoceptor antagonist silodosin in healthy men.** Lawrence A. Hill, Pharm.D., Weining Volinn, M.S., Gary Hoel, R.Ph., Ph.D.; Watson Laboratories, Salt Lake City, Utah, USA

**OBJECTIVES:** Silodosin, a highly selective alpha-1A-adrenoceptor antagonist, is safe and effective in relieving urinary symptoms associated with benign prostatic hyperplasia. This open-label, randomized-sequence, crossover study evaluated the effect of the cytochrome CYP3A4 inhibitor ketoconazole on the pharmacokinetics of silodosin in healthy men.

**METHODS:** Twenty-two healthy 18- to 45-year-old men were randomly assigned to 1 of 2 sequences: 4 days of treatment with 400 mg ketoconazole daily followed by 4 days of no treatment, or vice versa. All subjects also received a single dose of 8 mg of silodosin on day 2 of each treatment period. Serial blood samples were taken between -0.5 and 72 hours after silodosin dosing to analyze plasma concentrations of silodosin and its two main metabolites, KMD-3213G and KMD-3293. Vital signs and adverse events (AEs) were monitored throughout the study.

**RESULTS:** All subjects completed the study. Silodosin mean maximal plasma concentration ( $C_{max}$  [standard deviation]) was 234.4 (62.2) ng/mL in subjects receiving ketoconazole and 63.7 (22.8) ng/mL in those not receiving ketoconazole. KMD-3213G  $C_{max}$  was 184.3 (54.1) ng/mL with and 58.0 (24.5) ng/mL without ketoconazole. KMD-3293  $C_{max}$  was 100.2 (29.3) ng/mL with and 35.2 (16.2) ng/mL without ketoconazole. Ketoconazole increased the area under the curve (AUC)

by a factor of 3.1 for silodosin, 3.0 for KMD-3213G, and 2.5 for KMD-3293. Postdose time at  $C_{max}$  ( $T_{max}$ ) for silodosin (~2 hours), KMD-3213G (~5 hours), and KMD-3293 (~4 hours) was not affected by ketoconazole. The number of AEs was higher with ketoconazole (20; drug-related: 13) than without (8; drug-related: 3), but all AEs were mild and none was serious. The most common AE related to ketoconazole (and silodosin) was headache (7).

CONCLUSIONS: Ketoconazole substantially increased  $C_{max}$  of silodosin and its metabolites without affecting  $T_{max}$ . Ketoconazole had no apparent effect on the safety and tolerability of a single dose of silodosin.

**117. Maximum tolerated dose of silodosin, a highly selective  $\alpha$ -1A-adrenoceptor antagonist, for the treatment of symptoms associated with benign prostatic hyperplasia.** *Lawrence A. Hill, Pharm.D., Weining Volinn, M.S., Gary Hoel, R.Ph., Ph.D.; Watson Laboratories, Salt Lake City, Utah, USA.*

**OBJECTIVES:** A study was conducted in healthy subjects to determine the maximum tolerated dose of silodosin, a highly selective  $\alpha$ -1A-adrenoceptor antagonist.

**METHODS:** This double-blind, placebo-controlled, sequential dose-escalation study of silodosin involved 5 cohorts (6 subjects each) of healthy men, aged 18 to 45 years (body mass index, 18 to 33 kg/m<sup>2</sup>), who underwent 4 to 10 days (depending on dose) of in-patient therapy. In each dose cohort, 5 subjects were randomly assigned to receive silodosin and 1 to placebo. Doses were increased from 16 to 24, 32, 40, and 48 mg, if the current dose was tolerable. Safety and plasma concentrations of silodosin and its metabolites were evaluated.

**RESULTS:** Mean maximum plasma concentrations ( $C_{max}$ ) of silodosin and its major metabolite, KMD 3213-G, were observed 2 to 3 hours and 4 to 5 hours after dosing, respectively. Dose-dependent silodosin mean  $C_{max}$  increased from 129 ng/mL (16 mg) to 403 ng/mL (48 mg), and KMD 3213-G mean  $C_{max}$  increased from 224 ng/mL (16 mg) to 442 ng/mL (48 mg). Overall, 120 adverse events were reported, 98 by subjects receiving silodosin; all were mild, none was serious. The most common silodosin-related adverse event, postural hypotension (46 events), increased in number with increasing dose, from 7 (16 mg) to 12 (48 mg); 1 event in a subject receiving 32 mg caused study discontinuation. Maximum observed decreases in systolic and diastolic blood pressure were -13.0 and -4.0 mmHg, respectively, with 16 mg silodosin and -37.0 and -18.0 mmHg with 48 mg. Maximum observed increase in heart rate was highest (76.0 beats per minute) with 40 mg silodosin.

**CONCLUSIONS:** With daily doses of 16–48 mg, silodosin appeared safe and was tolerated by most subjects. As doses increased, postural hypotension and maximum changes in orthostatic measurements generally increased. Maximum tolerable dose appeared to be 48 mg.

**118. Effect of renal impairment on plasma concentrations of silodosin and its main metabolites in patients with symptoms of benign prostatic hyperplasia.** *Leonard S. Marks, M.D.,<sup>1</sup> Marc A. Gittelman, M.D.,<sup>2</sup> Lawrence A. Hill, Pharm.D.,<sup>3</sup> Weining Volinn, M.S.,<sup>3</sup> Gary Hoel, R.Ph., Ph.D.<sup>3</sup>; (1)University of California Los Angeles, Culver City, California, USA; (2)South Florida Medical Research, Aventura, Florida, USA; (3)Watson Laboratories, Salt Lake City, Utah, USA.*

**OBJECTIVES:** Post hoc analysis of a 12-week phase 3 clinical study of silodosin in patients with symptoms of benign prostatic hyperplasia evaluated the effect of estimated renal impairment on plasma concentrations of silodosin and its main metabolites.

**METHODS:** Men  $\geq 50$  years old with IPSS  $\geq 13$  and peak urinary flow rates of 4–15 mL/sec, who had no (estimated creatinine clearance [CC]  $> 80$  mL/min), mild (estimated CC =  $> 50$ –80 mL/min), moderate (estimated CC = 30–50 mL/min), or severe (estimated CC  $< 30$  mL/min) renal impairment, received placebo or silodosin 8 mg once daily. Plasma concentrations of silodosin and its main metabolites (KMD-3213G, KMD-3293) were determined 2–6 hours after initial dose (day 0) and at week 4 of treatment.

**RESULTS:** Of 461 study participants, 233 received silodosin. Renal impairment did not substantially affect silodosin plasma concentrations at day 0 (mean [standard deviation], 49.3 [32.2] ng/mL). However, silodosin concentrations at week 4 tended to be lower with no (31.2 [23.4] ng/mL, n=155) or mild (36.7 [29.5] ng/mL, n=70) renal

impairment than with moderate (57.8 [49.7] ng/mL, n=7) or severe (43.7 ng/mL, n=1). KMD-3213G concentrations were higher at week 4 (81.5 [51.3] ng/mL) than on day 0 (38.1 [24.8] ng/mL); concentrations at week 4 were lower with no (77.7 [47.9] ng/mL) or mild (85.4 [56.5] ng/mL) renal impairment than with moderate (127.3 [61.0] ng/mL) or severe (110 ng/mL). Concentrations at day 0 were similar across subgroups. KMD-3293 concentrations were higher in patients with moderate impairment (day 0, 37.3 [30.7] ng/mL; week 4, 42.8 [20.7]) than overall (day 0, 26.4 [17.6] ng/mL; week 4, 28.5 [17.9] ng/mL).

CONCLUSIONS: Steady state plasma concentrations of silodosin and its main metabolites were not affected by mild renal impairment but were slightly elevated in patients with moderate impairment.

## Women's Health

**119. Thorough QTc (TQT) interval assessment of a novel nonimmediate release oral tranexamic acid product on ventricular repolarization in fasting healthy women.** *Keith A. Moore, Pharm.D.,<sup>1</sup> Timothy S. Callahan, Ph.D.,<sup>2</sup> Pierre Maisson-Blanche, M.D.,<sup>2</sup> Isabelle Morin, B.Sc.,<sup>3</sup> Ted Marengo, M.Sc.<sup>3</sup>; (1)Xanodyne Pharmaceuticals, Inc, Newport, Kentucky, USA; (2)Biomedical Systems, Inc, St. Louis, Missouri, USA; (3)MDS Pharma Services, Montreal, Quebec, Canada.*

**OBJECTIVES:** Determine the effect of XP12B-MR, a tranexamic acid modified-release investigational product used to treat heavy menstrual bleeding (HMB), on cardiac conduction (ventricular repolarization) in healthy fasting women.

**METHODS:** 48 women, 18–49 years, received single oral doses of study medication utilizing a randomized, double-blind, 4-way crossover design. Two dose levels of XP12B-MR, a therapeutic dose (1.3 g) and a suprathreshold dose (3.9 g) of tranexamic acid (TA), a placebo control, and an active control (400 mg moxifloxacin) were administered followed by a 7-day washout. Triplicate digital ECGs were collected using a 12-lead Holter on Day 1 at -1, -0.67, and -0.33 hours pre-dose and at 0.5, 1, 2, 3, 4, 5, 6.5, 10, 14, and 24 hours post-dose. Analysis of variance was used to compare the baseline-adjusted, time-matched treatment-placebo differences in QTc intervals.

**RESULTS:** 41 women who completed the study were included in the ECG analyses. Both doses of XP12B-MR did not significantly alter the QTcF (Fridericia's correction) or QTcB (Bazett's correction) interval compared with placebo ( $P > 0.05$ ). The largest mean QTcF difference for both 1.3 g and 3.9 g TA doses was 3.57 msec and 3.10 msec, for all 10 post-dose time-matched evaluations, respectively. By contrast, the largest mean QTcF interval difference between active control (moxifloxacin) and placebo was 14.11 msec ( $P < 0.05$ ); the largest upper limit of the 95% confidence interval of the mean difference was 18.49 msec ( $P < 0.05$ ) for the QTcF interval. A linear relationship was observed between moxifloxacin plasma levels and baseline-adjusted differences in QTc ( $P < 0.001$ ).

**CONCLUSIONS:** The impact of XP12B-MR on QTc interval prolongation, a potential signal for ventricular tachyarrhythmia induction, was assessed. Even at suprathreshold doses, XP12B-MR did not prolong cardiac conduction in healthy women since the largest mean QTc interval difference between tranexamic acid and placebo at all time-matched evaluation points was  $< 5$  msec.

## CLINICAL PHARMACY FORUM

### Adult Medicine

**120. Implementation of the Follow Me Home Medication Reconciliation Program (FMHMRP).** *Manoukhathe Cassagnol, Pharm.D., CGP,<sup>1</sup> Danielle Ezzo, Pharm.D., BCPS, CGP,<sup>1</sup> Emily Ambizas, Pharm.D.,<sup>1</sup> Maha Saad, Pharm.D., BCPS, CGP,<sup>1</sup> Martin Lesser, Ph.D.,<sup>2</sup> Harold Steinberg, M.D.<sup>3</sup>; (1)St. John's University, Queens, New York, USA; (2)Long Island Jewish Medical, New Hyde Park, New York, USA; (3)Long Island Jewish Medical Center, New Hyde Park, New York, USA.*

**OBJECTIVES:** To describe a pharmacy-run discharge medication reconciliation program at a large, tertiary care hospital.

**METHODS:** This program entitled the Follow Me Home Medication Reconciliation Program (FMHMRP) will be run by four clinical pharmacists: two inpatient, one outpatient clinic pharmacist (at the institution), and one community pharmacist. In this bi-phasic program,

the inpatient pharmacist will conduct a pre-discharge medication counseling session for general medicine patients identified through a daily discharge census. During the session the pharmacist will review general medication counseling points as well as disease state counseling and differences in medications they were taking prior to admission. Patients will also be offered assistance in completing necessary third party insurance forms. An individualized medication card will be completed for each patient during this session and given to the patient at the end of the session. Preadmission medications will be compared to discharge orders and any differences will be considered a medication variance. Each variance will be discussed with the discharge physician in order to clarify the order and appropriate modifications will be made. The second phase is a post-discharge medication reconciliation involving patient follow-up in either an outpatient, hospital-based clinic setting or a community pharmacy setting. Patients will be followed up by the assigned clinical pharmacist 48 to 72 hours post-discharge via telephone then bi-weekly by telephone or personal interview for a total of 8 weeks. The pharmacist will provide counseling to reinforce medication compliance. Appropriate interventions will be made to resolve any problems identified and the patient's primary care physician will be made aware.

**RESULTS:** Implementation of the program is underway.

**CONCLUSIONS:** The FMHMRP will provide patients with a service that will help increase medication compliance and maximize patient safety during their transition period from the inpatient setting to home.

## Ambulatory Care

**121. Is there a correlation between patient's knowledge of hypertension and blood pressure control?** Eunice P. Chung, Pharm.D., Jodie C. Trinh, Pharm.D., Jeany K. Jun, Pharm.D., Alan D. Cundari, D.O.; Western University of Health Sciences, College of Pharmacy, Pomona, California, USA.

**OBJECTIVES:** The primary objective of the study was to determine if there is a correlation between patients' knowledge of hypertension and blood pressure control. The secondary objective was to investigate potential factors associated with better control of hypertension and higher disease knowledge.

**METHODS:** All adult patients receiving chronic hypertension management at a family medicine clinic, serving primarily indigent population, between March and April 2008 were screened for eligibility and consent. At the beginning of their routine clinic visit, patients completed a survey consisting of 16 point questionnaire for assessment of hypertension knowledge and additional questions related to lifestyle and management of hypertension. Blood pressure measured during the same visit was used for determining whether the blood pressure was controlled or uncontrolled based on the 7th Joint National Committee Report. A two-tailed Pearson's correlation test was used to analyze the relationship between the knowledge score and blood pressure control.

**RESULTS:** A total of 135 patients were enrolled and studied. The mean knowledge score was  $6.5 \pm 3.1$  (40.6%). Less than 3% of the patients surveyed knew their target blood pressure and only 32.6% of the patients knew the names of their hypertension medications. The knowledge scores for the studied patients did not correlate with BP control. There were no other identifiable lifestyle factors independently associated with blood pressure control or knowledge score.

**CONCLUSIONS:** The low knowledge score suggest that the demographics of the patients served at the clinic resulted in selecting hypertensive patients with low baseline knowledge. In this population, correlation between the knowledge score and better control of blood pressure could not be established. However, the result should not be generalized to all patients with hypertension as disease knowledge may still affect disease control in patients with higher knowledge.

**122. Evaluating patient satisfaction of e-mail communication to improve blood glucose control in type 2 diabetes mellitus.** Laura Perry, Pharm.D.,<sup>1</sup> Steve Smith, M.S.<sup>2</sup>; (1)The University of Findlay, Findlay, Ohio, USA; (2)The Toledo Hospital Family Medicine Residency, Toledo, Ohio, USA.

**OBJECTIVES:** To evaluate patient satisfaction of weekly e-mail communication with a pharmacist. To discuss the advantages and limitations of e-mail as a form of patient-provider communication.

**METHODS:** A three month, prospective, pharmacist-run, diabetes study was conducted at a family medicine residency outpatient clinic. Patient enrollment and data collection were performed between October 1, 2007 and February 29, 2008. A total of 12 patients were enrolled. Patients were required to send weekly e-mails containing self-monitored blood glucose levels to the pharmacist. The pharmacist reviewed the blood glucose readings and replied with any interventions. Changes in medication regimen, diet, or blood glucose testing frequency were implemented as needed though a pharmacist collaborative practice agreement. A patient questionnaire was given at the end of the study period.

**RESULTS:** Six patients completed the study; one patient was dropped due to a hospital admission and 5 patients failed to follow study protocol. Results of the patient satisfaction questionnaire (n=6) indicated patients felt the information shared with the pharmacist through secure e-mail was safe, useful, and easy to understand and follow. Overall mean percent compliance was 88 percent (95%CI 79 to 97%). Average change in self-monitored blood glucose was -40 mg/dL (95%CI -81 to 2 mg/dL, p=0.06) and average change in HbA1c was -0.82 % (95%CI -2.71 to 1.07, p=0.29). Number of pharmacist interventions averaged three per patient.

**CONCLUSIONS:** Patients that completed the study were satisfied with e-mail as a form of patient-provider communication. Although most patients had improved blood sugar control, the overall change in blood sugar was not significant.

**123. Preliminary results of a pharmacist managed oral anticoagulation service at a long-term care facility.** Haley M. Phillippe, Pharm.D.,<sup>1</sup> Joyce V. Loyed, Pharm.D.<sup>2</sup>; (1)Auburn University Harrison School of Pharmacy, Owens Cross Roads, Alabama, USA; (2)Salem Veterans Affairs Medical Center, Salem, Virginia, USA.

**BACKGROUND:** 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.

**OBJECTIVES:** 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 six months a retrospective chart review was conducted. Patients were included if they were anticoagulated for a minimum of 12 months, 6 months prior and 6 months post-pharmacist intervention. Information on demographics, indication for and length of warfarin therapy, INR values, and thromboembolic and bleeding events were recorded.

**RESULTS:** A total of 12 patients met our inclusion criteria. The post-pharmacist TTR was 50% compared to 29% before intervention. The extended TTR (goal INR  $\pm$  0.2) was 63% post-pharmacist intervention and 44% prior to the intervention. Before pharmacist intervention 52% of INRs were less than 2 and 2% were greater than 5, compared to 32% of INRs less than 2 and 0.86% greater than 5 following intervention. No adverse events were reported.

**CONCLUSIONS:** Although there were limitations to this small 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.

**124. Development of a pharmacist-managed diabetes care clinic in an urban community health center.** Christine A. Schumacher, Pharm.D.,<sup>1</sup> Kathy E. Fit, Pharm.D., BCPS,<sup>2</sup> Brooke L. Griffin, Pharm.D.,<sup>2</sup> Jill S. Burkiewicz, Pharm.D., BCPS<sup>3</sup>; (1)Midwestern University College of Pharmacy, Downers Grove, Illinois, USA; (2)Midwestern University Chicago College of Pharmacy, Downers Grove, Illinois, USA; (3)Midwestern University - Chicago College of Pharmacy, Downers Grove, Illinois, USA.

**OBJECTIVES:** This service is designed to develop a collaborative practice agreement between clinical pharmacists and physicians with the intent to improve adherence with ADA recommendations in diabetic patients in an urban community health center. A retrospective review conducted at the health center found that only 41.4 percent of patients with diabetes met the ADA recommend HbA1c goal of less than 7 percent.

**METHODS:** The clinical pharmacist-managed diabetes therapy management pilot program will be available for patients greater than 18 years of age with a diagnosis of type 1 or type 2 diabetes and a primary care provider at Mercy Family Health Center. Patients will be referred to the pharmacist-managed clinic for various indications, such as newly diagnosed diabetes, poor glycemic control, poor adherence, or a combination of these.

Within the pharmacist-managed clinic, pharmacists will review the patients' past medical history, determine adherence to their medication regimen and the level of the patient's disease state and glucometer use knowledge. Each patient will receive a comprehensive diabetes evaluation based on their individual needs as recommended by the American Diabetes Association standards of medical care. In addition, the pharmacist will interpret laboratory values and recommend appropriate medical referrals and lifestyle modifications. Medication recommendations will be made to the physician for consideration or medications will be adjusted per protocol with physician's approval.

**RESULTS:** The pharmacist-managed diabetes clinic has been approved by the Mercy Family Health Center medical director and will be provided one day per week. A diabetes care protocol has been approved for use and clinic materials as well as data collection forms have been developed. Additional results will be presented.

**CONCLUSIONS:** The development of a pharmacist-managed diabetes care clinic has potential to improve patient care and increase patients' and physicians' perceptions of the pharmacist's role in health care.

**125. Medication therapy management: providing clinical pharmacy services to wounded soldiers with psychiatric disorders.** *Laura P. Woods, Pharm.D., Toby L. Cooper, Pharm.D., BCPS, Gwendolyn H. Thompson, Pharm.D., M.P.A., BCPS, Nancy A. Radebaugh, R.Ph., Rania S. Kattura, Pharm.D., M.S.Phr; Carl R. Darnall Army Medical Center, Ft Hood, Texas, USA.*

**BACKGROUND:** The Carl R. Darnall Army Medical Center (CRDAMC) is a 119-bed, level II trauma, academic medical facility located at Fort Hood, Texas. CRDAMC accommodates greater than 70,000 emergency medicine visits annually from a population of 104,000 beneficiaries and manages 3,500 outpatient clinic appointments, 31 hospital admissions, and 4,800 prescriptions daily. CRDAMC also provides services to more than 1,000 post-combat wounded soldiers as part of the U.S. Army's 22,100 member Wounded Warrior/ Transition program.

**OBJECTIVES:** To describe the development, implementation, and longitudinal justification of a clinical pharmacy service model provided to post-combat wounded soldiers diagnosed with behavioral health related conditions and co-morbidities.

**METHODS:** In 2008, CRDAMC established clinical pharmacy services available to more than 1,000 soldiers wounded in Operation Enduring Freedom/Operation Iraqi Freedom, of which an estimated 80% carry a diagnosis of PTSD, TBI, and/or co-morbidities including depression, anxiety, chronic pain, alcohol or substance abuse. Initial development of services was based on three focus areas: direct patient care, medication management, and research and education. Implementation of our services was achieved using a Medication Therapy Management (MTM) model in collaboration with a multi-disciplinary healthcare team. Longitudinal justification is based on generating revenue valued units (RVU) equivalent to provider reimbursement in the civilian sector.

**RESULTS:** Impact of this program is being evaluated by: generated consultations (volume of enrolled patients), clinical interventions, and RVUs.

**CONCLUSIONS:** Clinical pharmacy services have been implemented to improve medication utilization among a population of combat injured soldiers. In addition, the initial service has expanded to include involvement with a sole prescriber program, process improvement initiatives, and establishing transition of care between the Army and Veterans Administration (VA) healthcare systems.

**126. Detecting and assessing cognitive deficits in Hispanics with type**

**2 diabetes: The role of a clinical pharmacist.** *Joshua Caballero, Pharm.D.,<sup>1</sup> Garry Souffrant, M.D.,<sup>2</sup> (1)Nova Southeastern University, Fort Lauderdale, Florida, USA; (2)Su Clinica Familiar, Harlingen, Texas, USA.*

**OBJECTIVES:** Type 2 diabetes has been associated with a decline in executive function (EF). EF is the cognitive process necessary for attention, planning, and decision making. Therefore, deficits in EF may cause difficulties with medication adherence. As a result, patients may be at higher risks for sub-optimal disease management or increased risk for adverse events. The objective of this pilot study was to determine if a clinical pharmacist can identify cognitive impairment in patients with type 2 diabetes and assess its impact on adherence.

**METHODS:** After clinic IRB approval, physicians identified adult Hispanic patients with type 2 diabetes. After obtaining consent, the clinical pharmacist collected demographic information (e.g., age, gender), laboratory values, and assessed adherence. Additionally, EXIT25 tests were administered to determine the level of EF impairment. Any patients with significant cognitive impairment or missing laboratory parameters were scheduled for further follow-up. Strategies to improve adherence were discussed with patients and caregivers.

**RESULTS:** A total of 46 patients (16 males, 30 females; average age: 61 years) were identified in a three-month period. Of these, 28 patients stated difficulties adhering to their medication regimens. Those who had difficulties with adherence had average EXIT25 scores of 14.1, compared to 12.8 in those who were adherent (p=NS). Twenty-eight percent of patients who had difficulties with adherence had a caregiver assisting in their medication management. Less than 20% of patients had a glycosylated hemoglobin within 3 months. An average of 15 minutes was used to counsel patients on improving adherence.

**CONCLUSIONS:** Clinical pharmacists may play an integral part in identifying diabetic patients who are experiencing cognitive decline. Additionally, clinical pharmacists may identify patients who need appropriate or current laboratory monitoring and improve adherence. However, more data are needed to determine how EF impairments are affecting adherence and contributing to inadequate disease state management.

**127. Health impact of a worksite pharmacist-directed wellness center on risks for cardiovascular disease in an employee cohort.** *Jamie L. Kearns, Pharm.D.,<sup>1</sup> Holly C. Lassila, Dr.Ph., R.Ph.,<sup>1</sup> Hildegard J. Berdine, Pharm.D., BCPS,<sup>2</sup> Christine K. O'Neil, Pharm.D., BCPS, FCCP,<sup>1</sup> Bruce Livengood, Pharm.D.,<sup>1</sup> (1)Duquesne University, Pittsburgh, Pennsylvania, USA; (2)Mylan School of Pharmacy, Duquesne University, Pittsburgh, Pennsylvania, USA.*

**OBJECTIVES:** The presence of a worksite pharmacist directed wellness center will decrease risk for cardiovascular disease as evidenced by improvements in selected clinical parameters.

**METHODS:** The Academic Research Center for Pharmacy Care (ARCPC) is a pharmacist-managed wellness center that serves the Duquesne University community. Screening data was collected from employees who visited from December 1, 2002 through September 30, 2008. Fasting levels of total cholesterol (TC), LDL-cholesterol (LDL), blood glucose (FBG) and triglycerides (TRIG) at baseline were compared to fasting levels obtained at subsequent visits.

**RESULTS:** Forty-five university employees visited the ARCPC from December 1, 2002 through September 30, 2008. Average age was 54 years with an even distribution between males and females. Of the cohort, all returned for a second visit and twenty-three returned for a third visit. Changes in clinical parameters included: (mean  $\pm$  SD at baseline, follow-up visit 1) total cholesterol 215.20  $\pm$  33.401, 210.44  $\pm$  13.710; LDL 132.61  $\pm$  9.811, 130.29  $\pm$  30.490; glucose 95.40  $\pm$  62.573, 89.50  $\pm$  .708 (NS paired t-test); triglycerides 137.62  $\pm$  62.573, 117.13  $\pm$  51.874 (significant paired t-test). Twenty-three patients continued for a third screening with the following clinical parameters: (follow-up visit 2  $\pm$  SD) total cholesterol 198.91  $\pm$  31.348; LDL 115.61  $\pm$  29.427 (significant paired t-test); blood glucose 89.50  $\pm$  8.708; triglycerides 123.78  $\pm$  69.094 (NS paired t-test).

**CONCLUSIONS:** The opportunity to access health screenings at the worksite reduced employee risk for cardiovascular disease. ARCPC screenings demonstrated improvements for the clinical parameters of total cholesterol, LDL-cholesterol, blood glucose and triglyceride levels of employees having consecutive visits with the pharmacist. Significant

changes in triglyceride levels resulted between the first and second visit (mean 11.7 months;  $p=0.024$ ). Positive trends for other parameters were also observed, evidenced by significant improvements in total cholesterol and LDL-cholesterol (mean 17.8 months;  $p=0.034$ ,  $.015$  respectively) by the second follow-up visit.

**128. Effectiveness of a collaborative lipid clinic developed in an academic heart hospital ambulatory care clinic.** *Marguerite Hevezi, Pharm.D., Scott Merryman, M.D., Vasudevan Raghavan, MBBS, M.D., MRCP, (UK), Trisha Jordan, Pharm.D., M.S., Melissa Snider, Pharm.D.; The Ohio State University Ross Heart Hospital, Columbus, Ohio, USA.*

**OBJECTIVES:** To establish the effectiveness of a collaborative lipid clinic partnering clinical pharmacists with physicians in an outpatient setting by evaluating lipid panel changes and achievement of targeted goals.

**METHODS:** Electronic medical records of patients seen between March 2006 and May 2008, having 3 or more visits, and have been seen at least three months apart in The OSU Comprehensive Lipid Management Clinic were reviewed. Descriptive statistics were used to compare baseline and most recent lipid panels to each other and to targeted lipid goals.

**RESULTS:** A total of 168 patients were included. The proportion of patients at targeted ATP III lipid goals increased from 32% at baseline to 71% for LDL-C, and from 42% at baseline to 74% for total cholesterol (TC). The mean baseline LDL-C was 141 mg/dL compared to the most recent mean LDL-C of 100 mg/dL, an absolute reduction of 41 mg/dL. Mean baseline TC was 226 mg/dL compared to most recent mean TC of 173 mg/dL, an absolute reduction of 53 mg/dL. Mean HDL-C increased by 5% from baseline. Targeted LDL-C goal was decreased for 71 patients (42%) due to physician assessment, 23 of them (32%) met their decreased LDL-C goal.

**CONCLUSIONS:** The collaboration of clinical pharmacists with physicians resulted in cardiovascular risk reduction by intensification of targeted LDL-C goal, and improving components of the lipid panel and proportions of patients at targeted goals.

**129. Pharmacist-physician collaborative management in optimising antihypertensive therapy for chronic kidney disease patients.** *Yee Ming Lee, M.Pharm.Sci., Lee Ying Yeoh, MBBS, Su Chi Lim, MBBS, Chee Fang Sum, MBBS, Tavintharan Subramaniam, MBBS, Ling Choo Lim, MBBS; Alexandra Hospital, Singapore, Singapore.*

**OBJECTIVES:** The optimization of antihypertensive and antiproteinuric agents such as angiotensin-converting-enzyme inhibitor (ACEI) and angiotensin-receptor-blocker (ARB) for chronic kidney disease (CKD) patients is hampered by the long appointment interval between physician visits. This study aims to determine if a pharmacist-physician collaboratively managed clinic will benefit CKD patients in achieving systolic blood pressure (SBP) goal  $<130$  mmHg and the time taken to achieve target SBP.

**METHODS:** CKD patients with nephropathy and/or uncontrolled BP were referred to the pharmacist-run clinic to titrate ACEI and/or ARB followed by other antihypertensive drugs based on patient's home BP, clinic BP, serum creatinine and potassium results. Baseline SBP was taken from the last doctor's visit. Time to target SBP was taken as time from the first pharmacist visit till patient's home or clinic SBP was  $<130$  mmHg.

**RESULTS:** Eighty patients (42 male, 38 female) with an average age  $64.4 \pm 11.8$  years, baseline glomerular-filtration-rate  $38.9 \pm 2.3$  ml/min and SBP  $150.3 \pm 23.8$  mmHg, attended the pharmacist-run clinic. The CKD distribution amongst the patients was 4% (stage 1), 11% (stage 2), 43% (stage 3), 36% (stage 4) and 6% (stage 5). At baseline, 14% ( $N=11$ ) of patients were at target SBP  $<130$  mmHg prior to attending the pharmacist-run clinic, but this increased significantly ( $P<0.005$ ) to 43% ( $N=34$ ) after attending the pharmacist-physician collaboratively managed clinic. The average time to achieve target SBP was  $1.71 \pm 2.39$  months.

**CONCLUSIONS:** The pharmacist-physician collaboratively managed clinic helped CKD patients achieve the SBP goal  $<130$  mmHg within an average  $1.71 \pm 2.39$  months.

**130. Black education and treatment of hypertension trial.** *Stephanie Maciejewski, Pharm.D., Robyn M. Kondrack, Pharm.D., Daniel E.*

*Hilleman, Pharm.D., Shavonne Washington-Krauth, B.S.Ed., Syed M. Mohiuddin, M.D.; The Cardiac Center of Creighton University, Omaha, Nebraska, USA.*

**OBJECTIVES:** The prevalence of hypertension along with morbidity and mortality secondary to hypertension is higher among blacks than whites. Despite the greater risk, black patients are under treated in comparison, with the disparity in treatment being multifactorial in nature. The primary objective was to determine the effectiveness of a specialized intervention strategy to control hypertension in the Omaha, Nebraska African American (AA) community.

**METHODS:** AA hypertensive patients, all receiving free antihypertensive medications, were randomized to two groups: control subjects receiving basic hypertension education and usual care with their providers and intervention subjects receiving in-depth hypertension and behavior modification counseling following JNC-VII. Each group received the same formulary with three tiers of medication and instructions to begin with first tier medications. The tiers ranged with the lowest cost and recommended first line therapy for BP control in the first, low cost and second line therapy in the second, and some brand-name alternatives were in the third.

**RESULTS:** There were no significant differences in demographics, with the majority being female (71.4%) 35–64 years (87.9%). The intervention subjects were maintained more frequently on the first tier of the formulary with BP control reached earlier than was seen in the control subjects. At 3 months, BP goals were achieved in 81% of intervention subjects ( $N=37$ ) compared to 57% in control subjects ( $N=36$ ),  $p=0.03$ . Although not statistical significance, at 12 month visit a more pronounced SBP control existed in the intervention group versus control (mean difference of 5 mmHg). The percent usage of the formulary in the order of tiers was 79%, 11%, 10% for the intervention and 59%, 22%, 19% for the control.

**CONCLUSIONS:** The intervention reached BP control faster with cost effective medications by 3 months compared to the control with the majority of patients reaching and maintaining BP control at 12 months.

**131. Establishing ambulatory care clinical pharmacy services in a free clinic through community engagement.** *Sallie D. Mayer, Pharm.D., M.B.A., BCPS, Daniel Cole Kildow, Pharm.D., Evan M. Sisson, Pharm.D., M.H.A., Brigitte L. Scat, Pharm.D., Daniel E. Carl, M.D.; Virginia Commonwealth University School of Pharmacy, Richmond, Virginia, USA.*

**OBJECTIVES:** To describe the development of ambulatory care pharmacy services in a free clinic under a community engagement grant.

**METHODS:** Ambulatory care faculty at the School of Pharmacy sought to expand services from the academic institution clinics into the community free clinics in order to better meet the needs of the indigent population in the city of Richmond as well as expand the opportunities for practice and teaching. The Center for High Blood Pressure (CHBP) is a not-for-profit nurse-run free clinic providing specialty care services to indigent patients in the city of Richmond with chronic disease. The clinic wished to expand its education initiatives and clinical care to include those high risk patients with both hypertension and diabetes. Together, the CHBP and the Virginia Commonwealth University School of Pharmacy received a community engagement grant to help fund this initiative. The purpose of this grant is to: 1) develop and implement a patient and staff diabetes education program; and, 2) pilot a clinical pharmacist practice model in which the pharmacist assumes a more extensive role in providing direct patient care and consultative services within the free clinic setting by developing collaborative practice with the physician medical director.

**RESULTS:** The clinical pharmacist and ambulatory care pharmacy resident provide direct patient care to patients with diabetes and hypertension in two half-day clinic sessions per week and a once weekly group diabetes class. Medication therapy changes are made under a collaborative practice agreement with the medical director. Advanced practice and service learning pharmacy students have begun to rotate through the CHBP.

**CONCLUSIONS:** Ambulatory Care pharmacy services have been successfully implemented at the CHBP. Clinical and economic outcomes are being collected and expansion of services to other free clinics in the area is being planned.

## Cardiovascular

**132. Development of a National Clopidogrel Card for Patients following Percutaneous Coronary Intervention.** *Sotiris Antoniou, B.Pharm.(Hons), M.Sc., Dip.Mgt., Anja Richter, B.Sc., Martin T Rothman, MBChB, FRCP, FACC, FESC; Barts and the London NHS Trust, London, United Kingdom.*

**OBJECTIVES:** To develop a credit-card sized card to facilitate appropriate information communicated to both the patient and across the interface to primary care physicians and support adherence and appropriate continuation of clopidogrel.

**METHODS:** Current literature was reviewed and key components identified for inclusion within the card. The finalised card was piloted locally then sent for endorsements from relevant national societies.

**RESULTS:** The finalised card is given to all patients post angioplasty at Barts and the London NHS Trust. Following endorsements from the British Cardiac Society, British Cardiac Intervention Society and made available through the UK Clinical Pharmacy Association, over 120,000 cards have been given to patients nationally to date (launched in September 2006). The card informs patients of reasons why clopidogrel has been initiated, the daily dose, the combination with aspirin, together with the planned duration of treatment. It also offers important information regarding their treatment such as possible adverse effects, and highlights the need to check with their doctor if any minor surgery is planned and lists important contact numbers in case of emergency. The card offers encouragement for further discussion and liaison regarding their treatment with their primary care physician.

**CONCLUSIONS:** In-stent thrombosis is a life threatening complication following stent insertion. Evidence demonstrates that premature withdrawal of antiplatelet therapy is the most significant factor associated with stent thrombosis. Information needs to be communicated across the interface to ensure continuation of therapy, with a need for patients to ensure ownership to prevent inappropriate abrupture of therapy.

We have developed a national clopidogrel card with positive feedback received from patients, medical staff and local PCT advisors. Centres outside UK have also expressed an interest in the card.

**133. Outcomes in a multi-disciplinary heart failure disease management program.** *Katharine O. Cornell, Pharm.D., BCPS, Mona Shaban, B.S., Tracy Connor-Riddick, P.A.-C, Laszlo Littmann, M.D., FACC; Myers Park Clinic, Carolinas HealthCare, Charlotte, North Carolina, USA.*

**OBJECTIVES:** To describe outcomes in a disease management program (DMP) serving indigent patients with advanced heart failure (HF). The team included a cardiologist, physician assistant, pharmacist, dietician, social worker, and nurse.

**METHODS:** Medical records of 128 patients attending the DMP during the June-August 2008 data collection period or who were seen in the HF Clinic more than 3 times from March 2006-June 2008 were reviewed. Patients' medical history, drug treatment, medication adherence by prescription refills, echo results, hospitalizations and emergency department visits were documented.

**RESULTS:** The patients were 69% male, 85% African-American, and 41% diabetic. Mean age was 56.3 years. Mean duration of follow-up was 3.5 years. Previous cocaine use was documented in 23%. All had systolic heart failure (72% non-ischemic). Mean initial ejection fraction (EF) was 18.1% and increased to 31.8%. Beta blocker (BB) titration to target doses of metoprolol succinate 200 mg daily or carvedilol  $\geq 25$  mg twice daily was tolerated by 66%. Fifty-three of 128 were adherent, obtaining  $\geq 80\%$  of doses. BB titration to  $\geq 1/2$  of target doses was tolerated by 84%, and 55% were adherent. Lisinopril  $\geq 10$  mg/day (or if intolerant, an angiotensin-receptor blocker) was prescribed for 73%. Patients took an average of 9.2 maintenance medications including 37% spironolactone, 30% digoxin, and 19% isosorbide dinitrate/hydralazine. Of 72 current patients who came  $\geq 1$  year, 13.9% had heart-failure related admissions and 12.5% had heart-failure related emergency department visits during the year.

**CONCLUSIONS:** In a multidisciplinary HF DMP providing frequent patient follow-up, medication optimization, patient education, and access to staff, we demonstrated that most could be titrated to at least half of the target BB dose, EFs could be markedly improved and

hospitalizations kept at a low level despite very low initial EFs, the fact that most patients were indigent, and many had a history of substance abuse.

## Clinical Administration

**134. Impact of a natural disaster on the practice of pharmacy: the reaction of pharmacists and other stakeholders directly and indirectly involved.** *Susan H. Staggs, Pharm.D.,<sup>1</sup> Kate Puetz, Pharm.D.,<sup>2</sup> Jordan F. Baye, Student Pharmacist<sup>1</sup>; (1)University of Iowa, Iowa City, Iowa, USA; (2)Iowa Pharmacy Association, Des Moines, Iowa, USA.*

**OBJECTIVES:** During the summer of 2008, the State of Iowa experienced a natural disaster of epic proportions. Due to extensive flooding, eighty-six percent of the counties in Iowa were Presidentially-declared disaster counties. Anecdotal information suggests that the profession of pharmacy was no less affected. Thus, the objectives of our paper are to: (1) compare various pharmacy practice settings and their responses/reactions to the flood; and (2) organize and disseminate data and experiences from pharmacy providers and other stakeholders to share best practices and lessons learned from the floods.

**METHODS:** A web-based survey was sent to all pharmacists in the state of Iowa. The survey included questions regarding patient volume increase or decreases, access to appropriate medical records, utilization of a pre-existing disaster plan, resources utilized during disaster, participation in recovery efforts, and demographic data on pharmacists and practice sites affected. On-site interviews were conducted with pharmacists whose infrastructure was directly affected by the flooding (i.e., closure or evacuation of the practice site). Additionally, interviews were conducted with the State Board of Pharmacy, wholesalers, and public and private payors.

**RESULTS:** A total of seven (out of 947) pharmacies were directly impacted by the flooding (one hospital, four community, one nuclear, and one family medicine site). Of the sites directly affected, the average number of days out of the site was 55 days (range 5-122; three sites remain under construction). Data regarding pre-existing plans, recovery efforts, access to medical records, patient volume increases/decreases and demographic data will be presented along with data from the other stakeholders.

**CONCLUSIONS:** The overall impact on pharmacies in the state of Iowa was minimal. Most sites were able to deliver the needed care to patients however, there were interruptions. Lessons learned included the necessity of a disaster plan and importance of communication with appropriate stakeholders.

**135. Description of pharmacist activity on inpatient use of erythropoiesis-stimulating agents.** *Michelle E. Allen, Pharm.D.,<sup>1</sup> Aimee LeClaire, Pharm.D.,<sup>1</sup> Mark A. Allen, M.S.<sup>2</sup>; (1)Shands at the University of Florida, Gainesville, Florida, USA; (2)University of Florida College of Pharmacy, Gainesville, Florida, USA.*

**OBJECTIVES:** To describe the impact of pharmacist activity secondary to initiation of a pharmacy and therapeutics (P&T) committee approved protocol for erythropoiesis-stimulating agents (ESA).

**METHODS:** Analysis of quality improvement data. Setting: University hospital. Patients: Three hundred and eight-five inpatients, ages 1 year of age and greater. Intervention: P&T authority allows pharmacists to perform the following activities without prior prescriber approval or verbal order for any patient who is greater than one year of age including, but not limited to dose standardization, therapeutic interchange, discontinue ESA if the hemoglobin (Hgb) is greater than 12 g/dL for chronic kidney disease or greater than 10 g/dL for all other indications, order multiple laboratory tests, and adjust ESA secondary to Hgb response.

**RESULTS AND MEASUREMENTS:** The evaluation questions from this study are related to impact and process of the protocol. The impact question is how much is ESA use decreasing by implementing this protocol, and the process question is how well is the protocol being followed. The impact and process outcomes were measured during four periods over a one-year time period. One pharmacy intervention is discontinuation of ESA orders secondary to elevated Hgb; during period one there were five orders discontinued out of 128 orders. During period two through four there were five out of 73, five out of 78, and four out of 106 orders discontinued. A process component is an

assessment of the completeness of pharmacist initial and follow-up documentation. Initial ESA assessment included documentation of Hgb. During periods one through four there were 26, 9, 9 and 6 instances, respectively, where initial documentation was either absent or incorrect. **CONCLUSIONS:** Pharmacist adherence to the ESA protocol has improved over time. The protocol has also been successful in reducing inappropriate use and as a result has led to cost savings.

**136E. Importing unlicensed medicines in a Portuguese university hospital.** Ana Rita Lopes, Pharm.D., Ana Cristina Rama, Pharm.D., Abreu Adelaide, Pharm.D., Maria Jose Saraiva, Pharm.D., Adelaide Lima, Pharm.D., Paula Pina, Pharm.D., Rita Joao Lopes, Pharm.D., Sebastiao Ferreira da Silva, Pharm.D., Jose Feio, Pharm.D., Odete Isabel, Pharm.D., Francisco Machado, Pharm.D.; HUC, Coimbra, Portugal.

**OBJECTIVES:** In Portugal, the national medicines regulatory agency (INFARMED) is responsible for the authorization to import unlicensed essential medicinal products. This procedure is needed for products which are not marketed in Portugal, are still under clinical evaluation or for authorized medicines that are under evaluation of its added therapeutic value. Our objective is to demonstrate the role of the hospital pharmacist in the management, distribution and surveillance of these medicines.

**METHODS:** Description of the procedures and participants in the medicines' importation for Portugal. Retrospective evaluation of the medicines imported during 2007 in our hospital.

**RESULTS:** For imported medicines, the hospital pharmacist is responsible to find a supplier and obtain the necessary documents, including the certificate of marketing authorization and of compliance with GMP, SPC and a leaflet in Portuguese. It may also be necessary a clinical justification and an informed consent of each patient.

In our hospital, during 2007, 108 medicines were imported, corresponding to 125 importation requests. Although our records cannot give us the time elapsed from request to medicines' availability, our experience shows us that it takes much more time than for approved medicines, which may compromise clinical results.

The imported medicines accounts for 2.88% of the hospital's medicines and 1.36% of the annual budget. These medicines are mainly diagnostic agents (n=34), antineoplastics or immunomodulating agents (n=19), cardiovascular drugs (n=11), anti-infectives (n=10) and antidotes (n=7). The medicines with preliminary data of clinical benefit accounted for 7.84% of the imported medicines and were used for the treatment of 119 patients.

**CONCLUSIONS:** The main objective of the hospital pharmacist is the distribution of the medicines required for the patients, whilst assuring its quality, efficacy, safety at the lowest price.

For this purpose, the hospital pharmacist may use the described method for the medicines' importation to guarantee the prescribed therapeutic plan.

Submitted to the 14th Conference of the EAHP (European Association of Hospital Pharmacists). Barcelona, Spain

## Clinical Pharmacy

**137. The pharmaceutical intervention in a cardiology and pulmonology wards.** Ana G. Parola, Pharmacist, Maria Helena Farinha, Pharm.D., Maria de Fátima Falcão, Pharm.D.; Pharmaceutical Services, Hospital de Egas Moniz, Hospital Centre Lisbon West, Lisboa, Portugal.

**OBJECTIVES:** Implementation of Pharmacotherapeutic Follow-up (PTF) in a Cardiology and Pulmonology Ward; PTF can be defined as a professional practice in which the Pharmacist is responsible for the patient needs, detecting drug-related problems (DRPs) and preventing/resolving negative results of medication (NRMs). The Dáder Methodology advocates the achievement of the patient's pharmacotherapeutic history through an interview conducted by the pharmacist. The health problems are evaluated in face of the medicines the patient uses, in order to identify NRMs. The Pharmacist will intervene, resolving or preventing the NRM (Pharmaceutical Intervention - PI).

**METHODS:** Documentation and analysis of PIs implemented in the departments of Cardiology and Pulmonology of Hospital Egas Moniz (HEM), Hospital Centre Lisbon West, according to the Dáder method of PTF in the year 2007.

The NRMs were classified according with 3 parameters: Necessity, Effectiveness and Safety; NRM<sub>1</sub>- need for additional drug; NRM<sub>2</sub>- identification of drug without indication; NRM<sub>3</sub>- not dose-dependent ineffectiveness; NRM<sub>4</sub>- dose-dependent ineffectiveness; NRM<sub>5</sub>- detection of not dose-dependent adverse reactions; NRM<sub>6</sub>- detection of dose-dependent adverse reactions. PIs have been classified into 3 types: dosage change (PI1); drug strategy adjustment, by removing, adding or replacing drugs (PI2); information/training of patients or healthcare professionals (PI3).

**RESULTS:** Throughout the year 2007 118 PIs were held in the Cardiology and 108 PIs in the Pulmonology departments. The NRMs of necessity corresponded to 41.2% and NRMs of safety to 41.6% of the total of NRMs detected.

PIs were accepted in 67.5% of cases in the Cardiology and 65.7% of cases in the Pulmonology departments. PI2 accounted for 61.5% of interventions made.

**CONCLUSIONS:** The Pharmacist should preferably be proactive, preventing NRMs. Participation in medical visits and employment of the Dáder method allows a broader involvement of the Pharmacist in qualified healthcare delivery.

## Clinical trials

**138. The hospital pharmacist in clinical trials.** Francisco Machado, Pharmacist, Sebastiao Silva, Pharmacist, Jose Feio, Pharmacist, Adelaide Lima, Pharm.D., Paula Pina, Pharm.D., Ana Rita Lopes, Pharm.D., Alexandra Torres, Pharm.D., Angelina Martins, Pharm.D.; HUC, Coimbra, Portugal.

**OBJECTIVES:** Clinical investigation demands the establishment of multidisciplinary teams. The security, responsibility, transparency and tracing of all the clinical trial medicine and medical devices used are fundamental for the clinical trial's credibility. The pharmacist participation in the investigational team contributes to increase the: security and adherence of clinical trials subject; heftiness and reliability of the data; describe and characterize the evolution of the activities undertaken by the pharmaceutical service's clinical trials unit (PSCTU), between 2005 and 2007. To evaluate the acceptance of this sector amongst the parts involved.

**METHODS:** Retrospective analysis of the data basis of the PSCTU.

**RESULTS:** The PSCTU is responsible for: storage, distribution, preparation and account for the clinical trials medicines and medical devices; therapeutic adhesion monitoring (analysis and promotion); treatment selection; patient training; information; maintenance of the blindness whenever it is necessary; analysis of the pharmacotherapeutic profile; dosage calculation according to the age, weight and renal function. The PSCTU are open 24 hours a day, 7 days a week. Some of the results from 2005, 2006 and 2007 respectively are: number of trials: 56, 69 and 88; number of patients: 219, 334 and 590; therapeutic adhesion average: 85%, 90% and 94%; number of molecules: 30, 36 and 58; investigational sites: 17, 22 and 30; principal investigators: 20, 24 and 30; sponsors: 23, 29 and 45.

**CONCLUSIONS:** In 2007, 100% of the clinical trials that took place in our hospital had the active participation of pharmacists. Today the pharmacist is seen as a fundamental element of the investigational team. Nowadays, in Portugal, the legislation regarding clinical trials demands the responsibility of a hospital pharmacist for the management of the clinical trials drugs.

## Community Pharmacy Practice

**139. From therapeutic innovation to good use: dibotermine alpha in fracture femur guideline.** Emmanuelle Cohen De Lara, Pharmacist, Resident,<sup>1</sup> Julie Rouprêt-Serzec, Pharmacist,<sup>1</sup> Mahamadou Tandia, Pharmacist,<sup>1</sup> Marysa Héricourt, Technician,<sup>1</sup> Agnès Certain, P.H.,<sup>2</sup> Philippe Arnaud, pharmacist<sup>1</sup>; (1)Hospital Bichat Claude Bernard, Paris, France; (2)Pharmacy, Hospital Bichat Claude Bernard, Paris, France.

**OBJECTIVES:** Dibotermine alpha, a human recombination protein is indicated in lumbar arthrodesis and tibia's fractures. A pharmacovigilance alert notified cases of liquid accumulation in March 2007 in non-approved clinical use. Such innovative and expensive drugs require clinical pharmaceutical implication for a rational and safe use. We report pharmaceutical management of dibotermine alpha.

**METHODS:** One patient medical history with femur's fracture treated with dibotermine alpha in March 2008 at the hospital Bichat Claude Bernard was reviewed.

**RESULTS:** After a motorbike accident, a 27-year-old man had a orthopaedic surgery reduction of his femur with external fixator. The patient underwent skin and osseous transplant, osteosynthesis by plate for a three-month period. The patient remained painful with pseudoarthrosis, so in January 2008 the orthopaedic surgeon chose Dibotermine alpha associated with a second spongy bone transplant. When the clinical pharmacist received the prescription, she insisted to obtain literature articles, in order to validate this non approved indication. Dibotermine alpha was stored in the hospital pharmacy. In February, a pharmacovigilance alert happened because of a lack of matrix in a batch. Pharmacist checked conformity of the product according to Health Authority recommendations. In March, dibotermine alpha was injected. One month later, the fixator was tolerated and the clinical evolution was satisfactory. A pharmacovigilance alert was notified in May concerning increasing infections on shinbone fracture treated with Dibotermine alpha. Our patient wasn't concerned. He went in re-education until June and the fixator was taken out in July.

**CONCLUSIONS:** Dibotermine alpha is not approved for femur's fracture. However, it presents beneficial effect in osteosynthesis without undesirable effect and complication. Thanks to Dibotermine alpha, despite a non approved indication and high cost, patient improvement was obtained and no rehospitalization was needed lowering financial costs. Pharmaceutical interventions permitted safe and good use.

**140. IMPACT of pharmaceutical evaluation of drug dosage adjustment according to renal function in a cardiology department of university hospital.** Julie Pouzoulet, Pharm.D., Roxana Mohammadi, Pharm.D., Nisryn Razzouq, Pharm.D., Muriel Paul, Pharm.D., Alain Astier, Pharm.D.; Henri Mondor University Hospital, Creteil, France.

**OBJECTIVES:** Up to now, cardiologists claimed to be aware of the importance of drug dosage adjustment (DDA) according to the renal function. The aim of this study was to evaluate if drug dosages were adjusted according to patients' creatinine clearance (ClCr).

**METHODS:** A prospective study was conducted analysing following items: drug prescribed, dosage, ClCr and DDA according to the renal function. The Clcr (ml/min) was estimated by using the Cockcroft and Gault formula. Patients were classified according to mild (Clcr: 60–90), moderate (30–60), severe (15–30) and terminal (<15) renal impairment (RI). We also highlighted the number of prescriptions that included DDA or not and the number of contraindications. Finally, we assessed the number of cases where physicians changed their prescriptions after our advice.

**RESULTS:** Hundred individual prescriptions were analysed. Among them, 17 patients had a normal renal function, 24 a mild RI, 40 a moderate RI and 19 a severe RI. No patient was in a terminal RI. There was no DDA according to renal function in 20% of cases, (11 moderate RI; 7 severe RI; and 2 mild RI). Perindopril was the most prescribed drug without dosage adjustment (DA): 11 prescriptions. Amiodarone was the second drug without any DA (3 prescriptions), followed by Tramadol and Paroxetine (2 prescriptions) and finally Pravastatin (1 prescription). Three contraindications were noticed: Metformin prescribed for a patient with a ClCr <80, Rosuvastatin and Fenofibrate were prescribed for a patient with a severe RI. Finally, 10 out of 20 prescriptions were modified by physicians after our advice.

**CONCLUSIONS:** This study showed that DDA was underperformed by cardiologists, even though 83% of patients had RI. Thus, considering the iatrogenic risk and potentially irreversible RI related to the lack of DA, pharmacists should play an essential role in increasing physicians' awareness of dosage adjustment in RI especially in the elderly.

## Critical Care

**141. Comparison of tight versus more liberal blood glucose target ranges in surgical trauma intensive care unit patients.** Jason S. Haney, Pharm.D., Cathy L. Worrall, Pharm.D., BCPS, BCNSP, FAPhA, Kit N. Simpson, D.P.H., Stuart M. Leon, M.D.; Medical University of South Carolina, Charleston, South Carolina, USA.

**OBJECTIVES:** Controversy exists regarding the optimal blood glucose (BG) target range for subpopulations of critically ill patients. This study

evaluated outcomes for surgical trauma intensive care unit (STICU) patients managed using a tight (80–110 mg/dL) vs. a more liberal (80–140 mg/dL) BG target range to determine if tight control (TC) is necessary in our patient population.

**METHODS:** A total of 180 charts (90 patients per group) from August 2007–August 2008 were retrospectively evaluated. Patients were included if they were managed by the surgical critical care team and deemed critically ill (ventilated or hemodynamically unstable for >24 hours). The primary outcome measure was ICU length of stay (LOS). Secondary outcomes measures included ventilator days, hospital LOS, infectious complications, and mortality. Assuming a  $9.3 \pm 6.8$  day ICU LOS with 86 patients in each group, we predicted 80% power to detect a 1.3 day decrease in ICU LOS after controlling for initial APACHE II scores. *T*-test and  $\chi^2$  were used to analyze continuous and categorical variables, respectively. Logarithmic transformation was used for non-normal measures. Ordinary least squares and logistic regression modeling were employed to control for confounding variables.

**RESULTS:** The initial APACHE II scores (18.8 vs. 17.7;  $p=0.0384$ ) and the number of diabetic patients (16 vs. 5,  $p=0.0182$ ) were higher in the TC group. The number of trauma patients (41 vs. 53;  $p=0.0384$ ) was higher in the liberal control group. All other baseline characteristics were similar between groups. ICU LOS and ventilator days were 3.7 days ( $p=0.014$ ) and 3.1 days ( $p=0.01$ ) shorter, respectively, for the TC group. TC patients were also 69.3% less likely to experience an infectious complication (OR 0.307; CI 95 0.143–0.658). Hospital LOS and mortality were not significantly different between groups.

**CONCLUSIONS:** Tight glycemic control significantly reduced ICU resource allocation and infectious complications in our STICU population.

**142. Results of a pharmacotherapeutic follow-up program in an intensive care unit.** Erica R. Viegas, M.D., Nadine P Ribeiro, M.D., Fátima P Falcão, M.D.; S. Francisco Xavier Hospital, CHLO, 1500 Lisboa, Portugal.

**OBJECTIVES:** Several studies have demonstrated the positive impact of clinical pharmacy services in Intensive Care Units (ICU). Patients in the ICU are typically receiving multiple medications, often by parenteral route. Interventions by clinical pharmacists have shown to reduce the frequency of drug related problems. The purpose of this study is to evaluate the results of pharmacotherapeutic follow-up in an ICU.

**METHODS:** An observational, longitudinal study was conducted between January and July 2008, revising prescribed pharmacotherapy. Setting: Intensive Care Unit of S. Francisco Xavier Hospital, CHLO (general hospital). Main Outcome Measures: Evaluation of Health Problems (HP), drug related problems (DRP) and pharmacist's interventions.

**RESULTS:** The study included 97 patients, 58 men and 39 women, median age of 45 years (20–94). The main health problem found was infection (79.4%), followed by cardiogenic shock, stroke and myocardial infarction. 228 DRP were identified, leading all to documented pharmacist's interventions (2.4 interventions per patient). The major cause of intervention was dose adjustment based on clinical pharmacokinetic monitoring (69.7%), risk of drug toxicity (18.4%), inadequate parenteral nutrition (5.3%), and the risk of ineffectiveness (4.8%). Thirty-five (80.2%) of all interventions concerned antibiotic treatment, 7.0% parenteral nutrition, 6.6% stress ulcer prophylaxis and 1.8% anticoagulant therapy. 91.7% of the interventions made were accepted by the physician and only 8.3% not accepted.

**CONCLUSIONS:** With this study we can conclude that a high number of pharmaceutical interventions are due to a small number of drugs. Once these DRP are mostly preventable, implementation of effective, continuous and systematic pharmacotherapy reviews are needed. Clinical pharmacists are the members of the multidisciplinary team that have the skills and the duty to provide this service. A clinical pharmacist positioned as member of the health care team contribute to maximize the results of pharmacotherapy, preventing DRP and improving clinical outcomes of critically ill patients.

**143. UKHealthCare off-label use process for recombinant activated factor VII.** Deanna M. McMahon, Pharm.D., Jeremy D. Flynn, Pharm.D., BCPS, John A. Armitstead, M.S., R.Ph., FASHP; UKHealthCare, Lexington, Kentucky, USA.

**OBJECTIVES:** Recombinant human coagulation factor VIIa (rFVIIa) is FDA-approved for the prevention and treatment of bleeding episodes in hemophiliacs. Use of rFVIIa is increasingly common in non-hemophiliacs for off-label indications. rFVIIa promotes hemostasis, but the lowest effective dose for off-label utilization, as well as the incidence of adverse events, are unknown. Given the concerns of limited efficacy and safety data, many institutions have developed guidelines to direct and monitor the use of rFVIIa. We have developed guidelines at UKHealthCare to standardize the ordering, dispensing, utilization and monitoring of FVIIa for its off-label use in adult patients.

**METHODS:** A committee representing the major medical and surgical disciplines, led by pharmacy services, met and agreed on the recommended off-label indications and associated rFVIIa dosing regimens.

**RESULTS:** The proposal was approved by the Pharmaceutical and Therapeutics (P&T) Committee at UKHealthCare with minor revisions. An order set was then developed to allow physicians to enter a "pharmacist to dose rFVIIa" through the electronic order entry system or call pharmacy directly to commence the process. Once initiated, a pharmacist responds by bringing the medication to bedside either in the intensive care unit or operating room. Prior to reconstitution, the pharmacist discusses with the ordering physician therapies failed, indication, dosing, factors that may decrease medication effectiveness, potential risks, and monitoring parameters based on the specific patient case. The pharmacist then prepares rFVIIa for administration as appropriate. A pocket reference describing the process was created and inservices are ongoing for involved parties. Finally, a report form is under development as a means of documenting the data for each case to be presented at the P&T meetings quarterly to track progress and address necessary changes.

**CONCLUSIONS:** The UKHealthCare off-label rFVIIa use process is an innovative clinical pharmacy service, bringing the pharmacist to the bedside to assist in the emergency management of patients.

**144E. Comparison of the antibiotic dose prescription through an antibiotic dose alert system and by a clinical pharmacist in critically ill patients with renal dysfunction.** *Barbara O. Claus, Hospital, Pharmacist, Kirsten E. Colpaert, Ph.,<sup>1</sup> Valerie Vanderstraeten, Pharm.,<sup>2</sup> Kristof Steurbaut, Engineer,<sup>1</sup> Johan M. Decruyenaere, Ph.D.,<sup>1</sup> Hugo Robays, Pharm<sup>1</sup>; (1)Ghent University Hospital, Ghent, Belgium; (2)Ghent University, Ghent, Belgium.*

**OBJECTIVES:** (1) To compare the adaptation of antibiotic dosage through an electronic alert system and by the clinical pharmacist at an Intensive Care Unit (ICU); (2) To evaluate the physician's prescription.

**METHODS:** A daily e-mail alert for dosage adaptation of antibiotics in renal dysfunction is generated based upon the patient's laboratory information for a 36-bed medical and surgical adult ICU. Algorithms for adaptation are developed in cooperation with the Department of Infectious Diseases (DID). Renal dysfunction is a 24 hour-creatinin clearance below 50 ml/min and/or dialysis. 1. A junior clinical pharmacist daily screened admitted patients. Alert information is kept hidden from both clinical pharmacists and physicians during the study. 2. A senior clinical pharmacist and an intensivist compared dosage adaptations with the prescription. Consensus was reached by discussion.

**RESULTS:** Out of 171 patients, admitted during 44 consecutive days (February–April 2008), 70 patients experienced at least one day of renal dysfunction. Pharmacist and alert respectively screened 1409 and 628 antibiotic prescriptions. In 48.2% of the prescriptions, pharmacist and alert advised the same dosage (higher, lower); in 41.9% the alert did not find the prescription. In 9.9% pharmacist and alert gave opposite advice. Analysis of the timeline of dose adaptation revealed that on average the adaptation of the pharmacist was formulated on day 1, for the alert on day 2, for the physician on day 3. Analysis of the physician's prescription showed that in 77.3% of all prescriptions and in 58.2% of prescriptions in patients with renal problems, physicians followed the algorithms of DID. In short episodes of acute kidney injury (<2 days) the physician did not adapt the dose.

**CONCLUSIONS:** An electronic alert can help trace renal dysfunction; a human approach is still necessary for translating electronically generated information.

Presented at the 37th European Symposium on Clinical Pharmacy of the European Society of Clinical Pharmacy, Dubrovnik, Croatia, October 21–24, 2008.

## Drug Information

**145. New module of regional drug and poisoning information center in Saudi Arabia.** *Yousef Ahmed Alomi, B.Sc., M.Sc., BCPS, Amani M. Aleman, B.Sc., Fahad S. Al-Refai, B.Sc., Areej S. Al-Jebreen, B.Sc., Amal M. Al-Smary, B.Sc.; King Saud Medical Complex, Regional Drug and Poisoning Information Center, Riyadh, Saudi Arabia.*

**OBJECTIVES:** To describe the New Module of Regional Drug and Poisoning Information Center in Kingdom of Saudi Arabia (KSA).

**METHODS:** American Society of Health-System Pharmacist (ASHP) Guidelines through the best practice standard 2008 with emphasis of drug information services, Adverse Drug Reaction System, Medication Errors program, Patient Education, Research and Clinical Trail, Pharmacokinetics, and Role of pharmacist in Bio-informatics were reviewed. National Hospital Standard of Saudi Arabia with emphasis on Pharmacy Standard from Central Board of Accreditation for Healthcare Institutions 2006 also was reviewed with WHO guidelines of Drug Information Services. The authors visited some local and regional Drug and Poisoning Information Center and review their activities in Saudi Arabia.

**RESULTS:** New module of Regional Drug and Poisoning Information Center had been established since October 2007. It consists of Drug Information Center, Poisoning and Clinical Toxicology Center, Bio-Information Center, Pharmacovigilance Center, Pharmacoeconomic Center, Clinical Pharmacokinetics Center, Research & Clinical Trail Center, Staff Development & Training Center, Documentation and Quality of Informatics, Administration and Financial Department, and Secretary Department. Policy and Procedures was written for each center and department, Standards of practice were established for each section. Workload and Human resources were analyzed with financial budget before starting the activities. We divided the plan into three stages, first stage to cover health care professional of our hospital (1350 beds) and MOH, then to cover more than eight hospitals, then to cover all public in the region and Saudi Arabia.

**CONCLUSIONS:** This new module will serve several hospitals at one region with different specialties, and utilize all the human and financial resources available in the region, and save a lot of money, it is better than establishing several small drug information centers.

**146E. Strategies for library Collection development for schools of pharmacy.** *Andrea L. McKeever, Pharm.D.,<sup>1</sup> Cathy H. Turner, Pharm.D.,<sup>2</sup> (1)South University School of Pharmacy, Savannah, Georgia, USA; (2)Belmont University School of Pharmacy, Nashville, Tennessee, USA*

**OBJECTIVES:** To provide guidance to schools of pharmacy for library collection development using insight from new programs. Library collection development is not only a required element of the Accreditation Council for Pharmacy Education (ACPE) 2007 Standard No. 29 (Library and Educational Resources) but is necessary to meet students' educational and faculty's professional needs. In pre-existing programs, library collections predominately undergo refinement; however, new programs are faced with the challenge of collection creation. Even though tools for collection development (i.e., AACP Basic Resources for Pharmacy Education and the Core Journal List) exist and are recommended for use by ACPE, limited guidance is provided on how to best utilize these tools to identify, compile, and triage references for acquisition.

**METHODS:** Experiences from two new schools of pharmacy were collected and summarized to develop strategies for library collection development. The entire process was evaluated from types of input (e.g., AACP lists, surveys) used at baseline to recurrent assessment of the collection by students and faculty for overall satisfaction and adequacy of holdings.

**RESULTS:** Inter-school collaboration helped to develop a stepwise approach to collection creation and refinement. Additionally, strengths and limitations of the collection development tools were identified along with recommendations for addressing their shortcomings.

**CONCLUSIONS:** Lessons learned can be shared with other new pharmacy programs for collection creation and pre-existing programs for collection refinement.

Presented at the American Association of Colleges of Pharmacy 2008 Annual Meeting and Seminars Poster Presentations, Chicago, Illinois, USA, July 19–23, 2008.

147. **Clinical trial registration and results reporting at ClinicalTrials.gov.** *Rebecca J. Williams, Pharm.D.*; ClinicalTrials.gov, National Library of Medicine, National Institutes of Health, Bethesda, Maryland, USA

**OBJECTIVES:** A registry and results database of ongoing and completed clinical research is, among other things, a mechanism to facilitate transparency, fulfill ethical obligations to research participants, and inform researchers and health care professionals of developing scientific evidence. Registration is supported by Federal and state laws as well as international policies. ClinicalTrials.gov is the largest public registry, with over 64,000 interventional and observational studies in 158 countries (October 2008). The registry was launched by the National Institutes of Health (NIH) in 2000 and expanded in 2007–08 in response to the Food and Drug Administration Amendments Act of 2007. The objective of this poster is to describe the new registration and results reporting requirements under the law and to highlight the potential utilities of a combined registry and results database to clinical pharmacists.

**METHODS:** *ClinicalTrials.gov* utilizes structured data elements to collect and display important information about a clinical study protocol and its results. We reviewed the data elements required by the new law, how they are being implemented in ClinicalTrials.gov, and explored potential utilities of a registry and results database.

**RESULTS:** Under the law, certain publicly and privately funded clinical trials must be registered within 21 days of enrollment and a subset are required to report results information within one year of trial completion. Key data elements required by law include trial design, target enrollment, name and type of intervention(s), primary and secondary outcomes, anticipated completion date and other administrative information. Information is required to be updated at least once yearly and specific data elements must be updated more frequently. Required summary results information includes participant flow, baseline characteristics, primary and secondary outcomes, and serious and other adverse events.

**CONCLUSIONS:** A combined clinical trial registry and results database increases transparency in clinical research and is a useful tool to clinical pharmacists.

## Education/Training

148E. **Impact of pharmacy students' recommendations during an ambulatory care advanced pharmacy practice experience.** *Lisa M. Lundquist, Pharm.D., BCPS*; Mercer University, Atlanta, Georgia, USA.

**OBJECTIVES:** To compare the acceptance rates of written versus oral recommendations made by pharmacy students on an ambulatory care advanced pharmacy practice experience (APPE).

**METHODS:** Fourth-year pharmacy students completing an ambulatory care APPE made written and oral pharmacotherapy recommendations to resident physicians in an internal medicine clinic at an urban, teaching hospital from March 2007 through October 2007 (excluding July). The types of recommendations and outcomes of the interventions were recorded using a data collection form. The primary endpoint was to determine differences in acceptance rates for written versus oral recommendations. Secondary endpoints included comparing the recommendation types and their corresponding acceptance rates.

**RESULTS:** A total of 507 pharmacotherapy recommendations were made by eight students during the 7 month study period; 52.4% (n=247) of these were written. A total of 98.5% of oral recommendations were accepted compared with 87.1% of written recommendations. The major types of recommendations and rates of acceptance included: prescription written incorrectly (100%), dosage change (87.1%), laboratory tests needed (91.3%), medication initiation based on evidence based medicine guidelines (79.7%), and medication discontinuation (95.7%). In addition, medication reconciliation and patient counseling were completed for 1425 patients.

**CONCLUSIONS:** Pharmacy student recommendations are well received by internal medicine resident physicians. High acceptance rates for pharmacotherapy recommendations may have the ability to positively impact patient care.

Presented at the Annual Meeting of American Association of Colleges of Pharmacy, Chicago, Illinois, USA, July 20–22.

149. **Assessment of attitudes and value placed on pharmacist board certification.** *Andrew Smith, Pharm.D.*,<sup>1</sup> *Tony Huke, Pharm.D.*,<sup>2</sup> (1)UMKC School of Pharmacy, Kansas City, Missouri, USA; (2)Truman Medical Center, Kansas City, Missouri, USA.

**OBJECTIVES:** With the possible addition of Ambulatory/Primary Care to the available board certifications offered by the Board of Pharmaceutical Specialties (BPS), a survey assessing the current attitudes towards board certification by hospital pharmacy administration was performed.

**METHODS:** A short survey was designed asking various demographic information such as size, type of hospital, the number of full-time and board certified pharmacists employed. The survey also ascertained information regarding value of board certification in the view of the institution and the incentives provided to become a board certified pharmacist. The survey was electronically sent to pharmacy directors within two large list serves. The University HealthSystems Consortium (UHC) is an alliance of 102 academic medical centers and 191 affiliated hospitals which represent approximately 90 percent of the not-for-profit teaching hospitals in the United States. Pharmacy Systems Incorporated (PSI) is a pharmacy management service that has 90 accounts that include acute care hospitals, long-term care facilities, rehabilitation hospitals and psychiatric hospitals. These two list serves were chosen to provide a broad sample of various practice sites for evaluation. Statistics run will be descriptive and bivariate analysis using SPSS version 16.0.

**RESULTS:** Data collection is ongoing and will be completed in January of 2009. Information presented will include demographic data, type and size of hospitals responding, percentage of board certified pharmacists. Attempts will be made to correlate the number of board certified pharmacist with the size or type of hospitals as well as correlating the value placed on board certification and available incentives for pharmacists.

**CONCLUSIONS:** Statements will be made as to the relationship of board certification and practice site demographics.

150. **Continuing professional development: pharmacist provided smoking cessation brief intervention program.** *Autumn L. Runyon, Pharm.D.*, *Monica L. Skomo, Pharm.D.*, *Pamela H. Koerner, Pharm.D.*, *Christine K. O'Neil, Pharm.D.*, *FCCP, BCPS*, *Andrea Reath, Pharm.D. Candidate*; Duquesne University, Mylan School of Pharmacy, Pittsburgh, Pennsylvania, USA.

**OBJECTIVES:** Smoking is the leading cause of preventable death in the United States. Studies have demonstrated that asking a patient, "Do you smoke?" is associated with increased cessation rates. However, this simple intervention is not a routine question posed by community pharmacists to patients. As Continuing Professional Development is becoming a model of pharmacist's lifelong learning, a project was developed to describe the impact of a smoking cessation intervention training program on pharmacist knowledge, confidence, and ability to conduct smoking cessation interventions.

**METHODS:** Advanced community preceptors from various community pharmacies are being recruited to participate in a live smoking cessation training program. The training program includes didactic training, active learning exercises to augment the lecture, and required brief smoking cessation interventions at their practice site on a regular basis following the training session. Each pharmacist will complete a self-assessment survey prior to, immediately following, and thirty days after the training program. The self-assessment survey seeks to measure pharmacist knowledge and confidence in their ability to conduct smoking cessation interventions. Pharmacists will provide a weekly report of the number of interventions conducted.

**RESULTS:** Data from the pre- and post-self assessment surveys will be collected and analyzed using descriptive and inferential statistics. Results will be presented at the 2009 ACCP/ESCP Meeting.

**CONCLUSIONS:** Community pharmacists come into frequent contact with tobacco users. Therefore, they have tremendous opportunities to positively impact tobacco cessation efforts. As the learning model for pharmacist's continuing education is beginning to change towards a systematic, cyclical process of self-directed learning, development of innovative practice strategies to further educate and empower pharmacists to conduct smoking cessation encounters is necessary. The goal is that information obtained will enable the pharmacist to have a positive impact on patient health outcomes.

**151. Identifying international health experiential opportunities at colleges of pharmacy in the United States.** Patricia Klein, Pharm.D., M.P.H.,<sup>1</sup> Patricia R. Wigle, Pharm.D., BCPS,<sup>2</sup> Matthew J. Brown, Pharm.D.,<sup>3</sup> Katie Clark, Pharm.D.,<sup>4</sup>; (1)Drug and Poison Information Center, Cincinnati, Ohio, USA; (2)University of Cincinnati, Cincinnati, Ohio, USA; (3)Chillicothe Veterans Affairs Medical Center, Chillicothe, Ohio, USA; (4)Grant Medical Center, Columbus, Ohio, USA.

**OBJECTIVES:** The primary objective for this study was to determine the availability of international health care experiential opportunities at United States (U.S.) Colleges of Pharmacy. A secondary objective was to share this information as a resource for preceptors interested in starting an international health care rotation at their institution.

**METHODS:** An international health care questionnaire was created and approved by the institutional review board. Experiential coordinators were identified using information provided on their respective college websites. The questionnaire was distributed via email to the experiential coordinators at 109 Colleges of Pharmacy.

**RESULTS:** This project had a 20% response rate, which included 5 private and 17 state-supported institutions. Thirteen (54.5%) offered an international health care experiential rotation. These experiences involved 25 countries and had been in existence from 1 to more than 20 years. The number of available rotation positions ranged from 1–24 with 2–50 student applicants per year. The application process involved an interview, an application, an essay, a letter of recommendation and/or a meeting with the experiential coordinator. The majority (69.2%) did not require any international health coursework prior to the trip. Cost ranged from \$1,500 to \$5,000 per student with 61.5% of students receiving some form of financial assistance. For institutions that do not have an international health care experience, the most often cited reasons were cost, liability and this type of rotation being a low priority item.

**CONCLUSIONS:** There is remarkable heterogeneity in the international health care rotations available at U.S. Colleges of Pharmacy. The diversity in type and length of experience, location, preceptorship, application process and cost is a fertile area for collaboration among schools to provide their students with the best chance for a unique opportunity to provide patient care. Response rates may have been influenced by potential misidentification of the experiential coordinator.

**152. Could the involvement of pharmacy students improve patients' knowledge about their anticoagulant treatment?** Melanie Brignone, Pharm.D.,<sup>1</sup> Ornella Conort, Pharm.D., Ph.D.,<sup>2</sup> Sara Nazaraly, M.Sc.,<sup>1</sup> Sandrine Houze, P.H., Ph.D.,<sup>3</sup> Agnès Certain, Pharm.D., Ph.D.,<sup>4</sup> Virginie Siguret-Depasse, Pharm.D., Ph.D.,<sup>5</sup> Eric Pautas, Pharm.D.,<sup>6</sup> Françoise Brion, Pharm.D., Ph.D.,<sup>5</sup> Nathalie Pons-Kerjean, Pharm.D.,<sup>7</sup> Olivier Bourdon, Pharm.D., Ph.D.,<sup>5</sup> Patrick Tilleul, Pharm.D., Ph.D.,<sup>1</sup>; (1)Pharmacy, Saint-Antoine Hospital, Paris, France; (2)Pharmacy, Cochin Hospital, Paris, France; (3)Parasitology, Bichat Hospital, Paris, France; (4)Pharmacy, Hospital Bichat Claude Bernard, Paris, France; (5)Pharmacy University Paris-Descartes, Paris, France; (6)Hematology, Louis Mourier Hospital, Colombes, France; (7)Pharmacy, Louis Mourier Hospital, Colombes, France.

**OBJECTIVES:** During their fifth-year course, pharmacy students in France are trained during one year in a hospital clinical department to apply their knowledge to current clinical practice. The objective of this study was to assess the impact of the pharmacy student's interventions in an educational program of VKA therapy.

**METHODS:** A multi-center, prospective study (7 hospitals) was conducted during 6 months. All patients treated with VKA were eligible, except those who didn't give their oral consent or who did not understand the French language. A standardized questionnaire was used during a face-to-face interview with pharmacy students in order to assess the patient's knowledge concerning their treatment. 14 questions were submitted before the intervention of a pharmacystudent (phase 1) and after his intervention (phase 2). Only patients who had a lack of knowledge in phase 1 (more than 2 wrong answers) were included in phase 2. Between phase 1 and 2, the role of pharmacy students was to improve the patient's knowledge and to give recommendations for a better management of treatment.

**RESULTS:** 170 patients (median age 71.5 years) were included. Education was necessary for 83 patients in phase 1, but only 52 were recruited by the students in phase 2. The mean number of good answers

to the questionnaire has improved significantly from 8.7 to 11.6 ( $p < 1.103$ ) from phase 1 to 2. INR monitoring and risk of overdosage were the two major items not well known that were dramatically improved by the student intervention.

**CONCLUSIONS:** The involvement of pharmacy students could allow a better knowledge of their treatment by the patient, contributing to a safer use of these oral anticoagulant treatments.

**153. Retention of knowledge and confidence level of cardiopulmonary resuscitation learned in a pharmacy skills patient assessment course.** Kristi A. Isaac, Pharm.D., AE-C, Cori M. Brock, Pharm.D., CDE; Xavier University College of Pharmacy, New Orleans, Louisiana, USA.

**OBJECTIVES:** The purpose of this study is to compare pre- and post-test results evaluating the retention of cardiopulmonary resuscitation (CPR) knowledge and assess the confidence level of second year pharmacy students enrolled in a patient assessment course.

**METHODS:** One hundred fifty-four second year pharmacy students received American Red Cross training as a requirement of a patient assessment lab. Two weeks after the instructor led training, resuscitation skills were assessed using the Little Anne and Baby Anne manikins. CPR knowledge was measured using a twenty-four question, multiple choice. Items regarding rate, depth and hand position for chest compressions as well as the correct sequence of basic life support were included. After twelve weeks post-training, CPR knowledge will be reevaluated via the same multiple-choice questionnaire. Students will complete a survey instrument to determine their confidence level regarding the provision of basic life support to a victim of cardiopulmonary arrest.

**RESULTS:** 100% of students participated in the CPR assessment at the beginning of the semester. 69% of students are female and 53% are African American. Although the majority of students passed the pretest, the majority did not pass the physical assessment of CPR technique on the initial attempt. Posttest results will be available in November.

**CONCLUSIONS:** Pharmacists have long been providers of CPR. Their participation in hospital systems has illustrated a reduction in the mortality rate associated with cardiac arrest. Despite these interventions, it has been argued that CPR skills taught in a pharmacy curriculum are unlikely to prepare students to perform in cardiac arrest situations because those skills are not likely used in pharmacy practice. As pharmacy services continue to expand, such statement is no longer true. Poor knowledge and skill retention after cardiopulmonary resuscitation training have been documented in as early as ten weeks following instructor led training.

## Endocrinology

**154. Differences in cell migration and protease secretion between normal and type-1 diabetic fibroblasts.** Kathryn A. Connor, Pharm.D.,<sup>1</sup> William J. Lindblad, Ph.D.,<sup>2</sup> Mamata Vallury, B.Pharm.,<sup>2</sup> Anjan Kowluru, Ph.D.,<sup>2</sup>; (1)The Regional Medical Center at Memphis, Memphis, Tennessee, USA; (2)Wayne State University, Detroit, Michigan, USA.

**OBJECTIVES:** To explore intrinsic differences between fibroblasts in the Type 1 diabetic lower extremity prior to wounding and normal dermal fibroblasts in order to better characterize the impaired healing response that causes chronic ulceration, infection and potentially amputation.

**METHODS:** Non-transformed fibroblast cell lines from Type 1 diabetics and genetically matched normals were obtained from the NIGMS-NIH cell repository at the Coriell Institute. Cells were maintained in Dulbecco's modified Eagle's medium containing 10% fetal calf serum, penicillin, streptomycin and either 450 mg/dl (high) or 100mg/dl (low) glucose. Cell migration was assessed at 24, 48 and 72 hours by measurement of cell movement away from a circular source of 50,000 cells deposited within a cloning ring.

**RESULTS:** Normal dermal fibroblasts migrated in a uniform halo of cells to a mean diameter of  $9.22 \pm 0.085$ mm at 72 hours. The migration pattern of diabetic fibroblasts was too diffuse to be quantified, suggesting a potential disruption of the extracellular matrix upon which the cells were plated, possibly due to an increased secretion of collagenolytic activity. Measurement of total active collagenolytic activity found that diabetic cells secreted 4.9 fold the level of proteolytic activity into the media over 24 hours compared to normal fibroblasts ( $0.00444 + 0.00208$  vs.  $0.000908 + 0.000458$  A520/min).

**CONCLUSIONS:** Dermal fibroblasts from Type 1 diabetics possess a

functional alteration that may disrupt migratory activity required for normal wound healing. Fibroblasts from Type 1 diabetics may secrete increased levels of collagenolytic activity able to degrade the sub-cellular matrix to which the cells adhere. Functionally, this allows them to lose attachment and diffuse over the culture plate, whereas normal fibroblasts remain attached and move by the migratory apparatus of the cell. These results expand upon previous knowledge of the impaired healing response in Type 1 diabetics that leads to significant morbidity.

## Family Medicine

**155E. Developing a new role of liaison for pharmacists in a family medicine clinic.** *Marie-Claude Vanier, B.Pharm., M.Sc.,<sup>1</sup> H el ene Lachance-Demers, B.Pharm., M.Sc.,<sup>2</sup> Am elie Garneau, B.Pharm., M.Sc.,<sup>2</sup> Catherine Cellini, B.Pharm., M.Sc.,<sup>3</sup> Natacha Beaulieu, M.Sc.,<sup>4</sup> Olivier Turpin-Lavall e, B.Pharm., M.Sc.,<sup>2</sup> Alain Turcotte, M.D.,<sup>2</sup> Lyne Lalonde, B.Pharm., Ph.D.<sup>1</sup>; (1)CSSS de Laval - Cit e de la Sant e and Facult e de Pharmacie, Universit e de Montr eal, Montr eal, Quebec Canada; (2)CSSS de Laval - Cit e de la Sant e, Laval, Quebec Canada; (3)Pharmacie Marc Champagne, Montreal, Quebec Canada; (4)Pharmacie Jean-Fran ois Gu evin, Montr eal, Quebec Canada.*

**CONTEXT:** Although our family medicine clinic (FMC) includes 1 FTE pharmacist, medication review for all patients is impossible. Access to clinical information and support from a liaison pharmacist could encourage involvement of community pharmacists (COM-pharm) in medication reviews.

**OBJECTIVES:** Develop pharmacist liaison service in a FMC in order to facilitate interventions of COM-pharm.

**METHODS:** Our FMC is a multidisciplinary group providing collaborative care to over 8000 patients. Liaison service was created within a larger study of interventions following reception of a physician's request for medication review and a standard prescription or a prescription enriched with clinical information. Forty-nine COM-pharm attended a workshop providing information on the liaison service and pharmacotherapy assessment case discussions. A FMC-pharm is available at the clinic to answer questions from COM-pharm and links with medical team if necessary. FMC-pharm documented communications with COM-pharm between November 2007 and April 2008 using standardized forms.

**RESULTS:** Forty-two pharmacies, 66 COM-pharm and 2 FMC-pharm participated in the study. FMC-pharm documented 58 communications with 27 COM-pharm related to 49 patients. Medication classes most frequently involved were: cardiovascular (33%), lipid lowering (22%), anti-diabetic (12%) and anticoagulants/antiplatelets (10%). Among 69 issues discussed, most frequent were: obtaining laboratory results or suggesting laboratory monitoring (33%), discordant medication charts (18%), dose too high (8%) and additional medication needed (8%). Among 93 actions taken by FMC-pharm, most frequent were: transferring to COM-pharm laboratory results (29%) or other information (21%), discussion with MD or note in patient's FMC file (21%), precising medication history (14%) and correcting patient's FMC chart (11%).

**CONCLUSIONS:** Personal link established through workshop and access to FMC-pharmacists encouraged communication between pharmacists. Liaison service was used regularly by COM-pharm, was easily integrated in the FMC-pharm tasks and resulted in additional information or correction of available information to FMC team in 48% of cases discussed.

Presented at the 96th Annual National Conference of Canadian Pharmacists Association, Victoria, British Columbia, Canada, May 31-June 3, 2008.

## Gastroenterology

**156. Pantoprasol versus ranitidine in the treatment of gastrointestinal hemorrhage.** *Gordana D. Vucic, M.Sc., Mirjana Kendrisic, M.D.;* Health Centre Sremska Mitrovica, Sremska Mitrovica, Serbia and Montenegro.

**OBJECTIVES:** Pantoprasol has become a safer alternative to ranitidine in the treatment of gastrointestinal hemorrhage.

**METHODS:** After approval of the local ethics committee two groups of patients were included in this prospective study. All of them suffered from peptic ulcer disease which was verified endoscopically (up to 24

hours from the start of bleeding). Group P (Pantoprasol) with 37 patients aged 37-67 years were administered continual infusion of pantoprasol (8 mg/h) up to 72 hours. Group R (Ranitidine) with 34 patients aged 32-71 years were administered bolus dose of ranitidine (5 mg/6h) up to 72 hours. Number of further hemorrhage (need for the operation), hospital stay and total cost of the treatment were analyzed. Statistics were analyzed with Chi Squared and Student's test.

**RESULTS:**

	Group P	Group R	P value
Number of patients	37	34	NS
Gastric ulceration	27	25	NS
Duodenal ulceration	10	9	NS
Need for operation	1	7	P<0.05
Mean hospital stay	9+3	17+4	P<0.05
Cost in EUR	185.54	336.31	P<0.05

**CONCLUSIONS:** We can say that the use of continuous infusion of pantoprasol is more efficient than the use of ranitidine in the treatment of gastrointestinal hemorrhage. Number of repeated hemorrhage is significantly lower in patients within P group. Hospital stay in P group is shorter, total cost of treatment is lower, so the cost-benefit ratio is better.

## Geriatrics

**157. Implementation of clinical pharmacy in Belgian nursing homes: challenges identified during two interventional studies.** *Charlotte L. Verrue, M.Pharm.,<sup>1</sup> Els L. Mehuys, M.Pharm., Ph.D.,<sup>1</sup> Mirko S. Petrovic, M.D., Ph.D.<sup>2</sup>;* (1)Ghent University - Faculty of Pharmaceutical Sciences, Gent, Belgium; (2)Ghent University Hospital - Department of Geriatrics, Gent, Belgium.

**OBJECTIVES:** The descriptive "Prescribing in Homes for the Elderly in Belgium" (PHEBE) study highlighted quality problems during the administration and prescription of medications in nursing homes (NH's). This resulted in 2 interventional studies, each targeting one of the problem areas. (Partial) study results have been presented at the ESCP conferences in Istanbul (2007) and Dubrovnik (2008). This paper aims at summarising the different challenges encountered during both studies.

**METHODS:** Qualitative assessment of one pre-post study in 2 NH's (evaluating an educational session on good medication administration practices given by a pharmacist to the nursing staff) and one non-randomised controlled trial in 2 NH's (assessing the effect of medication reviews on the quality of prescribing).

**RESULTS:** Challenges identified during the first study were the high rate of staff turnover (meaning that the sessions should be repeated regularly), the need of up-to-date ready-to-use educational packages for the delivering community pharmacists, a psychological threshold for pharmacists to speak in front of an audience, and the dependence of the success of the intervention on the goodwill of the nursing staff. Questions also rose on whether this kind of nurse education should become a standard service provided by the delivering pharmacists (free of charge), or whether it could be an extra-remunerated service. The second study identified problems such as need for legal access to medical records, need for practical tools (electronic charts, communication charts with nurses / GP's), need for legal recognition of clinical NH pharmacists, financial issues, need for regular follow-up and need of mentality change towards a multidisciplinary collaboration.

**CONCLUSIONS:** Our studies have shown that pharmacists can have an important role in the optimisation of pharmacotherapy in Belgian NH's. However, several legal, financial and practical issues need to be addressed before clinical pharmacy services can be implemented in daily practice.

**158. Identification of problems related to medication processes at a geriatric ward.** *Charlotte S. Roth, Pharmacy Candidate;* Sygehusapotek Fyn, Odense, Denmark.

**OBJECTIVES:** The collaboration project between the geriatric ward and the clinical pharmacist was initiated with discussions, resulting in a list of possible focus areas for clinical pharmacy interventions. The primary target was agreed to be identification of errors related to the medication processes involving prescription, dispensing and administration of drugs.

**METHODS:** The clinical pharmacist participated at ward rounds after reviewing the medical charts of selected patients. Interventions were suggested and discussed with the physicians before approaching the patients. The clinical pharmacist participated at morning conferences and assisted a registrar during the ward rounds. The clinical pharmacist observed nurses with main focus on their medication handling procedures. Observations and suggestions of interventions were collected.

**RESULTS:** On admission, the physicians reduced significant numbers of drugs given to the geriatric patient. The ward rounds typically involved 8-10 patients. The patients often had several diagnoses. Interventions to the medication regimens included either medications stopped, paused, new drugs initiated or change of doses. Frequent reasons for changes were interactions, infections, pains, electrolyte imbalances and troubleshooting for patients not able to administer tablets themselves. Mistakes observed when nurses dispensed drugs at the ward included: incorrect dose, double-medication or wrong drug. The time for administration of medicine did not necessarily coincide with the time reported in the charts.

**CONCLUSIONS:** The study identified a range of issues affecting the quality of the patients' care and patient safety. As a result, targets for future clinical pharmacy interventions at the geriatric ward are suggested to be rational pharmacotherapy, quality control of the prescribing process and handling of drugs. Education for patients and staff is also a target area identified during the problem identification period.

**159. Is high-dose statin therapy safe in the elderly?** *Séverine Gupta, Pharm.D.*,<sup>1</sup> *Isabelle Peyron, Pharm.D.*,<sup>1</sup> *Christelle Laguillier, Pharm.D.*,<sup>2</sup> *Nadine Oboa, Pharm.D.*,<sup>1</sup> *Anna Sarfati, Pharm.D.*<sup>1</sup>; (1)APHP Hôpital Charles Foix, Department of Pharmacy, Ivry Sur Seine, France; (2)APHP Hôpital Charles Foix, Department of Clinical Chemistry, Ivry Sur Seine, France.

**OBJECTIVES:** The aim of this study is to perform a one day survey of statin prescriptions in a French geriatric hospital and to analyze the blood lipid levels in patients receiving a statin.

**METHODS:** Patients who receive statins were selected and had laboratory tests performed: total cholesterol (TC); low-density lipoprotein cholesterol (LDL-C); and high-density lipoprotein cholesterol (HDL-C).

**RESULTS:** 167 of 730 (22.8%) hospitalized patients receive a statin. A blood lipid levels analyze is performed in 136/167 patients: 88 female and 48 male, mean age 81 ±10 years, 20 patients are hospitalized in geriatric care units, 34 patients in reeducation and readaptation units, and 82 are institutionalized patients. The laboratory test results show that: 74 (54%) patients have hypocholesterolemia (TC: 117 ± 20 mg/dL, LDL-C: 63 ± 16 mg/dL, HDL-C: 35 ± 1.0 mg/dL), 60 (44%) patients have normocholesterolemia, and 3 (2%) patients have hypercholesterolemia. 43 patients of 136 receive high dose statin therapy (rosuvastatin 5 mg/d (n=5) or 10 mg/d (n=3), atorvastatin 40 mg/d (n=31) or 80 mg/d (n=1), pravastatin 40 mg/d (n=1)) and 31 of this 43 patients (72%) were hypocholesterolemic. Statin treatment has been stopping in 8 hypocholesterolemic patients.

**CONCLUSIONS:** Statins are widely used in elderly patients but result frequently in hypocholesterolemia. Several studies have demonstrated an association between hypocholesterolemia and intracerebral hemorrhage, and hemorrhagic stroke risk increased with age. Low LDL-C and low HDL-C concentrations may be associated with an increased risk of infectious disease. Furthermore elderly patients may be more susceptible to adverse events when receiving high doses of statins because of polytherapy and reduced hepatic and renal function. Since studies with high dose of statin were not performed in elderly cohorts, what is the benefit/risk ratio of aggressive reduction in cholesterol levels in elderly patients?

**160. Prescribing trends of diuretics in elderly patients.** *Lilian M. Azzopardi, B.Pharm. (Hons), M.Phil., Ph.D.*, *Anthony Serracino-Ingloft, B.Pharm., Pharm.D.*, *Maurice Zarb-Adami, B.Pharm., Ph.D.*, *Maria Grech, B.Pharm., (Hons)*; Department of Pharmacy, University of Malta, Msida, Malta.

**OBJECTIVES:** Diuretics are among the most frequently prescribed drugs

in Western Society with approximately 20% of the geriatric population on long-term diuretic therapy. The objective of this study was to assess the use of diuretics in elderly patients.

**METHODS:** Protocols regarding the use of diuretics in hypertension and congestive heart failure were drawn up. The protocols were reviewed by a panel of experts. Subsequently, patient files of fifty patients over the age of 65 years (mean age 82 years, age range 67–99 years; females 38 and males 12) and suffering from hypertension (9), congestive heart failure (12) or both (29) were reviewed. A patient profile sheet was used to collate data. Compliance of prescription of diuretics with the protocols was assessed. Analysis of data with two variables was done using the  $\chi^2$  test using SPSS version 15.0. The study was carried out at two geriatric institutions, namely Zammit Clapp Hospital and St Vincent de Paule Residence.

**RESULTS:** The diuretics used were bendroflumethiazide, bumetanide, furosemide, and spironolactone. Spironolactone was found to be underprescribed in 13 out of 17 eligible cases. The other diuretics were correctly prescribed in 32 patients out of 38 patients for bumetanide, in 9 patients out of 11 patients for bendroflumethiazide, and in 7 patients out of 8 patients for furosemide.

**CONCLUSIONS:** The developed protocols were accepted by the panel and could be used to evaluate prescribing trends of diuretics in the two institutions. Bendroflumethiazide, bumetanide and furosemide were the most likely diuretics to be used correctly whereas spironolactone is underprescribed. More education to healthprofessionals practising in the institutions is required about the use of spironolactone according to the protocols.

**REFERENCE:** Walma E, Hoes A, Does E, van der Dooren C, van Prins A. General practice: withdrawal of long-term diuretic medication in elderly patients; a double blind randomized trial *BMJ* 1997;315:464-468.

**161. Utilization of technology to prevent and minimize inappropriate use of sedative/hypnotic agents in elderly inpatients.** *Olga Hilas, Pharm.D., BCPS, CGP*; St. John's University, Queens, New York, USA.

**OBJECTIVES:** To utilize technology in an effort to prevent and minimize inappropriate use of sedative/hypnotic agents among elderly inpatients.

**METHODS:** A geriatric advisory group of a large urban healthcare system (consisting of physicians, nurses and a pharmacist) collaboratively reviewed all sedative/hypnotic agents on formulary and reached a consensus on appropriate indications for use and drug dosages for patients 60 years of age and older.

**RESULTS:** Geriatric pop-up warnings, dosing recommendations and therapeutic alternatives were created for incorporation into the computerized order entry system.

**CONCLUSIONS:** Sedative/hypnotic agents are often prescribed and used inappropriately in elderly patients, which can lead to numerous adverse events and consequences. The use of technology to prevent and minimize these potential sequelae may prove to be of great value.

## Health Policy

**162. Developing an evidence-based provincial model for remuneration of pharmacist clinical services: policy implications from the perspective of government in British Columbia, Canada.** *Elaine Chong, B.Sc.(Pharm), Pharm.D., BCPS*,<sup>1</sup> *Ariel Lade, Senior Economist*,<sup>2</sup> *Elisheba Muturi, M.Sc., MLIS, MAS*,<sup>1</sup> *Regina McGowan, Policy, Analyst*,<sup>2</sup> *Aileen Mira, BSP, ACPR*,<sup>1</sup> *Glenda P. MacDonald, BSP, ACPR, Pharm.D.*,<sup>1</sup> *Sarah Jennings, B.Sc., B.Sc.(Pharm)*,<sup>1</sup> *Mitch Moneo, Director, Policy & Communications*,<sup>2</sup> *Brett Wilmer, Director, Economic Analysis*,<sup>2</sup> *Darlene Therrien, Executive Director*,<sup>2</sup> *Paul Mochrie, Executive Director*,<sup>3</sup> *Suzanne C. Malfair Taylor, B.Sc.(Pharm), Pharm.D., BCPS, FCSHP*<sup>1</sup>; (1)Drug Use Optimization Branch, Pharmaceutical Services Division, BC Ministry of Health Services, New Westminster, British Columbia Canada; (2)Policy Outcomes, Evaluation and Research Branch, Pharmaceutical Services Division, Victoria, British Columbia Canada; (3)Business Management, Supplier Relations and Systems Branch, Pharmaceutical Services Division, BC Ministry of Health Services, New Westminster, British Columbia Canada.

**BACKGROUND:** Canada's publicly-funded healthcare system is experiencing changes in the scope of practice of non-physician healthcare professionals with resultant expectations of funding for

services. As of January 1, 2009, pharmacists in British Columbia (BC) will have authority to adapt prescriptions which includes: (1) renewing for continuity of care; (2) changing dose, formulation, or regimen to enhance patient outcomes; and (3) substituting within the same therapeutic class to better suit patient needs.

**OBJECTIVES:** Pharmaceutical Services Division (PSD), BC Ministry of Health Services set out to: (1) develop an innovative, evidence-based provincial model for remuneration of pharmacist clinical services in conjunction with expanded definitions of professional practice activities; and (2) apply this model to situations that result in pharmacist-initiated prescription renewals.

**METHODS:** A mixed-methods approach was used to add context and generalizability to the model. Quantitative data came from a systematic review of published reports; policy documents; an existing costing study; and a provincial, national, and international environmental scan of clinical service remuneration models. Qualitative data came from interviews with selected informants and stakeholders. A working group with clinical and policy representation produced and validated the model using a resource-based relative value scale.

**RESULTS:** Quantitative and qualitative results were compared. Impact on pharmacist resources was delineated and cost of professional activities were estimated and compared to fees billed by other healthcare professionals. The building block for the model was determined to be the resolution of medication management issues. The model is specific and flexible enough to describe a comprehensive spectrum of pharmacist clinical services including those that result in a prescription renewal as well as possible future clinical scenarios.

**CONCLUSIONS:** An innovative, evidence-based provincial model for remuneration of pharmacist clinical services was developed, with specific reference to services that result in pharmacist-initiated prescription renewals. Policy implications for this model were explored from a provincial government perspective.

## Infectious Diseases

**163. Optimization of anti-infective utilization secondary to technological advances in the field of rapid microbiology diagnostic tests.** Edward H. Eiland III, Pharm.D., M.B.A.,<sup>1</sup> Lea S. Eiland, Pharm.D.<sup>2</sup>; (1)Huntsville Hospital, Huntsville, Alabama, USA; (2)Auburn University Harrison School of Pharmacy, Huntsville, Alabama, USA.

**OBJECTIVES:** To justify the acquisition and implementation of Target Enriched Multiplex Polymerase Chain Reaction (tem-PCR) in the hospital setting to attain timely diagnostic results for various infectious diseases (e.g., Staphylococcal infections) leading to more judicious anti-infective intervention. Additionally, knowing that diagnostic capabilities are easier to describe than achieve, and both accuracy and timeliness is of importance we aim to show how the adoption of microbiologic diagnostic techniques can preserve reimbursement rates from Centers for Medicare & Medicaid Services (CMS) as they further enforce never events and various directives to better correlate quality of care provided to Medicare patients and the payment rendered.

**METHODS:** A comparative analysis of current microbiologic diagnostic techniques and their associated costs and timing parameters were evaluated versus literature describing rapid microbiologic diagnostic capabilities from both the patient and payer perspective. The following data were analyzed: cost of currently available culture and sensitivity reporting compared to rapid microbiologic diagnostic tests; time to reporting of final microbiology results; portion of total costs allocated to empiric antimicrobial therapy; and ease of use and adaptability for healthcare professionals.

**RESULTS:** The tem-PCR methodology provides results to the clinician in less than four hours. It differentiates between four types of staphylococcal organisms and provides more specific resistance information. Comparing the techniques, tem-PCR provides more timely information resulting in earlier changes in antimicrobial regimens, thus decreasing morbidity and mortality, as compared to current microbiological tests and results.

**CONCLUSIONS:** The tem-PCR technique should be considered by hospitals to provide staphylococcal culture and resistance information quicker, thus resulting in appropriate antimicrobial use and improved patient outcomes. In addition, by proving through laboratory tests that patients had prior infections upon admissions, this can increase or maintain current reimbursement rates from CMS.

**164. Impact of an infectious diseases clinical pharmacist on antibiotic use in outpatient clinics.** Marisel Segarra-Newnham, Pharm.D., M.P.H., FCCP, BCPS; Veterans Affairs Medical Center, West Palm Beach, Florida, USA.

**OBJECTIVES:** Describe the impact of an infectious diseases (ID) clinical pharmacy specialist on antibiotic use in community-based outpatient clinics (CBOC) affiliated with a Veterans Affairs (VA) Medical Center.

**METHODS:** Our VA medical center has six contract CBOCs that provide primary care services for some of our veterans. Medications prescribed by providers at these CBOCs are mailed from our facility; however, exceptions are made for urgent medications that patients need to start in a more timely fashion, such as antibiotics, and these medications can be filled at local pharmacies. Some of the more expensive antibiotics require pre-approval by a pharmacist before these medications can be filled. An ID pharmacist is available for consultation to the pharmacist or CBOC providers for specific cases. Recommendations made are tracked for documentation purposes without any patient-specific identifiers. We reviewed the types of recommendations and cost-avoidance provided by the ID pharmacist from August 2001 to July 2008. Recommendations were categorized as: (1) add drug; (2) decrease dose; (3) discontinue drug; (4) increase dose; (5) non-formulary drug approval; or (6) education.

**RESULTS:** Over the seven year period reviewed, 622 therapeutic recommendations were made by the pharmacist. The most common recommendations were to educate providers on ID topics (38%), to discontinue chronic antibiotics (28%), and for non-formulary approvals (21%) with 40% of requests approved. A total of 260 antibiotic courses were avoided. It is not possible to determine if education provided helped avoid additional courses. These recommendations resulted in a net cost-avoidance of \$39,000 for drug acquisition costs alone.

**CONCLUSIONS:** An ID clinical pharmacy specialist providing antibiotic-related recommendations for CBOC providers decreased costs by about \$5,500 per year and avoided over 250 courses of unnecessary antibiotics over a seven year period. A similar program could be adapted at other institutions with a pre-approval process in place.

**165. Relationships between antibiotics usage and nosocomial-acquired gram-negative bacteria drug resistance: an experience in a medical center at South Taiwan, 2001–2006.** Chen F. Fangting, master, Chen I. I-Ling, master; Chang Gung Memorial Hospital -Kaohsiung, Kaohsiung, Taiwan.

**OBJECTIVES:** To monitor the relationship between antibiotics control and the trend of antimicrobial susceptibility.

**METHODS:** We performed a retrospective analysis for the antimicrobial susceptibility of extended-spectrum cephalosporins (ceftriaxone, ceftazidime, cefepime, flomoxef, cefiprome),  $\beta$ -lactam- $\beta$  lactamase (amoxicillin/clavulanic acid, ampicillin/sulbactam), carbapenem (meropenem, imipenem, ertapenem), aminoglycoside (amikacin, gentamicin), extended-spectrum penicillin (piperacillin), oral and parenteral form of fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin) against nosocomial acquired *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter* spp, *Acinetobacter baumannii*, *Morganella morganii*, *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia* and other non-fermentative Gram-negative bacilli (GNB) among 2001 to 2006 after hospital-wide antibiotic control program. Data on semiannual patient-days and antimicrobials consumption was defined by daily dose (DDD) per 1000 patient-days. Using Pearson's correlation coefficient determines the relationship between antibiotic consumption and trends in antimicrobial resistance. Linear regression was used to analysis the trends of antimicrobial consumption and the trends of rates among these nosocomial acquired GNB pathogens with time. An *r*-value  $>0.7$  (or  $<0.7$ ) and a *P*-value  $<0.05$  were considered statistically significant.

**RESULTS:** The trends of incidences of nosocomial infections among these GNB pathogens were not statistic change except a significant increasing incidence in *Stenotrophomonas maltophilia* ( $P=0.018$ ). In spite of the trends of consumption of representative antimicrobial agents were increased for broad spectrum cephalosporins,  $\beta$ -lactam- $\beta$  lactamase, carbapenems and quinolones ( $P<0.01$ ) and but significant decreased consumption for aminoglycosides ( $P<0.001$ ). The trends of susceptibility rate among these GNB pathogens were found that ciprofloxacin, piperacillin, ceftazidime and gentamicin resistance to *Morganella morganii* were significant decreased ( $P<0.01$ )

aminoglycosides resistance *Klebsiella pneumoniae* and *Pseudomonas aeruginosa* were also significant decreased ( $P < 0.01$ ).

**CONCLUSIONS:** During this period, most broad spectrum antimicrobial consumption was growing, but no decreasing nosocomial acquired GNB susceptibility rate. It was a significant positive correlation between the decrease in the use of aminoglycosides and the decreased prevalence of aminoglycoside resistance to GNB.

**166. Role of antimicrobial stewardship in controlling fluoroquinolone resistance against gram-negative organisms: impact of antimicrobial stewardship practice difference on resistance trend in two academic medical centers.** Roy Guharoy, Pharm.D., Elizabeth Radigan, Pharm.D., Jennifer Daly, M.D., Donald Blair, M.D.; University of Massachusetts Memorial, Worcester, Massachusetts, USA

**OBJECTIVES:** Widespread use of fluoroquinolones (FQs) have resulted in the escalation of resistance to commonly encountered gram negative pathogens. The objective of our presentation is to describe the impact of practice difference in two academic medical centers on FQ resistance trend against gram negative pathogens. FQs are restricted and available for use upon infectious disease approval in hospital A. Clinical justification of all quinolone usage is reviewed during multi-disciplinary infectious disease (ID) team round in hospital A and interventions are made as appropriate.

**METHODS:** Defined daily dose of FQ agents and resistance were compared from 2003–2006.

**RESULTS:**

Defined daily dose/1000 patient days.

	2003	2004	2005	2006.
Hospital A	21	22	29	43.
Hospital B	105	95	98	120.

FQ Resistance trend (% of all isolates): Hospital A vs. Hospital B.

	Hospital A				Hospital B.			
	2003	2004	2005	2006	2003	2004	2005	2006.
<i>E. coli</i>	8%	10%	16%	18%	4%	7%	20%	23%.
ESBL +								
<i>E. coli</i>	N/A	N/A	0	0	N/A	57%	71%	72%.
<i>K. pneumoniae</i>	1%	2%	6%	4%	17%	19%	10%	13%.
ESBL +								
<i>K. pneumoniae</i>	N/A	N/A	0%	0%	N/A	82%	96%	84%.
<i>P. aeruginosa</i>	25%	21%	17%	25%	48%	45%	46%	44%.
<i>P. mirabilis</i>	5%	4%	11%	12%	5%	8%	16%	25%.
<i>S. marcescens</i>	1%	5%	9%	4%	11%	5%	3%	7%.

**CONCLUSIONS:** Recent emergence of plasma-mediated resistance to FQ is a significant concern for potential treatment failure. Hospital A with controlled FQ use had lower resistance rate against gram negative organisms. Judicious use of FQs can prevent resistance and emergence of ESBL producing organisms.

## Information technology

**167. The importance of clinical decision support systems (CDSS) for therapeutic individualization in a computerized physician order entry (CPOE).** Sebastiao Silva, Pharm.D.,<sup>1</sup> Francisco Machado, Pharm.D.,<sup>1</sup> Jose Feio, Pharm.D.,<sup>1</sup> Artur Rebelo, Pharm.D.,<sup>1</sup> Pedro Costa, Eng.,<sup>2</sup> Anabela Heliskowsky, Eng.,<sup>2</sup> Orlando Rodrigues, Eng.,<sup>2</sup> Rui Janeiro, M.D.,<sup>1</sup> Odete Isabel, Pharm.D.<sup>1</sup>; (1)HUC, Coimbra, Portugal; (2)CPC-H, Porto, Portugal.

**OBJECTIVES:** Patient safety is essential for the quality of healthcare. CPOE has proven to reduce drug errors. Today's healthcare requires degrees of individualization which demands CDSS. According to Gaude et al, 27.6% of dose adjustment alerts are related to renal insufficiency and 17.2% patient's age. Our aim is to demonstrate the potential of a CDSS for dose adjustment taking the patient's age and renal function into account. This was done by analysing the patients that would benefit from such a system.

**METHODS:** From our drug master list we selected 12 active substances (antibiotics) for which we added dose adjustment information according to the creatinine's clearance and age. We gathered data from August 2007 to August 2008 to evaluate the adherence to our CPOE, and the patients that would benefit from this CDS.

**RESULTS:** Our CPOE has been implemented in over 95% of the hospital's drug circuit (>1400 beds, ambulatory, oncology, etc.) For the

period in study we had the following Results.

- 288.269 CPOE prescriptions
  - ◆ 41.473 from which had direct pharmacist intervention
- 0 paper based prescriptions
- 40.870 patients with on-line prescriptions from whom:
  - ◆ 5.780 were over 70 years old;
  - ◆ 1.517 patients had information on creatinine, weight and height.

**CONCLUSIONS:** The CDSS dose adjustment for renal impairment has improved the therapeutic plan in almost 4% of the patients, whilst in terms of age has proved to have the potential to improve at least 14% of the patients. By increasing the number of molecules with information on their dose adjustment, the number of patients benefiting will be much higher. The integration of clinical decision support systems improves the safety, effectiveness and rationality in the prescription of drugs. The next generation of CPOE with CDSS will include information on the patient's genome, therefore contributing to an even higher degree of individualization.

## Medication Safety

**168. Medication reconciliation by a pharmacist in the emergency department.** Andrea J. Kent, Pharm.D., Louise A Harrington, B.Sc.Pharm., Jill D Skinner, B.Sc.Pharm.; Colchester East Hants Health Authority, Truro, Nova Scotia Canada.

**OBJECTIVES:** Medication reconciliation is a process by which patients' home medications are compared to admission orders and discrepancies brought to the attention of the prescriber. Currently, many of our pharmacists' interventions are made at discharge: A pharmacist working in the emergency department (ED) will identify interventions earlier and prevent medication errors.

**METHODS:** A retrospective chart review was done to establish a baseline medication error rate. After which, a multidisciplinary team developed a medication list and order form. To identify home medications the pharmacist interviewed the patient and contacted the community pharmacy. The list was reconciled with admission ordered within 24 hours of admission. The pharmacist identified discrepancies, notified the physician and documented interventions. After completion of the 8 week trial, a random sample of 100 charts from the study population was reviewed with the same criteria as the baseline chart review and staff were surveyed on the form and process.

**RESULTS:** During the trial, the pharmacist completed medication histories and reconciled orders on 98 patients, which represents 35% of the patients admitted. A total of 124 medication discrepancies were found, the majority of errors involved home medications omitted on admission. The baseline review had 147 unreconciled medications per 100 admissions while the intervention group had 69 per 100 admissions, indicating a 53 percent reduction. Post study surveys were completed by 52 staff members. The majority of the respondents felt the form was accurate (72%), clear (78%), useful (70%), comprehensive (68%) and saved time (75%).

**CONCLUSIONS:** Medication errors occur frequently in our emergency department admission orders. The pharmacist in the emergency department was able to identify discrepancies in a timely manner and intervene to prevent 53% of medication errors.

**169E. Evaluation of a Pharmaceutical Care Program to the Cardiologic Patient.** M. Montero Sr., Pharm.D., M.A. Roch, Pharm. D., I. Font, Pharm.D., Head, Section, Mj Fernández, Pharm. D., V. Moreno, Pharm. D., J.I. Poveda, Pharm. D., Head, Department; University Hospital La Fe, Valencia, Spain

**OBJECTIVES:** Analyze the benefits of a pharmaceutical care program on the cardiologic patient; based on conciliation, information and patient satisfaction, to improve the safety in the use of drugs.

**METHODS:** Observational study carried out from January to March 2007 to patients (N=264) attended in the Area of Cardiology. An interview was realized after the admission and the patient was given discharge information about how medications should be administered. Seven days later there was evaluated the clinical usefulness of the welfare process being valued the adherence, drug related problems, efficiency of the intervention and patient satisfaction (telephonic questions). All this in an attempt of reducing the number of visits not programmed to urgencies and in contraposition of those patients that

were not included in the program.

**RESULTS:** 114 patients were (middle ages 67.7) included in the program, and 150 patients (middle ages 69.1) were excluded. In the program group 53 drug related problems were identified: 28.3 % of indication, efficiency: 54.7 % and safety: 17.0 %. The interest for the received information was 92.3 %; 94.4 % of the patients were satisfied with the pharmacist intervention and 93.3 % recognized a better knowledge of the medication. After a year of the pharmaceutical intervention the average number of visits to urgencies was of 1.5 in the first group, lower than those without intervention (2.2); as well as the average number of hospitalizable income decreased from 1.4 to 0.9 if the patients were included in the program.

**CONCLUSIONS:** The experience has confirmed satisfaction by the patients, increasing demand and the positive outcomes obtained, leads us to increase patients of others areas in the experience.

**170. Quality assurance in a university hospital compounding area: a comparison between American and European standards.** *Carmen López-Cabezas, Pharm.D., Mercè Roca, Pharm.D., Carles Codina, Pharm.D., Josep Ribas, Pharm.D.; Hospital Clinic Barcelona, Barcelona, Spain.*

**OBJECTIVES:** Quality assurance is particularly important in the manufacture of sterile products to minimize microbiological contamination and other potential risks for patients. American (FDA) and European (EMA) Regulatory Agencies have their own regulations in this area (Good Manufacturing Practice rules). ASHP has edited The Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products as an alternative way of achieving a quality product in a working environment of a hospital pharmacy service. In Europe the reference document is GMP for Sterile Medicinal Products. Study goals were: (1) To evaluate differences between the standards defined in the ASHP-Guidelines and the European GMP (EU-GMP); (2) To assess conformity of our compounding area to both of them.

**METHODS:** A comparative table considering EU-GMP and ASHP-Guidelines was built. For each ASHP recommendation, the respective European Standard was assigned. Hospital conformity was assessed to the EU-GMP and ASHP-Guidelines. It was evaluated considering three categories: Fully Compliant (fulfilment of 100% of statements); Partially Compliant (more/equal than 50%); and Non-Compliant (less than 50%).

**RESULTS:** Both documents are concordant about the main general standards, although the level of requirement for GMP is higher for garb, aseptic techniques and sanitation. Full, partially and non-compliance values to ASHP recommendations were 13 out of 22 statements, 8/22 and 1/22, respectively. In reference to the EU-GMP, these values resulted to be 12/22, 6/22 and 4/22, in that order.

**CONCLUSIONS:** As expected, concerning main general standards, both documents display a high level of agreement. In this study, the EU-GMP non-conformity values show the difficulty of applying GMP standards at a hospital pharmacy setting, even in a third level hospital. Taking into account the previous American experience, a European survey of quality assurance activities for pharmacy-compounded sterile preparations might be appealing, in order to assess the real situation and facilitate Pharmacy services to approach similar quality standards.

**171E. Pharmacist participation in the medication reconciliation process at medical wards of Ramathibodi Hospital.** *Taniya Paiboonvong, M.Sc., Preecha Montakantikul, Pharm.D., BCPS, Pramote Tragulpiankit, Ph.D.; Mahidol University, Bangkok, Thailand*

**OBJECTIVES:** To determine medication errors (MEs) and drug related problems (DRPs) in the medication reconciliation process at the time of hospital and discharge. In addition, effectiveness of a pharmacist to prevent MEs was also determined.

**METHODS:** The pharmacist identified MEs and DRPs in medication reconciliation process, during admission through discharge. 107 patients were recruited between February and April, 2008 at medical wards of Ramathibodi Hospital. Patient's medication history was collected to compare with medication order at the time of admission. All patients were followed to identify MEs and DRPs at hospital discharge.

**RESULTS:** MEs was found in 32 out of 107 patients (30%) in 56 items (1.8 items per patient) while 16 out of 100 patients (16.0%) were found at discharge in 18 items (1.1 items per patient). Most MEs were

categorized as category B (78.6%) which could be prevented by the pharmacist (86.4%) at admission, and all MEs were categorized as category B (100%) which could be prevented by the pharmacist (94.4%) at discharge. Vitamins and minerals were commonly found to be MEs at admission (18.6%) while antidiabetic agents (33.3%) were responsible for MEs at discharge. DRPs were identified in 39 patients (36.4 %) in 67 items (1.7 items per patient) at admission while 18 out of 100 patients (18%) were identified at discharge in 22 items (1.2 items per patient). Omission of medication was most commonly found at admission (64.3%) and discharge (55.6%). Therefore, the need for additional drug therapy was also commonly found at admission (58.2%) and discharge (63.6%). Most of the pharmacist's interventions for MEs and DRPs were accepted by physician.

**CONCLUSIONS:** The pharmacist's participation in the medication reconciliation process appeared to be beneficial in identifying MEs and DRPs, including prevention in MEs and DRPs at interface of care.

Presented at the 2009 International Congress on Clinical Pharmacy.

## Nephrology

**172. Impact of pharmacist-initiated interventions in the dialysis unit of a Lebanese tertiary teaching hospital.** *Rony Zeenny, Pharm.D.,<sup>1</sup> Abir Saade, Pharm.D. Candidate,<sup>1</sup> Wael Abi Ghanem, R.Ph.<sup>2</sup>; (1)Lebanese American University, Byblos, Lebanon; (2)Saint Georges Hospital-University Medical Center, Beirut, Lebanon.*

**OBJECTIVES:** Dialysis patients often require multiple and complicated drug therapy to manage their progressive medical conditions. They are also at increased risk of drug-related adverse events and complications. The study objective was to determine the impact of a clinical pharmacist in a dialysis unit in a Lebanese tertiary teaching hospital.

**METHODS:** All dialysis patients' charts at a 200-bed Lebanese tertiary care teaching hospital have been screened to identify opportunities for pharmacist interventions. Data collection included patient's demographics, medical conditions, medications appropriateness, and relevant clinical markers results (laboratory values). Interventions were recommended to the attending nephrologists and documented.

**RESULTS:** The charts of 58 patients, 26 (45%) men, mean (SD) age was 61 (19.5) years, have been reviewed during October 2008. A total of 146 pharmacist-initiated interventions have been documented to date. The recommendations were classified as: (1) laboratory-based dose adjustments in: (a) erythropoietin agents [15.8%], (b) phosphate binders [17.8%], (c) vitamin D analogues [17.2%], and (d) iron therapy [10.9%]; (2) disease state therapy management [35.6%]; and (3) renally-based dose adjustments [2.7%]. Currently, the reported Interventions acceptance rate is 83%.

**CONCLUSIONS:** The study provides evidence that pharmacist-initiated efforts were able to optimize therapy dosing, minimizing drug related problems and significantly improve clinical outcome in dialysis patients. This positive impact provides an enhanced support to the integration of a clinical pharmacist to the dialysis unit and the benefits of a physician-pharmacist partnership.

## Neurology

**173. Guidelines for the use of temozolomide in adult brain tumors treatment in the French context.** *Patrick Tilleul, P.H., Ph.D.,<sup>1</sup> Melanie Brignone, P.H.,<sup>1</sup> Yasmine Hassani, M.Sc.,<sup>1</sup> Luc Taillandier, M.D.,<sup>2</sup> Sophie Taillibert, M.D.,<sup>3</sup> Stephanie Cartalat-Carel, M.D.,<sup>4</sup> Isabelle Borget, P.H.,<sup>5</sup> Olivier Chinot, M.D., Ph.D.,<sup>6</sup>; (1)Pharmacy, Saint-Antoine Hospital, Paris, France; (2)Neurology, Saint-Julien Hospital, Nancy, France; (3)Neuro-Oncology, La Pitie Salpetriere Hospital, Paris, France; (4)Neurology, Pierre Wertheimer Hospital, Lyon, France; (5)Gustave Roussy Institute, Villejuif, France; (6)Neuro-Oncology, La Timone Hospital, Marseille, France.*

**OBJECTIVES:** Temozolomide is an oral alkylating cytotoxic agent of second generation. In France, it is indicated in the treatment of high-grade malignant glioma, in case of newly diagnosed glioblastoma multiforme as well as in recurrent or progressive malignant glioma (glioblastoma multiforme or anaplastic astrocytoma). However, temozolomide is also used, off label, in other clinical situations. The main objective of this study was to establish recommendations and guidelines for relevant prescriptions of temozolomide in primary brain

tumors and brain metastasis in adults in the French context.

**METHODS:** A systematic literature review was performed in several databases. The methodological quality and clinical relevance of the literature review were analysed by 6 French experts in neuro-oncology and pharmacists. The relevance of temozolomide use was quoted in an evidence level of validity (A to E), according to the recommendations scale adopted by the Haute Autorité de Santé, or HAS (French National Health Authority), for specific situations (other brain tumors, in the elderly, in different administration schedules, associated with other drugs). The use of temozolomide in melanoma and for pediatric patients was not evaluated.

**RESULTS:** Based on the level of evidence of the literature, the use of temozolomide can be justified for high-grade and low-grade glioma (with a B2 score), whereas, it appeared to be more controversial or even not recommended for the other indications (scores C to E). Regarding the dosing schedule and administration scheme, as well as the co-administration with other anticancer drugs, a C score was attributed for these off-label situations.

**CONCLUSIONS:** This study has contributed to the evidence-based medicine and can help clinicians in their practices. It is the first step of a global evaluation, which aims to analyse the clinical practices and the conformity of temozolomide prescriptions in patients suffering from brain cancer and/or metastasis.

## Nutrition

**174. Comparison of two types of total parenteral nutrition prescription methods in preterm neonates.** *Maria Skouroliaou, Ph.D.,<sup>1</sup> Katerina Koutri, R.D.,<sup>2</sup> Maria Stathopoulou, R.D.,<sup>1</sup> Ekaterini Vourvouhaki, M.D.,<sup>1</sup> Ifigenia Giannopoulou, Ph.D.,<sup>1</sup> Antonios Gounaris, M.D.<sup>3</sup>;* (1)Harokopio University, Athens, Greece; (2)Mitera Maternity Hospital, Athens, Greece; (3)General Hospital of Piraeus "Ag. Panteleimon", Piraeus, Greece.

**OBJECTIVES:** This study assessed the results of utilization of standardized computerized total parenteral nutrition (TPN) protocols and regimens for preterm neonates and compared them to the results of protocols and regimens prescribed by individual neonatologists on neonate outcomes.

**METHODS:** Two groups of 30 preterm infants (28–36 weeks) with respiratory failure born in a Greek maternity hospital were recruited for the study. Standardized, computer based protocols were applied for the prescription of individualized TPN formulations (to gestational age, weight, clinical status) in the first group, while on the other, regimens prescribed by neonatologists were used. Macro- and micronutrients provided by the different TPN protocols were recorded. Body weight was blood count and biochemical profile were performed at the beginning and at the end of parenteral nutrition support. The number of days of TPN support as well as the total number of days of hospitalization was recorded.

**RESULTS:** Standardized protocols provided more energy (p-value: 0.05), protein (p-value: 0.023) and micronutrients than the non-standardised. Neonates that receive standardized TPN gained weight (+44 ± 114 gr) and had better blood count and biochemical values during TPN support compared to the other group, that lost weight (-53 ± 156 gr). These differences were also statistically significant (p value<0.05). Regarding the total days of hospitalization, no differences were found between the two groups.

**CONCLUSIONS:** The use of standardized protocols in preterm neonates resulted in more adequate provision of nutrients, weight gain and better blood count profile compared with protocols prescribed by individual physicians. TPN support is an important task in neonate clinics and its implementation demands the standardization of the procedures in order to be safe, effective and to provide individualized nutrition support.

**175. Impact of a clinical pharmacist on undernutrition caring.** *Celine M. Michel, M.Pharm., M.Sc.,<sup>1</sup> Anne Spinewine, M.Pharm., M.Sc., Ph.D.,<sup>2</sup> Ariane Mouzon, M.Pharm., M.Sc.,<sup>3</sup> Jean-Daniel Hecq, M.Pharm., M.Sc., Ph.D.,<sup>4</sup> Jacques Jamart, M.D.,<sup>5</sup> Alain Dive, M.D.<sup>6</sup>;* (1)Clinical Pharmacy, Cliniques Universitaire Mont-Godinne, Yvoir, Belgium; (2)Clinical Pharmacy Center, School of pharmacy, Catholic University of Louvain, Brussels, Belgium; (3)Clinical Pharmacy, Cliniques Universitaires de Mont-Godinne, Yvoir, Belgium; (4)Pharmacy, Cliniques Universitaires

de Mont-Godinne, Yvoir, Belgium; (5)Unité de Biostatistique, Cliniques Universitaires de Mont-Godinne, Yvoir, Belgium; (6)Critical care unit, Cliniques Universitaires de Mont-Godinne, Yvoir, Belgium.

**OBJECTIVES:** Undernutrition is associated with increased length-of-stay, morbidity and mortality. Unfortunately, undernutrition remains underdiagnosed and undertreated. Clinical pharmacists can potentially contribute to improved care of this syndrome. Objectives were to evaluate the impact of a clinical pharmacist working in collaboration with doctors, nurses and nutritionists on the quality of care of undernutrition.

**METHODS:** Prospective 6-month study. Six care units were randomised into two groups, each including one medical, one surgical and one mixed unit. In the intervention group a clinical pharmacist worked in collaboration with other health care professionals to improve the care of undernutrition. Predefined quality indicators were collected in both groups during the study period, but the pharmacist was unaware of them. A qualitative survey was performed after the intervention period.

**RESULTS:** The number of complete screening (weight, height, appetite or weight loss) was significantly (p<0.001) higher in the intervention group (330 [48.2%] vs. 272 [27.0%]). The number of enteral nutrition prescriptions did not differ between the two groups, but there were more prescriptions for parenteral nutrition in the intervention group (p<0.001). Finally, triglycerides were more frequently monitored during parenteral nutrition in the "intervention" group (p<0.001). In general, the interventions of the clinical pharmacist were seen as useful or very useful by other healthcare professionals. Physicians find that their knowledge in nutrition is insufficient. Pre-existing computer tools in the hospital appear to be underused.

**CONCLUSIONS:** Involvement of a clinical pharmacist contributed to better care of undernutrition, even though the input might have been limited by the lack of a multidisciplinary nutrition team (for example to increase the proportion of enteral nutrition prescribed). The pharmacist also identified barriers for improvement, and this will lead to the implementation of new procedures, training material and enhanced communication between practitioners.

## Obstetrics and Gynaecology

**176E. Spinal versus general anaesthesia for planned Caesarean section in pregnant healthy women.** *Gordana D. Vucic, M.Sc., Mirjana Kendrisic, M.D., Prim; Health Centre Sremska Mitrovica, Sremska Mitrovica, Serbia and Montenegro.*

**OBJECTIVES:** Study has compared intensity of postoperative pain, nausea, number of vomiting episodes and total cost of drugs for introducing and keeping patient in spinal and general anaesthesia in pregnant healthy women after elective Caesarean section in spinal and general anaesthesia.

**METHODS:** This controlled trial study has encompassed 48 females undergoing elective Caesarean section in spinal anaesthesia and 48 females undergoing elective Caesarean section in general anaesthesia. Spinal anaesthesia was obtained with 2.5 ml of heavy spinal bupivacaine and general anaesthesia was obtained with mixture of oxygen (40%), nitrous oxide (59.2%) and sufentanil (0.8%) as volatile agent, 6 l/min. The intensity of postoperative pain, nausea and number of vomiting episodes were assessed for 3 hours after operation was finished, on every hour. The Results have been entered in Likert scale questionnaires for every patient.

**RESULTS:** There was statistically significant difference in:

1. Intensity of postoperative pain in the 1st, 2nd and the 3rd hour after procedure was higher among patients in G.A. (general anaesthesia) than among patients in S.A. (spinal anaesthesia) group (p<0.0001).
2. Intensity of nausea in the 1st hour after procedure was higher among patients from G.A. group (p=0.001).
3. Total cost of drugs used for general and spinal anaesthesia was higher for general than for spinal anaesthesia (p<0.0001).

There was no statistically significant difference in:

1. Intensity of nausea in the 2nd and the 3rd hour (p>0.05) and number of vomiting episodes in the 1st, 2nd and the 3rd hour (p>0.05) after the procedure between patients from G.A. and S.A. group.

**CONCLUSIONS:** Considering the simplicity of its use, the speed of

onset and balancing the risks and benefits for mother and her foetus spinal anaesthesia is better option for Caesarean section than general anaesthesia.

Presented at the 68th FIP World Congress, Basel, Switzerland 30 January 2008–31 August 2008.

## Oncology

**177. The Role of Clinical Pharmacist in Detecting and Preventing Medication Errors in Cancer Chemotherapy.** Manal H. El-Hamamsy, Ph.D., Nermin A., Heba M., Mohamed M. Al Azizi, Ph.D., Abou-elsaoud El Zawahry, M.D.; faculty of Pharmacy Ain Shams University, Cairo, Egypt.

**OBJECTIVES:** To detect and prevent medication errors by clinical pharmacy interventions.

**METHODS:** This study was both a retro- and prospective evaluation with descriptive analysis, conducted at the Clinical Pharmacy Department, National Cancer Institute (NCI), Cairo, Egypt during the period of March 2006 to October 2007. A total of 200 patients were divided to two groups. Group A: is a control group, consists of 100 patients admitted to NCI for receiving their chemotherapy cycles without clinical pharmacy interventions; Group B: is the studied group, consists of 100 patients admitted to NCI for receiving their chemotherapy cycles with clinical pharmacy interventions. Clinical pharmacy interventions include: (1) Detecting medication errors by using a modified form of the American Society of Hospital Pharmacists (ASHP) worksheet; (2) Correcting those errors and sending recommendations to the medical staff.

**RESULTS:** This study was succeeded in detecting 3504 medication errors, 1956 of them detected in the control group and did not subjected to correction by clinical pharmacist. The other 1948 medication errors were detected in the studied group and subjected to clinical pharmacy corrections. The means of medication errors showed no statistically significant difference between the 2 groups before clinical pharmacy interventions. The clinical pharmacy interventions reduced the number of medication errors from 1548 to 444 in the studied group and the difference of medication errors means before and after initiating the clinical pharmacy interventions was statistically significant ( $p=0.004$ ).

**CONCLUSIONS:** The clinical pharmacy interventions among cancer patients are very important, as demonstrated by reducing the number of medication errors, improving clinical outcomes through increasing chemotherapy efficacy, reducing the toxicity and lowering the treatment cost among cancer patients.

## Pediatrics

**178. Effect of computerized prescriber order entry with decision support on antibiotic errors in neonatal late onset sepsis.** Sandra S. Garner, Pharm.D., Toby H. Cox, Pharm.D., Michael G. Irving, M.S., B.S., Elizabeth G. Hill, Ph.D., Robin Bissinger, Ph.D., NNP, David J. Annibale, M.D.; Medical University of South Carolina, Charleston, South Carolina, USA.

**OBJECTIVES:** Neonates are more adversely affected by medication errors than other populations. Computerized prescriber order entry with decision support (CPOE-DS) may be one mechanism of reducing errors. This project evaluated the effects of CPOE-DS on medication errors in neonatal late onset sepsis (LOS).

**METHODS:** Prior to ( $n=153$ ) and after ( $n=147$ ) initiation of CPOE-DS, neonatal LOS antibiotic orders were independently evaluated by two pediatric clinical pharmacists for prescribing errors, potential errors, and omissions. Prescribing errors included overdoses or underdoses ( $>10\%$  deviation from recommended doses), inappropriate route or schedule, inappropriate antibiotic selection, and drug-drug or drug-disease state interactions. Potential errors included misspelled drugs, leading decimals, trailing zeroes, impractical doses, and error-prone abbreviations defined by our institution or the Institute for Safe Medication Practices (ISMP). Omissions were missing information required by institutional policy or recommended by ISMP. Multiple errors and omissions in a single order were counted individually.

**RESULTS:** CPOE-DS reduced the mean  $\pm$  SD number per order of potential errors from  $1.01 \pm 0.79$  to  $0.06 \pm 0.24$  ( $p<0.0001$ ) and omissions from  $0.17 \pm 0.38$  to  $0.08 \pm 0.27$  ( $p<0.0001$ ) while prescribing errors increased from  $0.45 \pm 0.75$  to  $0.67 \pm 0.84$  ( $p=0.011$ , Wilcoxon

rank-sum test). Based on multiple logistic regression, there is an 11-fold increase in the odds of prescribing errors using CPOE-DS among patients with renal dysfunction (OR=11.0, 95% CI=2.57 to 47.01,  $p=0.0012$ ). Of 24 prescribing errors with CPOE-DS in renal dysfunction, 18 were lacking dosing adjustments. However, 12 of 18 had serum concentrations monitored after 1-2 doses or the patient had improved renal function, died, or drug discontinued within 24 hours.

**CONCLUSIONS:** CPOE-DS dramatically reduced potential errors and omissions in antibiotic orders for neonatal LOS. However, prescribing errors increased due to a higher probability of errors in patients with renal dysfunction. These results will help to further refine decision support for dose adjustments in renal dysfunction included in this CPOE-DS system.

**179. Impact of having a clinical pharmacist in a Paediatric Intensive Care Unit.** Hoda M. Badran, M.S., clinical pharmacy, Wael S. Selem, M.D., Rasha Z. Al Anani, Bpharm; HMC, Doha, Qatar.

**OBJECTIVES:** To assess the benefit of having a clinical pharmacist as a member of a healthcare provider team on patient care in a paediatric intensive care unit (PICU) during 2008. To prioritize the most needed areas for the clinical pharmacist to focus on based on that benefit.

**METHODS:** This is an observational prospective case series conducted in an 18-bed PICU in a JCI accredited teaching hospital (Hamad Medical Corporation), Doha, Qatar. The paediatric clinical pharmacist who initiated the clinical pharmacy service in PICU, from October 2005, performed daily multidisciplinary team rounds, with documentation of all her pharmaceutical interventions for six months.

**RESULTS:** 311 paediatric patients were admitted to the (PICU) during the study period. 640 pharmaceutical interventions were made by the clinical pharmacist. 98% of the intervention was accepted by the multidisciplinary team. the main drug associated problem were: no indication for drug use 24%, inappropriate dose 21%, no drug prescribed for medical state 14%, no drug level requested for narrow therapeutic index drugs 11%. 44% of the interventions improved drug efficacy, 13% avoided toxicity. 67% of the interventions where that may have resulted in improvement of patient care whilst that may result in decreasing patient mortality/morbidity and or decreased hospitalization days represented 17%. Approximately 48% of the intervention targeted anti-infective medication and 85% of PN (parental nutrition) orders were optimized by the clinical pharmacist. 88% of the intervention resulted in cost saving. The clinical pharmacist participated in developing antibiotic guidelines for paediatrics and provided educational sessions and work shops for medical staff on PN.

**CONCLUSIONS:** The clinical pharmacist plays a major role in providing optimum care for patients by giving direct intervene in patient medical therapy and providing continues education to medical team. In addition, the contribution of the clinical pharmacist helps in cost saving. Moreover, the acceptability rate of clinical pharmacist's interventions is encouraging.

## Pharmaceutical Care

**180. Development and validation of a pharmaceutical care plan for patients with type 2 diabetes.** Dalal Al-Taweel, M.Pharm., M.Sc., M.R.Pharm.S.,<sup>1</sup> Steve Hudson, Professor,<sup>2</sup> Abdelmoneim A. Hussein, B.Pharm., M.Pharm., Ph.D.<sup>3</sup>; (1)Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, United Kingdom; (2)Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow G4 0NR, United Kingdom; (3)Kuwait University, Kuwait City, Kuwait.

**OBJECTIVES:** To identify the pharmaceutical care issues associated with patients with type 2 diabetes, and based on that develop a standardised pharmaceutical care plan that would structure the identification and assessment of care provided to this patient group as part of a scheme for maintaining continuity of care.

**METHODS:** An extensive literature review resulted in the identification of care issues associated with patients with type 2 diabetes. Based on these data, a prototype pharmaceutical care plan was designed and field-tested at multiple sites. Based on the results of the field-testing and on opinions of experts in the field, obtained via a nominal group technique, the data fields, design of a patient profile and pharmaceutical care plan were designed and validated. To supplement the care plan, a guideline

for completion of the care plan was also produced.

**RESULTS:** There were 77 candidate data fields and 82 pharmaceutical care issues identified for inclusion in the prototype care plan; some 72 data fields and 36 care issues were prioritised for inclusion. The draft care plan was modified following the receipt of suggestions from the nominal group. The field testing study sample consisted of 39 patients at four study sites (22 females, median age 71 years). A research group meeting after the field testing resulted in a finalised care plan being developed and subsequently validated by a nominal group.

**CONCLUSIONS:** A pharmaceutical care plan would significantly benefit in structuring the documentation and would guide the care provider of the necessary medication checking and patient monitoring required. Greater awareness of the importance of standardised pharmaceutical care documentation is necessary in the future when electronic means of documenting care are exploited.

### Pharmacoepidemiology

**181. Adverse drug reaction documentation by clinical pharmacists in Riyadh City, Saudi Arabia.** *Yousef Ahmed Alomi, B.Sc., M.Sc., BCPS, Naif Bakarman, B.Sc.; King Saud Medical Complex, Regional Drug and Poisoning Information Center, Riyadh, Saudi Arabia.*

**OBJECTIVES:** To describe the adverse drug reaction (ADR) documentation by clinical pharmacists in Riyadh city, Saudi Arabia.

**METHODS:** Data was collected through a questionnaire; they asked to select which items they report of the following: patient demographic data, adverse drug reaction probability, drug that induced adverse events, severity level of adverse drug reaction, probability to avoid drug events, and cost avoidance from adverse drug reaction. This questionnaire was distributed to all clinical pharmacists working in Riyadh city.

**RESULTS:** Questionnaires were distributed to 61 clinical pharmacists, 40 of them had answered of questionnaire response rate is 65.6%. Of those, 77.5% documented patient demographic data, 82.5% adverse drug reaction probability, 75% drug induced adverse events, 75% severity level of adverse drug reaction, 40% probability to avoid drug events, and 7.5% cost avoidance from adverse drug reaction%. Most of the clinical pharmacists document ADR manually and not computerized.

**CONCLUSIONS:** Most of clinical pharmacists were not document the avoidance probability of ADR, and cost impact of ADR. Although, clinical pharmacist identify and document ADR, absence of very important items of ADR documentation will affect negatively to the quality of pharmaceutical care and in particular ADR.

### Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**182. Pharmacokinetic study of amikacin in Egyptian neonates with sepsis.** *Manal H. El Hamansy, Engi A., Mohsen A., Hesham A., Ph.D., M.D.; Faculty of Pharmacy, Ain Shams University, Cairo, Egypt.*

**OBJECTIVES:** Purpose was to study the pharmacokinetics of once and twice daily dosing of amikacin in neonates with sepsis.

**METHODS:** Thirty neonates of gestational age  $\geq 36$  weeks with sepsis admitted between March 2007 to October 2007 in Neonatal Intensive Care Unit of Gynecology hospital Ain-Shams University were divided into two groups: group I (n=15), neonates received amikacin at a dose of 15 mg/kg once per day; and group II (n=15), received amikacin at a dose of 7.5 mg/kg twice per day. Amikacin serum levels were measured after 1-hr IV infusion (peaks) and just before the next dose (troughs) at day 3 of therapy. Nephrotoxicity was assessed by serum creatinine, urine output and urinary N-acetyl  $\beta$ -D-glucosaminidase (NAG).

**RESULTS:** group I, group II, respectively, had a steady state mean peak amikacin concentration of  $27.72 \pm 6.62$   $\mu$ g/ml versus  $16.32 \pm 5.81$   $\mu$ g/ml ( $p < 0.001$ ), and trough concentration of  $2.26 \pm 1.47$   $\mu$ g/ml versus  $4.598 \pm 2.53$   $\mu$ g/ml ( $p < 0.001$ ). All the patients in the group I had achieved a safe trough level  $< 10$   $\mu$ g/ml while 2 patients had trough concentration  $> 10$   $\mu$ g/ml in the group II. The calculated pharmacokinetic parameters were in group I & group II, respectively:  $Cl = 63.82 \pm 15.91$  ml/kg/hr and  $73.47 \pm 18.1$  ml/kg/hr;  $V_d = 0.54 \pm 0.09$  l/kg and  $0.61 \pm 0.13$  l/kg,  $t_{1/2} = 6.1 \pm 1.042$  hr and  $5.95 \pm 1.11$  hr. No significant difference was found between the two groups in clinical efficacy or renal toxicity.

**CONCLUSIONS:** Amikacin given every 24 hr to septic neonates

achieved constant effectiveness than the twice daily regimen and no evidence of increased nephrotoxicity.

### PRN

**183. Highlighting the ambulatory care PRN.** *Mitzi Wasik, Pharm.D., BCPS<sup>1</sup>, Christina E. DeRemer, Pharm.D.,<sup>2</sup> Sheila L. Stadler, Pharm.D.,<sup>3</sup> Alissa Smith, Pharm.D.,<sup>4</sup> Sunny A. Linnebur, Pharm.D.,<sup>5</sup> Gloria R. Grice, Pharm.D.,<sup>6</sup> Jeanette L. Altavela, Pharm.D., BCPS<sup>7</sup>;* (1)University of Illinois at Chicago, Chicago, Illinois, USA; (2)Medical College of Georgia, Augusta, Georgia, USA; (3)Kaiser Foundation Health Plan of Colorado, Aurora, Colorado, USA; (4)South Carolina College of Pharmacy, Greenville, South Carolina, USA; (5)University of Colorado Health Sciences Center, School of Pharmacy, Denver, Colorado, USA; (6)St. Louis College of Pharmacy, St. Louis, Missouri, USA; (7)Greater Rochester Independent Practice Association, Rochester, New York, USA.

**OBJECTIVES:** (1) Increase visibility and membership of the Ambulatory Care PRN within ACCP and ESCP; (2) Increase awareness of professional development, networking opportunities, and highlight accomplishments of current members of the Ambulatory Care PRN.

**METHODS:** This poster will describe the current demographics of the Ambulatory Care PRN, including age, training, BCPS certification, education, and primary practice location. A brief timeline of the history of the PRN will be presented. To promote research and scholarly activity, a summary of the grant recipients and their projects will be summarized. A brief update of each of the PRN committees will be presented in addition to a preview of what PRN members might expect to read in the biannual PRN newsletter.

**RESULTS:** none to be presented.

**CONCLUSIONS:** Overall, the poster will provide a summary of the many professional activities of the PRN.

### Psychiatry

**184. Polypharmacy in United States veterans with post-traumatic stress disorder.** *Ravindra Pathak, Pharm.D., Ph.D., MBA,<sup>1</sup> Abril Atherton, Pharm.D.,<sup>2</sup> Debra Macdonald, B.S., Pharm<sup>3</sup>;* (1)Salt Lake City Veterans Affairs (VA) Medical Center, Salt Lake City, Utah, USA; (2)VA Salt Lake City HCS, Salt Lake City, Utah, USA; (3)VA Salt Lake City Health Care System, Salt Lake City, Utah, USA.

**OBJECTIVES:** The aim of this study was to elucidate some of the polypharmacy issues in the United States veterans with post-traumatic stress disorder (PTSD). PTSD is a form of anxiety that occurs following exposure to one or more traumatic events. About 20% of PTSD patients experience persistent symptoms lasting over a year. These patients have varying degrees of neuropsychiatric abnormalities that cause adverse physical and psychosocial outcomes. Psychiatric interventions are often augmented with pharmacotherapy to manage symptoms of PTSD. Psychoactive medications targeting different neurological pathways are combined. Specific examples include anticonvulsants for mood stabilization, antidepressants and benzodiazepines for depression and anxiety, and antipsychotics for agitation. While combination therapy is medically appropriate, it also puts the patient at risk for medication related adverse outcomes.

**METHODS:** Data were obtained from the VA Information Systems and Technology Architecture (VISTA) system. PTSD patients were included if they had  $\geq 5$  psychoactive medications. Descriptive statistics was used to summarize findings. We identified 123 PTSD patients who had active prescriptions for  $\geq 5$  psychoactive medications over a specified 6-month study period. A spreadsheet tool was used to categorize medications belonging to the same class, similar indications or mechanism of actions, serious drug interactions, multiple prescribers, patient compliance, and dosing issues. Findings were presented to prescribers with the opportunity to create action plans for specific patients. Prescribers were also asked for justification of polypharmacy and the need for more than the recommended dose.

**RESULTS:** Unique action plans were generated for 37% of patients. Comorbidities such as depression, insomnia and pain were common. The primary reason for polypharmacy was insufficient patient response. Noncompliance rate was  $> 25\%$  and  $> 60\%$  patients were in need for lab follow-ups. Details of action plans along with other findings will be presented.

**CONCLUSIONS:** In summary, this study enhances awareness of patient safety issues associated with use of polypharmacy in PTSD.

## Rheumatology

**185. Pharmaceutical care for patients with rheumatoid arthritis on methotrexate: an extension of clinical pharmacy in an out-patient clinic.** Louise A. Azzopardi, B.Pharm. (Hons), M.Phil (Glas),<sup>1</sup> Steve Hudson, Professor,<sup>2</sup> Anthony Serracino Inglott, B.Pharm., Pharm.D.,<sup>3</sup> Franco Camilleri, M.D., MRCP,<sup>4</sup> Paul J. Cassar, M.D., MRCP,<sup>4</sup> Bernard Coleiro, M.D., MRCP,<sup>4</sup> Karen Cassar, M.D., MRCP,<sup>4</sup> Carmel Mallia, M.D., MRCP<sup>5</sup>; (1)Clinical Pharmacy Section, Mater Dei Hospital, Msida, Malta; (2)Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow G4 0NR, United Kingdom; (3)Pharmacy Department, University of Malta, Msida, Malta; (4)Rheumatology Division, Department of Medicine, Mater Dei Hospital, Msida, Malta; (5)Department of Medicine, University of Malta, Msida, Malta.

**OBJECTIVES:** The aim of the study was to identify pharmaceutical care issues in relation to the management of rheumatoid arthritis patients. Quality of life tools were used as outcome measures.

**METHODS:** Patients attending a Rheumatology Out-Patient Clinic were screened by the pharmacist for pharmaceutical care issues. The pharmaceutical care issues were categorised into drug therapy problems requiring changes or checks. The drug therapy problems were further classified as additional medication needs, unnecessary drug prescribed, ineffective drug prescribed, sub optimum dose, dose too high, adverse drug reaction and inappropriate compliance. Eighty-eight rheumatoid arthritis patients on methotrexate participated in the study. The health assessment questionnaire and the SF36 questionnaires were used pre and post the pharmaceutical care session to assess any significant improvement in the patients' quality of life after the pharmacist's intervention.

**RESULTS:** A total of 106 pharmaceutical care issues were identified. Of the total care issues, which were categorized as either checks or changes to pharmacotherapy, 72% were changes and 28% were checks. The majority of the changes were related to inappropriate compliance (29%). The majority of the checks were related to adverse drug reactions (70%). Both the health assessment questionnaire and the SF36 questionnaire showed a statistically significant improvement ( $p < 0.05$ ) in the quality of life of the patients following the pharmaceutical care session with the pharmacist.

**CONCLUSIONS:** The individualised pharmaceutical care plan offered by the pharmacist was essential in addressing drug therapy plan problems. The focus of the pharmaceutical care plan on drug safety issues highlights the use of the plan in risk management in this patient group.

## Women's Health

**186. Development and implementation of treatment protocols for the management of symptoms in pregnancy.** Lilian M. Azzopardi, B.Pharm. (Hons), M.Phil., Ph.D., Anthony Serracino-Inglott, B.Pharm., Pharm.D., Maurice Zarb-Adami, B.Pharm., Ph.D., Roberta Fenech, B.Pharm. (Hons); Department of Pharmacy, University of Malta, Msida, Malta.

**OBJECTIVES:** To develop protocols for the management by community pharmacists of common ailments presented in pregnancy and to assess pharmacist compliance with the protocols.

**METHODS:** Protocols on the management of dyspepsia with or without nausea and vomiting, headache and migraine, urinary tract infections, and vaginal infections in pregnancy were developed. A focus group consisting of a gynaecologist, two general practitioners and two pharmacists was established to review protocol validity, practicality and applicability. A questionnaire consisting of five case studies was distributed to 200 pharmacies with a copy of the developed protocols. Pharmacists were asked to complete the questionnaire to indicate steps that they would follow when dealing with the case scenarios presented after they had gone through the protocols. Data was analysed using Microsoft Office Excel 2003.

**RESULTS:** Out of the 200 questionnaires distributed, 131 (66%) were completed. The average percentage compliance for all the four protocols was 20%. It was highest for dyspepsia (24%, range 0–54%) followed by headache (20%, range 0–48%), urinary tract infections (18%, range

0–48%), and vaginal infections (18%, range 0–68%).

**CONCLUSIONS:** The average compliance of the pharmacist interventions with the protocols is relatively low. The reasons for this low compliance rests mainly due to the fact that most pharmacists refer complaints by patients immediately and do not assess symptoms presented and recommend preparations where appropriate.

## RESIDENTS AND FELLOWS RESEARCH IN PROGRESS

### ADR/Drug Interactions

**187. Vitamin D levels and statin-induced myopathy: a retrospective analysis.** Jamie L. Killion, Pharm.D., Lauri Witt, Pharm.D., Monica G. Schaefer, Pharm.D.; Kansas City Veterans Affairs (VA) Medical Center, Kansas City, Missouri, USA.

**OBJECTIVES:** Recent literature suggests individuals with vitamin D deficiencies are more likely to experience statin-induced myopathies.<sup>1</sup> The intent of this study is to identify the relationship between vitamin D levels and statin-induced myopathies at the Kansas City Veterans Affairs Medical Center (KCVA). We hypothesized that the incidence of statin-induced myopathy exceeds 5% and vitamin D levels less than 30 ng/mL are associated with an increased incidence of statin-induced myopathy.

**METHODS:** This retrospective cohort study consists of veterans with at least one prescription for an HMG-CoA reductase inhibitor from the KCVA between July 1, 2005 and July 1, 2008. Adverse drug reaction data and 25-OH vitamin D levels were compiled for patients meeting the inclusion criteria.

**RESULTS:** Preliminary data analysis reveals 22,471 patients met the inclusion criteria. Of these 6,951 had vitamin D levels reported. Approximately 61% had vitamin D levels less than 30 ng/mL. The incidence of statin-induced myopathy at the KCVA was 15.1% and 51 cases of rhabdomyolysis were identified during the study period. Additional statistical analyses are currently underway and will include a multivariate logistic regression analysis to calculate the correlation between statin-induced myopathy, vitamin D levels and nine other identified risk factors as well as an odds ratio of developing statin-induced myopathy with any vitamin D insufficiency.

**CONCLUSIONS:** Statin-induced myopathy frequently leads to discontinuation of therapy and suboptimal treatment of hypercholesterolemia. The rate of statin-induced myopathy reported in this study corresponds well with other estimates and demonstrates that statin-induced myopathy is more common than previously reported in clinical trials. Further investigation will determine if low vitamin D levels are positively correlated with statin-induced myopathy. If this association does exist future studies should examine whether patients are able to tolerate statin therapy following vitamin D replacement.

1. Goldstein MR. Myopathy, statins, and vitamin D deficiency. *Am J Cardiol.* 2007;100(8):1328.

**188. Proton pump inhibitor contribution to cardiovascular events in users of clopidogrel.** John T. Holmes, Pharm.D., Brooke Pugmire, Pharm.D., Rex Force, Pharm.D.; Departments of Family Medicine and Pharmacy Practice, Idaho State University, Pocatello, Idaho, USA.

**OBJECTIVES:** Recent pharmacodynamic data indicate proton pump inhibitors (PPIs) may reduce the antiplatelet effects of clopidogrel; however, limited clinical outcomes data have been published. In this retrospective analysis we compared the rates of cardiovascular events in users of clopidogrel plus PPI versus clopidogrel alone in patients with a history of cardiovascular disease.

**METHODS:** Medicaid claims data were queried from January 1997 through November 2008 to identify patients with a hospitalization for acute coronary syndrome, stroke, transient ischemic attack, coronary artery bypass graft, or percutaneous coronary intervention. Patients with a claim for clopidogrel within 60 days were identified and divided into two groups, clopidogrel + PPI (C+P) or clopidogrel alone (C). Patients with a second event within 180 days were identified and rates were compared between groups. Cardiovascular event rates will be adjusted for differences in risk factors between groups. Comparisons will also be made for patients not receiving clopidogrel.

**RESULTS:** Preliminary results indicate 6,382 patients had a first event. Of these, 957 (15.0%) had a claim for clopidogrel within 60 days; 248

also received a PPI within 60 days (C+P) while 709 received clopidogrel alone (C). A second event was identified in 59 (23.8%) of C+P patients and 168 (23.7%) of C patients,  $p=0.975$ .

**CONCLUSIONS:** In the preliminary analysis, no significant difference in cardiovascular events was found between patients with previous cardiovascular disease receiving clopidogrel plus PPI versus clopidogrel alone. Completed analysis of the data will be available at the time of presentation.

**189. Evaluation of agreement between the drug interaction probability score (DIPS) and Naranjo scale (NS) for drug interaction-induced ADRs in warfarin patients.** *Katherine M. Malloy, Pharm.D., Daniel A. Lewis, Pharm.D., BCPS, Kelly M. Smith, Pharm.D., BCPS, FASHP, FCCP, Douglas T. Steinke, Ph.D., George A. Davis, Pharm.D., BCPS, UKHealthCare, Lexington, Kentucky, USA.*

**OBJECTIVES:** This study examined the agreement between the NS and DIPS tools in determining the probability that warfarin ADRs resulted from drug interactions. While the NS was introduced over 20 years ago and is considered a gold standard for causality evaluations, it was not designed to assess drug interactions. The DIPS was recently developed for this purpose, though there is no direct comparison to systematically validate the NS. Evaluating concordance between the two will help identify the most reliable tool for recognizing ADR trends, causality, and preventability in accordance with the Joint Commission 2008 National Patient Safety Goals.

**METHODS:** Warfarin ADRs documented in our institutional spontaneous ADR reporting database from January 2002 to June 2008 were reviewed for drug interactions. Data included patient demographics, precipitant and object drugs, and determination of Naranjo/DIPS scores and probabilities. Final analysis will include descriptive statistics and the degree of agreement between the NS and DIPS, reported as a weighted kappa statistic.

**RESULTS:** Approximately 100 ADRs due to warfarin interactions are under review. Demographics for the first 25 ADRs include average patient age of 63 years, 64% male, and 24% critically ill. The most common interacting drugs include fluoroquinolones (32%), NSAIDs (16%), and sulfamethoxazole/trimethoprim (16%), leading to an increased INR in 84% of patients and bleeding in 52%. Probability scores are 4.7 and 4.5 for the NS and DIPS, respectively ( $p=0.387$ ), indicating possible/probable causality. Statistically significant, moderate agreement was found using the weighted  $\kappa$  statistic ( $\kappa=0.52$ ) with 74.4% overall agreement ( $p<0.0001$ ).

**CONCLUSIONS:** Preliminary analysis demonstrates that the NS and DIPS tools yield comparable results. As the DIPS was developed to examine the probability of a drug interaction precipitating an ADR, our results thus far indicate that it is a valuable tool in this form of causality evaluation.

## Adult Medicine

**190. Appropriate use of stress ulcer prophylaxis in general medicine patients.** *Jennifer R. Niernerg, Pharm.D.,<sup>1</sup> Leah M. Nanney, Pharm.D. Candidate,<sup>2</sup> David S. Chun, Pharm.D., BCPS<sup>1</sup>; (1)St. Elizabeth's Hospital, Belleville, Illinois, USA; (2)Southern Illinois University Edwardsville, School of Pharmacy, Edwardsville, Illinois, USA.*

**OBJECTIVES:** This study compared the appropriate use of stress ulcer prophylaxis in general medicine patients before and after physician education.

**METHODS:** For a one month period, 122 patient medical records were reviewed to determine if the utilization of acid suppressive therapy (AST) to prevent stress ulcers was appropriate. A didactic lecture given by a registered pharmacist was then provided to the Saint Louis University (SLU) Family Practice Residents outlining risk factors, recommended treatment options, and potential complications of AST as it relates to stress ulcer prophylaxis based on the American Society of Health-System Pharmacists guidelines and a review of published medical literature. Following the educational intervention, 54 patient medical records from a one month period were evaluated to assess the appropriateness of AST for stress ulcer prophylaxis. The charts reviewed were those of patients admitted to the general medicine floors at a 498-bed community hospital receiving care from the SLU medical teams and given histamine-2 antagonists or proton pump inhibitors. Appropriate

stress ulcer prophylaxis before and after physician education was compared using the  $\chi^2$  test ( $\alpha = 0.05$ ). Institutional Review Board approval is pending.

**RESULTS:** During the month prior to the educational intervention, 80 patients were prescribed AST for stress ulcer prophylaxis and 6 patients (7.5%) met criteria for stress ulcer risk. Following a didactic lecture, 29 patients were prescribed AST for stress ulcer prophylaxis with 1 patient (3.4%) meeting criteria for high risk. Research is still in progress and results will be completed by February 1, 2009.

**CONCLUSIONS:** By expanding this type of pharmacist-driven educational programming to target the misuse of other medications, the intervention can potentially prevent unnecessary medication cost.

## Ambulatory Care

**191. The impact of enoxaparin on INR in patients monitored by point-of-care device.** *Larissa N. Hall, Pharm.D., Amy N. Thompson, Pharm.D., BCPS, Kelly R. Ragucci, Pharm.D., FCCP, BCPS, CDE; MUSC Medical Center/South Carolina College of Pharmacy, Charleston, South Carolina, USA.*

**OBJECTIVES:** Evaluate the impact of enoxaparin on international normalized ratio (INR) in patients monitored by point-of-care (POC) devices in outpatient clinics.

**METHODS:** Patients 18 years of age and older receiving warfarin plus enoxaparin and monitored by pharmacists at outpatient clinics are eligible for enrollment. Institutional review board approval was obtained and all patients receive written informed consent. Blood samples are obtained by the i-STAT<sup>1</sup> PT POC device and by laboratory venipuncture at one visit while each patient is receiving warfarin plus enoxaparin and again at another visit while each patient is receiving warfarin only. Demographics are collected by the primary investigator from the outpatient electronic medical record. Descriptive statistics are provided for preliminary data. Enrollment and data collection is currently ongoing and will be completed by March 2009.

**RESULTS:** Of the thirteen patients consented to study enrollment, the mean age of patients is 46 years. The indication for anticoagulation in the majority of patients is deep vein thrombosis (DVT). For patients receiving warfarin plus enoxaparin, the mean INR by POC device was 2.2 compared to 2.0 by laboratory venipuncture, resulting in a 10% mean increase in INR results obtained by the POC device. For patients receiving warfarin only, the mean INR by POC device was 2.9 compared to 2.6 by laboratory venipuncture, resulting in an 11.5% mean increase in INR results obtained by POC device. Two patients had as much as a 30% increase in INR result by POC device compared with laboratory venipuncture. The POC result for one patient warranted discontinuation of enoxaparin, while the laboratory result necessitated continuation of enoxaparin.

**CONCLUSIONS:** This study demonstrates that enoxaparin may have an impact on INR results obtained by the POC device. Further studies are needed to determine the clinical significance of this impact.

**192. Formulary conversion of ezetimibe/simvastatin to rosuvastatin: evaluation of a cost savings initiative.** *Augustus Hough IV, Pharm.D., Cheryln Beckey, Pharm.D., BCPS, CDE, Julie Groppi, Pharm.D., CDE; Veterans Affairs Medical Center, West Palm Beach, Florida, USA.*

**OBJECTIVES:** The goal of this project is to evaluate the efficacy and safety of a cost savings initiative involving a formulary conversion of ezetimibe/simvastatin to rosuvastatin at the West Palm Beach Veterans Affairs Medical Center.

**METHODS:** Retrospective evaluation of the first one hundred patients converted per facility protocol from ezetimibe/simvastatin (5 mg/40 mg or 10 mg/80 mg) to rosuvastatin (10 mg or 20 mg), respectively. Exclusion criteria included patients without appropriate baseline or follow-up labs. The primary efficacy measure was change in low-density lipoproteins (LDL-C) after conversion compared to baseline. Secondary measures included changes in high-density lipoproteins (HDL-C), triglycerides, total cholesterol, AST, and ALT. Other data collected included: percent of patients remaining at their respective LDL-C target at follow up, changes in adjuvant lipid lowering therapies, and reasons for rosuvastatin discontinuation.

**RESULTS:** Approximately 40% (100/252) of patients reviewed were included in this analysis. The average age was 71.7 years old (100%

male) and 83% of patients had coronary heart disease or a risk equivalent. Five patients required rosuvastatin dose increase and one provider elected to decrease the rosuvastatin dose at follow up. Small but statistically significant increases in LDL-C, total cholesterol, and triglycerides of 8.3%, 6.2%, and 12.9%, respectively ( $p < 0.05$ ) were seen at follow-up of 6-12 weeks post conversion. There were no statistically significant changes in HDL-C, AST, or ALT. Seventy-four percent of patients maintained an LDL-C less than 100 mg/dL. Of the 100 patients included, there have been no reported adverse events.

**CONCLUSIONS:** Overall, this was a safe and effective formulary conversion. While there was a small but statistically significant increase in LDL-C, the majority of patients remained below their LDL-C goal. Limitations include the retrospective nature of the analysis and uncertainty in compliance and time between initiation of therapy and follow-up labs.

**193. Evaluation of the incidence and risk factors of fenofibrate-associated nephrotoxicity.** *Rebecca L. Owens, Pharm.D., BCPS,<sup>1</sup> Michael A. McKnight, B.S.,<sup>2</sup> Christopher R. Frei, Pharm.D., M.Sc., BCPS,<sup>1</sup> Laurajo Ryan, Pharm.D., M.Sc., BCPS,<sup>1</sup> John R. Downs, M.D.,<sup>2</sup> William D. Linn, Pharm.D.<sup>3</sup>;* (1)The University of Texas at Austin and The University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA; (2)University of Texas Health Science Center San Antonio, San Antonio, Texas, USA; (3)University of the Incarnate Word, San Antonio, Texas, USA.

**OBJECTIVES:** Patients with hypertriglyceridemia treated with fenofibrate may experience increases in serum creatinine (SCr). This effect was described in one randomized controlled trial and several observational studies. However, the specifics of fenofibrate-associated nephrotoxicity are not clearly delineated. This study will identify the incidence and potential risk factors of nephrotoxicity in veterans on fenofibrate.

**METHODS:** A single center, retrospective chart review was conducted in the South Texas Veterans Health Care System. Data were collected on baseline demographics, concurrent medical conditions, medications, laboratory results, and fenofibrate use. Nephrotoxicity was defined by the Acute Kidney Injury Network as an elevation in serum creatinine  $\geq 0.3$  mg/dL. Student's *t*, Kruskal Wallis,  $\chi^2$ , and Fisher's Exact tests were used for statistical analyses.

**RESULTS:** Interim review of 306 patients identified the incidence of nephrotoxicity as 34% ( $n=102$ ). Longer length of treatment ( $p < 0.0001$ ) and higher initial dosage ( $p < 0.0001$ ) were significantly associated with nephrotoxicity. Time to peak SCr was 5 months (range 3 to 10) with 73% returning to baseline in 3.5 months (range 2 to 6). There were no significant differences in age, gender, ethnicity, body mass index, smoking status, or alcohol use between patients with an increase in SCr and those without (all  $p > 0.05$ ). Patients who experienced nephrotoxicity were more likely to have Type 2 diabetes (72% vs. 46%,  $p < 0.0001$ ), microalbuminuria (16% vs. 6%,  $p = 0.008$ ), chronic kidney disease (11 vs. 2%,  $p = 0.001$ ), or congestive heart failure (7% vs. 2%,  $p = 0.04$ ). These patients also had higher utilization of ACE inhibitors (62% vs. 45%,  $p = 0.004$ ), beta-blockers (48% vs. 33%,  $p = 0.01$ ), calcium channel blockers (37% vs. 18%,  $p = 0.0002$ ), thiazolidinediones (27% vs. 14%,  $p = 0.009$ ), or furosemide (13% vs. 3%,  $p = 0.001$ ). There was no difference in non-steroidal anti-inflammatory drug use ( $p = 0.99$ ).

**CONCLUSIONS:** This retrospective review suggests a higher incidence of fenofibrate-associated nephrotoxicity than previously reported, particularly in veterans with concomitant diabetes or chronic kidney disease.

## Cardiovascular

**194. Evaluation of nonprescription medication use in heart failure patients.** *Jill H. Cwik, Pharm.D.,<sup>1</sup> Stephanie C. Lemon, Ph.D.,<sup>1</sup> Maichi T. Tran, Pharm.D., BCPS,<sup>1</sup> Jennifer L. Donovan, Pharm.D.,<sup>2</sup> Theo E. Meyer, M.D., D.Phil<sup>1</sup>;* (1)University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, USA; (2)Massachusetts College of Pharmacy and Health Sciences, Worcester, Massachusetts, USA.

**OBJECTIVES:** Patients that use nonprescription and herbal medicine are at a risk for adverse effects, drug-drug and drug-disease interactions, poor adherence to prescription medications and other renal or hepatic complications due to self-prescribing. Heart failure patients are high risk for complications and adverse effects as the majority of patients are

elderly, take multiple prescription products and have multiple chronic conditions. However, there are limited data on the use of nonprescription medications in the heart failure population. The purpose of the study is to assess the prevalence of nonprescription medications use in the ambulatory heart failure patient population and the impact of nonprescription medication use on hospital admissions, prescription medication adherence, and quality of life.

**METHODS:** Patients were recruited to participate in a study of medication adherence study at the UMass Heart Failure and Wellness Center. Patients were verbally administered a questionnaire at a clinic visit. Frequency distributions describe nonprescription medication use; chi-square statistics compare nonprescription medication use according to patient characteristics; and logistic and linear regression models assess the association of nonprescription medication use with admissions, adherence and quality of life.

**RESULTS:** The majority took at least one nonprescription medication at least weekly (84%). There was a range of prevalence of taking common nonprescription medications: aspirin (57%), vitamins and minerals (53%), non-aspirin pain-relievers (36%), herbal supplements (31%), stool softeners (15%), antacids (7%), and diphenhydramine/antihistamines (3%). Analyses of the associations of patient characteristics with nonprescription medication use and of nonprescription medications with outcomes are underway.

**CONCLUSIONS:** Nonprescription medication use is common among ambulatory heart failure patients. The information gathered in this study will aid in the design of a patient education tool to be administered by pharmacists and other health care professionals.

**195. Incidence of methadone induced QT-interval prolongation in patients with cardiovascular disease.** *Wesley R. Zemrak, Pharm.D., J. Michael Boyd, Pharm.D., Kerry Pickworth, Pharm.D.;* The Ohio State University Medical Center, Columbus, Ohio.

**OBJECTIVES:** The purpose of this study was to describe the use, risk factors for ventricular arrhythmias, pro-arrhythmic incidence, and monitoring of oral methadone in a cardiovascular hospital at a tertiary care center.

**METHODS:** This study has been reviewed and approved by the institutional review board. Patients with cardiovascular disease on oral methadone were retrospectively identified by a medication use inquiry via the pharmacy computer system between July 1, 2007 and June 30, 2008. Data collected includes: age, gender, comorbidities, methadone dosage, serum electrolyte levels, concomitant medications (particularly agents known to contribute to QT prolongation), measurements of QT-intervals by electrocardiograms, hospital length of stay, and arrhythmic events.

**RESULTS:** A total of 38 patients with cardiovascular disease receiving oral methadone were identified. The study population consisted of a mean age of 54.8 years (range 32–81), heart failure 36.8% (14/38), and an average length of stay of 8 days (range 1–45). The mean daily dose of methadone and number of EKGs per patient were 41.7 mg (range 5–185 mg) and 2.4 (range 0–9), respectively. A total of 8 arrhythmic events occurred, 1 case of Torsade de Pointes (2.6%) and 7 cases of ventricular tachycardia (18.4%). The majority of patients (65.8%) received  $\leq 1$  concomitant QT-interval prolonging medication; however patients who had pro-arrhythmias were receiving  $\geq 2$  concomitant QT-prolonging agents.

**CONCLUSIONS:** Overall, the pro-arrhythmia event rate with methadone was alarmingly high, given the small study population examined. The lack of electrocardiographic monitoring (mean of 2.4 EKGs per patient) restricts the ability to prospectively identify patients with QT-interval prolongation and in some cases led to adverse outcomes. Patients receiving greater than 40 mg of methadone per day and at least two concomitant QT-interval prolonging agents were at highest risk for an event and should be prospectively monitored with daily EKGs while receiving therapy.

**196. Innovative clinical pharmacy services for patients undergoing percutaneous coronary interventions in a tertiary cardiology center.** *Julie Methot, B.Pharm., Ph.D.,<sup>1</sup> Isabelle Taillon, M.Sc.,<sup>1</sup> Marie-Josée Boily, M.Sc.,<sup>2</sup> Sylvain Gilbert, B.Sc.,<sup>1</sup> Karine Lejeune, M.Sc.,<sup>2</sup> Michelle Bernard-Genest, M.Sc.,<sup>2</sup> Olivier Bertrand, M.D., Ph.D.<sup>3</sup>;* (1)Quebec Heart Institute (Hôpital Laval)/Faculty of Pharmacy, Université Laval, Quebec, Quebec

Canada; (2)Quebec Heart Institute (Hôpital Laval), Quebec, Quebec Canada; (3)Quebec Heart Institute (Hôpital Laval)/Faculty of medicine, Université Laval, Quebec, Quebec Canada.

**OBJECTIVES:** During the past 5 years, clinical pharmacy services for patients undergoing percutaneous coronary interventions have been developed in a tertiary care center in cardiology. The objective of this ongoing study is to describe the clinical pharmacy activities realised by hospital pharmacists on a percutaneous coronary unit in Quebec Heart Institute (Quebec, Canada). The secondary objective was to measure the degree of acceptance of the interventions by referral physicians.

**METHODS:** This is a descriptive longitudinal study performed during one-year period beginning in April 2008 including all patients older than 18 years old referred for percutaneous coronary interventions. Clinical pharmaceutical activities have been compiled using a validated data collect chart by the pharmacist who dispensed pharmaceutical care (one pharmacist/day). During one month period the acceptance level of interventions by referral physician have been compiled.

**RESULTS:** By now (after 8 months of data collection), pharmacists have delivered pharmaceutical care for 156 equivalent working days, analysed 3,063 pharmaceutical profiles ( $19 \pm 3$  per day) and performed 685 drug histories ( $4 \pm 1$  per day). During this period, 2,259 drug interventions were performed ( $14 \pm 5$  per day). The pharmacist's interventions concerned mainly adjunction of required drug (50%) and re-prescription of usual drug taking by the patient (28%). Furthermore, pharmacists have performed 2,620 in-hospital prescriptions ( $16 \pm 4$  per day), 1,122 hospital discharge prescriptions ( $7 \pm 2$  per day), 831 pharmaceutical counselling ( $5 \pm 2$  per day) and 831 anticoagulant follow-up ( $1 \pm 1$  per day) during this period. Most of their recommendations are highly accepted (>90%) by referral physicians excepting increase dosage recommendation (62.5% of acceptance).

**CONCLUSIONS:** The pharmacists are able to perform clinically relevant pharmaceutical activities including highly accepted intervention by referral physicians for patients undergoing percutaneous interventions in a tertiary care center. Our description of pharmacist involvement in this field may help other pharmacists developing pharmaceutical care for those patients.

**197. Accuracy assessment of pharmacogenetically-predicted warfarin dosing in patients of a university hospital anticoagulation clinic.** Paul B. Shaw, Pharm.D.,<sup>1</sup> Jennifer L. Donovan, Pharm.D.,<sup>2</sup> Maichi T. Tran, Pharm.D.,<sup>1</sup> Pam Burgwinkle, N.P.,<sup>1</sup> Joel Gore, M.D.,<sup>1</sup>; (1)UMass Memorial Medical Center, Worcester, Massachusetts, USA; (2)Massachusetts College of Pharmacy and Health Sciences, Worcester, Massachusetts, USA.

**OBJECTIVES:** This study assessed and compared the predictive accuracy of two previously published, distinct, pharmacogenetically-based warfarin dosing algorithms which utilize cytochrome P450 2C9 isoenzyme (CYP2C9) and/or vitamin K epoxide reductase complex subunit 1 (VKORC1) genotypes along with clinical parameters.

**METHODS:** In this retrospective cohort study, the medical records of 80 patients of a tertiary medical center-affiliated outpatient anticoagulation clinic were reviewed. The study population was 66% Caucasian, had a mean age of 60 years, and was split equally between male and female with DVT/PE being the most common indication (49%) for therapy followed by atrial fibrillation (33%). Patients meeting the following criteria were included:  $\geq 18$  years of age, enrollment in clinic between January 1, 2007 and September 30, 2008, achievement of stable, therapeutic warfarin dose, and CYP2C9 and VKORC1 genotypes available.

**RESULTS:** Algorithm #1, which incorporates only CYP2C9 genotype but includes seven clinical factors, produced a correlation coefficient ( $r^2$ ) of 0.38. Algorithm #2, which includes both CYP2C9 and VKORC1 genotypes but the limited clinical parameters of only age and height, yielded a  $r^2$  of 0.45. The median percent difference and absolute difference between predicted and actual daily warfarin dose were (-7%, -0.3 mg) and (-25%, -1.7 mg) respectively for algorithms #1 and #2.

**CONCLUSIONS:** Predictive algorithm #2 yields the closer correlation based on  $r^2$  between predicted and actual dose. However, it systematically underestimates warfarin dose by a significant median amount of 1.7 mg per day. Conversely, algorithm #1 yields a poorer correlation coefficient but a smaller median difference between predicted and actual dose. Based on these results, it is not possible to

conclude which dosing algorithm is more accurate in our anticoagulation clinic population.

**198. Torsemide versus furosemide plus metolazone for symptomatic chronic heart failure.** Elizabeth J. Greenhalgh, Pharm.D.,<sup>1</sup> Vicki L. Groo, Pharm.D.,<sup>1</sup> Thomas Stamos, M.D.,<sup>2</sup> Robert J. DiDomenico, Pharm.D.,<sup>3</sup>; (1)University of Illinois at Chicago Medical Center, Chicago, Illinois, USA; (2)University of Illinois at Chicago, College of Medicine, Chicago, IL; (3)University of Illinois at Chicago, Chicago, Illinois, USA.

**OBJECTIVES:** Increasing doses of loop diuretics are often necessary to control symptoms of fluid overload in refractory chronic heart failure (HF) patients. Furosemide (F) is commonly used in heart failure patients; however, its absorption is variable and unpredictable and diuretic resistance may occur. A common approach to managing fluid overload in refractory patients is to add metolazone (M) to existing F, but this is often associated with increased adverse effects. An alternative to this strategy is to convert patients to torsemide (T), a loop diuretic with an improved pharmacokinetic profile that has been associated with fewer hospitalizations and improved quality of life. Our primary objective is to determine if T is equally effective at improving symptoms of volume overload with fewer adverse effects than combination of F and M (F+M) in patients with symptomatic chronic HF.

**METHODS:** This is a prospective, randomized, unblinded study comparing T alone to the combination of F+M. Adult HF patients taking  $\geq 120$  mg of F per day who have unresolved symptoms of fluid overload and who require an escalation in diuretic therapy are eligible for inclusion. Patients are being randomized to either an equivalent T dose or the addition of M 2.5 mg daily to their current F dose. The primary endpoint is worsening renal function (increase in serum creatinine of  $\geq 0.3$  mg/dL) at 1-week follow-up. Secondary endpoints include changes in NYHA class, weight, and 6-minute walk test, and electrolyte disturbances.

**RESULTS:** Enrollment is ongoing, and a total of 40 patients will be enrolled.

**CONCLUSIONS:** As this research is in progress, no conclusions can be made at this time.

## Community Pharmacy Practice

**199. Impact of community pharmacy-based management of a targeted diabetic population.** Mindy L. Jock, Pharm.D.,<sup>1</sup> Teresa B. Klepser, Pharm.D.,<sup>2</sup> Jennifer Hagerman, Pharm.D.,<sup>3</sup> Michael Bouthillier, B.S.Pharm., Pharm.D.,<sup>4</sup> Donald G. Klepser, Ph.D., M.B.A.,<sup>5</sup>; (1)ProMed Family Practice, Portage, Michigan, USA; (2)Ferris State University, Portage, Michigan, USA; (3)Ferris State University, Flint, Michigan, USA; (4)Ferris State University, Grand Rapids, Michigan, USA; (5)University of Nebraska Medical Center, Omaha, Nebraska, USA.

**OBJECTIVES:** Community pharmacists who have access to patient laboratory data, prescription records and refill histories can provide better patient specific medication therapy management that will lead to measurable improvement in key laboratory indices in patients with diabetes.

**METHODS:** A program to manage diabetic patients in an independent pharmacy located in a non-teaching family medicine clinic was developed; 70 diabetic patients are seen by the clinic weekly. Of those, approximately 10 patients weekly utilize our study pharmacy. In the pharmacy, new prescriptions, vital signs and laboratory data [hemoglobin A1C (HgHbA1c), blood pressure, and low density lipoprotein (LDL), Scr] are reviewed. Interventions are based on American Diabetes Association goals for HgA1c, blood pressure, and low density lipoprotein (LDL). Additionally, each patient's medication refill profile is evaluated for compliance, concurrent prescriptions and cost/formulary issues. The clinic provider is contacted with recommendations prior to filling the prescription.

**RESULTS:** Twelve month changes in percentage of patients at HgA1c <7%, blood pressure <130/80 mm/Hg, low density lipoprotein (LDL) <100 mg/dl will be compared to a matched, non-intervention cohort.

**CONCLUSIONS:** This model may be adapted to other community pharmacies or ambulatory care clinic settings or applied to a variety of chronic diseases. Limited data are available regarding the impact of community pharmacist interventions pursuant to the access of patient medical data.

**200. Implementation and Evaluation of a Blood Pressure Monitoring Service in Grocery Store Chain Pharmacies.** Mindy B. Guerra, Pharm.D.,<sup>1</sup> Thane A. Kading, R.Ph.,<sup>2</sup> Karen Farris, Ph.D., Professor,<sup>3</sup> Jay D. Currie, Pharm.D.<sup>4</sup>; (1)University of Iowa/Hy-vee Pharmacy, Cedar Rapids, Iowa, USA; (2)Hy-Vee, Cedar Rapids, Iowa, USA; (3)University of Iowa, Iowa City, Iowa, USA; (4)College of Pharmacy, The University of Iowa, Iowa City, Iowa, USA

**OBJECTIVES:** (1) Determine if grocery store community pharmacists, working with patients and physicians can lower patients' blood pressure (BP) and increase adherence; (2) Determine patients' and providers' opinions of the pharmacist-provided BP service; (3) Determine patients' willingness to pay for this service.

**METHODS:** *Design:* A BP service was provided to patients on hypertension medications. Patients had their BP checked at least once a month over five months, were given BP educational materials, refill history was reviewed, and BP readings were faxed to providers. Drug-therapy recommendations were faxed to providers and discussed with patients. *Subjects:* 127 patients at six Midwestern grocery store chain pharmacies. *Data Collection:* Patient charts were reviewed to obtain BP readings, refill history, and pharmacist care notes. Satisfaction surveys were faxed to providers' offices and included information on the usefulness of the service and likelihood of referring patients into the program. Surveys containing patient satisfaction with the service and willingness to pay were given to patients. *Outcomes measured:* Percent of patients at goal BP, mmHg reduction in BP from baseline, medication adherence, and patient and provider satisfaction.

**RESULTS:** An increase in the percentage of non-diabetic patients at goal systolic and diastolic BP was noted. The proportion of people without diabetes with DBP at goal increased from month 1, 93.3% (n=31) to month 4, 95.7% (n=22). SBP also improved for these individuals - month 1, 60.6% (n=20) and month 4, 72.9% (n=17). Among people with diabetes, goal DBP was achieved by 60% (n=9) in month 1 and 75% (n=9) in month 4. Goal SBP was achieved by 33.3% (n=5) in month 1 compared to 50% (n=6) in month 4.

**CONCLUSIONS:** Grocery-store pharmacist delivered BP monitoring service had a positive effect on BP. Increased BP measurements with physician-pharmacist co-management of patients with uncontrolled hypertension improved BP control.

## Critical Care

**201. Utilization of transdermal lidocaine patches in rib fractures caused by thoracic blunt trauma injuries.** Gina Alvis, Pharm.D., Brian S. Smith, Pharm.D., BCPS, Timothy Emhoff, M.D. FACS, Jeffrey J. Fong, Pharm.D., BCPS; UMassMemorial Medical Center, Worcester, Massachusetts, USA.

**OBJECTIVES:** Patients with traumatic rib fractures require early and adequate pain control. Inadequate analgesia may result in pulmonary decline requiring intubation that may increase morbidity and extend length of stay (ICU LOS). Narcotic analgesics are most commonly used to treat pain but have significant side effects. At our institution, lidocaine patches are used to help minimize systemic narcotic use and related side effects.

**METHODS:** Data was pooled from the hospital database using ICD-9 codes to identify patients with rib fractures from 2005-2007. Rib fracture patients were divided into groups: those who received lidocaine patches (L), those without lidocaine (control). Patients with less than two rib fractures, history of opioid tolerance (narcotic abuse history or chronic pain conditions) or prior use of lidocaine patches were excluded.

**RESULTS:** Forty patients were included in this analysis. Both groups had similar baseline demographics except for a higher number of rib fractures in the L group [5.7 ± 2.6 vs. 3.9 ± 1.9], [mean ± SD] (p=0.018). Despite more baseline rib fractures in the L group, morphine exposure was no different between groups [140mg (82-779) vs. 120mg (64-283)] [median, (IQR)], (p=0.314). Patient outcomes was similar in both groups: ICU LOS was [1 day (0-5.6) vs. 1.5 day (0-8.8)], (p=0.925) and length of hospital stay was [9.4 ± 6.7 days vs. 11.7 ± 13.1 days], (p=0.968). Administration of laxatives was similar between groups [L (80%), control (100%)] (p=0.5).

**CONCLUSIONS:** Opiate use appears similar in the amount and side effects between the groups. Patient ICU LOS also appears comparable between groups with a trend towards fewer days in the L group. The

study is limited by our retrospective observational design and small sample size. We anticipate stratifying our cohort according to measures of severity of illness, collecting data on 100 patients, and completing final analysis by February.

**202. Evaluation of atrial arrhythmias following non-cardiac thoracic surgery.** Stephen J. Lemon Jr., Pharm.D.,<sup>1</sup> Jeremy D. Flynn, Pharm.D., BCPS<sup>2</sup>; (1)UK HealthCare - Pharmacy Services, University of Kentucky, Lexington, Kentucky, USA; (2)UK HealthCare - Pharmacy Services, Department of Pharmacy Practice & Science, College of Pharmacy, University of Kentucky, Lexington, Kentucky, USA.

**OBJECTIVES:** Atrial arrhythmias (AA) occur frequently after non-cardiac thoracic surgery and may be associated with increased morbidity and mortality, length of stay (LOS), and utilization of health care resources. The true incidence, exact mechanism, and related outcomes of AA following non-cardiac thoracic surgery are unknown. Current practice at the University of Kentucky does not include routine prophylaxis for patients undergoing thoracic surgery, thus an evaluation of postoperative AA in patients undergoing a thoracotomy was studied to determine if pharmacotherapeutic intervention is necessary.

**METHODS:** A retrospective analysis was conducted using the University HealthSystem Consortium (UHC) Clinical Database to identify adult patients who underwent a thoracotomy for excision or diagnosis of lung cancer at the University of Kentucky Hospital from January 2001 to June 2008. We collected and analyzed patient age, number of ICU days, total LOS, overall mortality, APACHE II score, and billing data.

**RESULTS:** Of 820 patients identified, 112 patients (14%) developed an AA. The average patient age in the AA group was 66.6 years compared to 58.3 years in the non-AA group. Overall mortality was 7.14% in the AA group and 3.11% in the non-arrhythmia group. Average ICU LOS was 8.4 days in the AA group and 6.6 days in the non-arrhythmia group. Mean cost associated with postoperative AA was approximately \$46,000 compared to \$33,000 in the non-AA group. APACHE II score data collection and analysis is currently ongoing and expected to be completed by March 2009.

**CONCLUSIONS:** Preliminary results indicate the development of an atrial arrhythmia following thoracotomy for excision or diagnosis of lung cancer is associated with increased mortality, LOS, and health care expenditures. At this point, both the mechanism and optimal prophylaxis/treatment strategies for atrial arrhythmias following noncardiac surgery are unclear.

**203. Implementation of a diabetic ketoacidosis order set reduces the risk of hypoglycemia.** Courtney A. Sheehan, Pharm.D., BCPS, Judith A. Jacobi, Pharm.D., BCPS, FCCM, FCCP, Kari L. Roemke, Pharm.D., BCPS; Clarian Health/Methodist Hospital, Indianapolis, Indiana, USA.

**OBJECTIVES:** Diabetic ketoacidosis (DKA) is a medical emergency with life-threatening complications. Timely initiation of appropriate intravenous fluids and insulin decreases morbidity and mortality. An order set for the treatment of DKA was developed to facilitate appropriate treatment processes and reduce the risk of hypoglycemia related to use of a standard insulin infusion protocol.

**METHODS:** A retrospective review of patients admitted with DKA and managed with an order set after February 2008 were compared to historical controls treated in 2006-2007 at a community teaching hospital. Both groups were treated with an insulin infusion but controls infusions were titrated to standard blood glucose (BG) goals (most 80-110mg/dL) and intervention patients were managed with a DKA order set that included an adjusted BG titration goal (initial 150-200mg/dL).

**RESULTS:** In controls, anion gap closed in 11.3 ± 7.9 hours versus intervention at 11.4 ± 4.7 hours (p=0.94). Blood glucose was lowered to less than 150 mg/dL in 10.7 ± 5.5 hours in controls and in 12.2 ± 5.5 hours for intervention patients (p=0.21). There were 2.3 ± 3.9 incidences of hypoglycemia in controls versus 0.9 ± 1.3 in intervention patients (p=0.06). A recurrence of a widened anion gap occurred in 23.4% of controls and in 15% of intervention patients (p=0.32).

**CONCLUSIONS:** The use of an order set for the management of DKA with an adjusted BG titration goal shows a trend to a reduction in the incidence of hypoglycemia without lengthening time to anion gap clearance or to blood glucose less than 150 mg/dL. Research still in progress, anticipated completion date of March 2009.

## Education/Training

**204. Evaluation of a preceptor development program in a tertiary care health system.** *Heather Somand, Pharm.D.,<sup>1</sup> Dennis M. Gates, R.Ph., M.S.<sup>2</sup>*; (1)Harper University Hospital, Detroit, Michigan, USA; (2)Children's Hospital of Michigan, Detroit, Michigan, USA.

**OBJECTIVES:** The objective of this study is to evaluate the efficacy and utility of four one-hour preceptor development presentations given at the Detroit Medical Center (DMC), a large, tertiary care health system which trains both PGY1 and PGY2 pharmacy residents.

**METHODS:** Identification of potential topic presentations was made by both the DMC residency steering committee and individual preceptors. Selection of the four topic presentations for the 2008–2009 residency was completed by the DMC residency director and the programming coordinator. At the conclusion of each presentation, an anonymous five-point scale survey will be completed by each preceptor in attendance. The survey will evaluate the utility of the program topic, the format of the education and conduciveness to learning, and the potential influence the program may have on their own precepting approach. The survey responses will be assessed by the programming coordinator. Any additional comments provided in the evaluations will also be collected and assessed.

**RESULTS:** Results of the surveys will be presented to the residency steering committee to provide guidance for future preceptor development programs. Two presentations were provided in the fall of the 2008, with two more scheduled for early 2009. Results of the five-point scale surveys for the first two presentations are below, with values of five being the best.

Title	Dealing with Problem Residents	Bringing out the Best in yourself and Others
No. in attendance	20	28
No. of evaluations completed	9	23
Content		
Level of interest	4.7	4.4
Level of value	4.9	4.3
Increased understanding	4.9	4.0
Level of influence on approach to subject	4.8	4.1
Presenter/Presentation		
Material best learned via live presentation	4.8	4.6
Organization	4.6	4.5
Conducive to learning	4.7	4.5
Level of interaction	4.7	4.4
Audiovisual Aids/Handouts	3.9	4.1

**CONCLUSIONS:** To date, the preceptor development presentations are effective and useful and will be considered for yearly education.

**205. The biopharmaceutical industry: a survey of students' perceived knowledge and interest.** *Benjamin P. Exter, Pharm.D., James Scanlon, Pharm.D., Raymond Kim, Pharm.D., Hamdan Almas, Pharm.D., Michael Steinberg, Pharm.D., Courtney Jarvis, Pharm.D.;* Massachusetts College of Pharmacy and Health Sciences, Worcester, Massachusetts, USA.

**OBJECTIVES:** Upon graduation Doctor of Pharmacy (Pharm.D.) candidates are faced with various career opportunities. Different schools of pharmacy schools expose students to diverse curricula, preparing them for careers in community, institutional, managed care, and industry settings. Data from the 2008 Bureau of Labor Statistics within the US Department of Labor suggest that the majority of Pharm.D. candidates gravitate towards careers in community and institutional settings. No current literature is available that has investigated pharmacy students' level of knowledge and interest in the biopharmaceutical setting. This study's goal is to assess the level of knowledge and interest that pharmacy students have in a biopharmaceutical industry setting.

**METHODS:** An online survey, containing twenty-two questions, was offered to participants from November 1, 2008 to December 14, 2008. The population solicited for participation consisted of over 500 pharmacy students currently enrolled in professional course years 1–4, from three different schools of pharmacy in New England.

**RESULTS:** Over 300 completed surveys have been received so far. Preliminary results indicate a trend of Pharm.D. candidates having limited exposure to opportunities that exist within the biopharmaceutical industry once they graduate. This was demonstrated

by only 17% of respondents admitting levels of 'knowledgeable' or 'very knowledgeable' to a question assessing their level of knowledge of these opportunities. Interestingly, only 38% of respondents indicated any level of interest in a career in the biopharmaceutical industry.

**CONCLUSIONS:** This study illuminates the need to provide additional education to Pharm.D. students on the many career opportunities, specifically in the biopharmaceutical industry, that are available to them upon graduation from a school of pharmacy.

**206. Meeting expectations for National Patient Safety Goal Requirement 3E: a health literacy focused patient education program.** *Kristin Tuiskula, Pharm.D.,<sup>1</sup> Shannielle Danner, Pharm.D. Candidate,<sup>2</sup> Kelly Bennett, Pharm.D. Candidate,<sup>2</sup> Monina Lahoz, Ph.D.,<sup>2</sup> Andrea Gorman, M.S., R.D., L.D.N.,<sup>1</sup> George Abraham, M.D., M.P.H.,<sup>1</sup> Karyn Sullivan, R.Ph., M.P.H.<sup>2</sup>*; (1)St. Vincent Hospital, Worcester, Massachusetts, USA; (2)Massachusetts College of Pharmacy and Health Sciences, Worcester, Massachusetts, USA.

**OBJECTIVES:** The National Patient Safety Goal Requirement (NPSG) 3E states "Reduce the likelihood of harm associated with the use of anticoagulant therapy". One implementation expectation pertains to patient/family education, which includes the importance of follow up monitoring, compliance, dietary restrictions, and the potential for adverse drug reactions and interactions. At our institution, currently available warfarin patient education materials focus on dietary precautions. The purpose of this project is to: (1) conduct a health literacy assessment of the current materials; and (2) revise and then assess whether the revised materials meet the NPSG 3E patient education expectations.

**METHODS:** Three authors independently conducted a health literacy assessment of the current and newly revised warfarin education materials. Suitability (content, literacy demand, graphics, layout and typography, learning stimulation/motivation, cultural appropriateness) was assessed using the Suitability Assessment of Materials (SAM) instrument. The readability of the materials was assessed using the Fry Formula and Flesch-Kincaid Grade Level program. Current materials were revised to make them more suitable to patients. The results of the health literacy assessments, from the current and revised materials, were compared.

**RESULTS:** The draft version scored better than the original on the SAM: 67.2% ± 5.9 vs. 43.5% ± 13.8; both SAM percentage ratings fell in the "adequate" category. SAM features scored as "not suitable" on the original pamphlet were improved in the draft version. Readability scores indicated that the draft version read at a lower grade level than the original pamphlet: Fry Formula- Grade 4 vs. 11; Flesch-Kincaid- Grade 6.9 vs. 9.8.

**CONCLUSIONS:** Preliminary data indicate that while the health literacy assessment scores of the draft pamphlet are better than the original version, there is room for further improvement. This project is ongoing and is anticipated to be completed in February 2009.

**207. Evaluation of patient education for transdermal fentanyl.** *Megan R. Stapleton, Pharm.D., Jolynn Sessions, Pharm.D., BCOP;* Charles George Veterans Affairs Medical Center, Asheville, North Carolina, USA

**OBJECTIVES:** The US Food and Drug Administration has warned of serious adverse effects associated with misuse of transdermal fentanyl. Focused patient education by healthcare professionals is a possible solution for teaching patients the proper use of their patches. This study compared baseline and follow-up questionnaires assessing knowledge gained from a telephonic educational session between a pharmacist and each patient receiving an active outpatient prescription for transdermal fentanyl.

**METHODS:** A database search was conducted to identify all outpatient prescriptions for transdermal fentanyl at the CGVAMC from October 20, 2008 through November 14, 2008. Patients were mailed a notification of the study and a template for informed consent. They were called 2–3 weeks later and provided a baseline questionnaire including 13 demographic questions and 10 core questions. A 10-minute educational session followed regarding administration and safety of the patches. Patients were then called 2–3 weeks later and provided a follow-up questionnaire with the same core questions and 5 questions regarding recommendations. Scores to the questionnaires were assessed and areas

for improvement noted. Appropriateness of prescribing of transdermal fentanyl was also assessed using national Veterans Affairs' guidelines.

**RESULTS:** Outpatient transdermal fentanyl was prescribed to 46 patients during the study's time-frame. As a sampling of the 10 initial core questions: (1) Can you use heating pads? 11% responded yes; (2) Can you cut your patch? 22% responded yes. Only 11% correctly responded that you clip the hair at the site of the patch, and 33% correctly responded that you discard the patch down the toilet.

**CONCLUSIONS:** Baseline questionnaires revealed an opportunity for further improvement in patient education. Pharmacist-led telephonic educational sessions or other means of education may aid to improve patient knowledge and safety. Complete results and conclusions will be presented at a later date. This study was supported by the Charles George VAMC in Asheville, North Carolina, USA.

## Endocrinology

**208. Triple renin-angiotensin-aldosterone-system (RAAS) inhibition: safety and efficacy of angiotensin-converting enzyme inhibitor (ACEI), angiotensin II receptor blocker (ARB), and direct renin inhibition combination therapy.** *Andrea N. Traina, Pharm.D.,<sup>1</sup> Michael P. Kane, Pharm.D.,<sup>1</sup> Robert S. Busch, M.D.,<sup>2</sup> Gary Bakst, M.D.,<sup>3</sup> Jill M. Abelseth, M.D.,<sup>3</sup> Robert A. Hamilton, Pharm.D.,<sup>4</sup>; (1)Albany College of Pharmacy, Albany, New York, USA; (2)The Endocrine Group, LLP, Albany, New York, USA; (3)The Endocrine Group, Albany, New York, USA; (4)Albany College of Pharmacy and Health Sciences, Albany, New York, USA.*

**OBJECTIVES:** Dual RAAS inhibition with ACEI and ARB therapy reduces proteinuria and progression of CKD compared to single inhibition of RAAS. Addition of the direct renin inhibitor aliskiren to previously established dual RAAS inhibition provides additional RAAS inhibition, and may provide additional proteinuria reduction. We report our experience (safety and efficacy) of triple RAAS inhibition therapy for treatment of diabetic nephropathy.

**METHODS:** Review of electronic medical records (EMR) of 3 private practice endocrinologists was performed using the search term "tekturna OR aliskiren" from January 1, 2007–October 30, 2008. Study population included patients receiving aliskiren as add-on to dual RAAS inhibition therapy for nephropathy and proteinuria with at least 3 months follow-up. Primary efficacy endpoint: comparison of baseline Al/Cr levels with those after minimum three months of aliskiren therapy; secondary efficacy endpoint: change in blood pressure. Safety was assessed by comparing baseline and three month Scr and serum potassium levels, and documenting adverse drug reactions (ADRs). Patients served as their own controls. Paired *t*-tests were performed to compare baseline data to follow-up; *p*-values <0.05 were considered statistically significant.

**RESULTS:** EMR review provided 280 patient records containing search terms. Seven male patients, average age 66 (±12) years and mean diabetes duration 23 (±5) years, met inclusion criteria. Mean baseline levels were Al/CR 413 (±366), serum potassium 4.8 (±0.5) mEq/L, serum creatinine 1.1 (±0.2) mg/dL, systolic BP 118.6 (±6.9) mmHg, and diastolic BP 69.1 (±3.2) mmHg. No significant differences were seen after an average of 7.4 (3–13) months follow-up. No adverse drug reactions or drug discontinuations were reported.

**CONCLUSIONS:** Short-term triple RAAS inhibition, while well tolerated, was not associated with reduction in proteinuria when added to dual RAAS inhibition. Larger, longer-term studies to determine the safety and efficacy of triple RAAS inhibition are needed.

**209. Retrospective analysis of continuous subcutaneous insulin infusion therapy in type 2 diabetic patients and a survey assessing patient satisfaction with insulin pump therapy.** *Chad K. Gentry, Pharm.D.,<sup>1</sup> L. Brian Cross, Pharm.D.,<sup>1</sup> Benjamin N. Gross, Pharm.D.,<sup>1</sup> Joni C. Foad, Pharm.D.,<sup>1</sup> Sherif Yacoub-Wasef, M.D.,<sup>2</sup> Emily Ham, R.N.,<sup>2</sup> Kim Nuss, P.A.-C<sup>2</sup>; (1)University of Tennessee / Holston Medical Group, Kingsport, Tennessee, USA; (2)Holston Medical Group, Kingsport, Tennessee, USA.*

**OBJECTIVES:** This study retrospectively assessed changes in total daily insulin dose, glycated hemoglobin (HbA1c), weight, and body mass index after conversion from multiple daily injections (MDI) of insulin to continuous subcutaneous insulin infusion (CSII) therapy.

**METHODS:** Electronic medical records of 29 type 2 diabetic patients of

at least 18 years of age and at least 6 months of insulin pump therapy were retrospectively analyzed. Baseline characteristics such as HbA1c, total daily insulin requirements, and weight at the time of conversion from MDI to CSII were collected and compared at 6, 12, 24, and 36 months. Patients will be asked to complete a satisfaction survey comparing MDI to CSII.

**RESULTS:** There was reduction in mean total daily insulin requirement from baseline to 6 months (1.32 units/kg/day vs. 1.09 units/kg/day; *p* <0.001) and in HbA1c (9.17 vs. 7.93; *p* <0.001). However, weight increased over the 6 month time interval (106.5 kg vs. 109.4 kg; *p* <0.001). Data for the 12, 24, and 36 month intervals are currently being collected and will be available for presentation with the patient satisfaction questionnaire results.

**CONCLUSIONS:** The use of CSII therapy in patients with type 2 diabetes is a viable option. When compared to MDI, CSII may provide patients with type 2 diabetes better glycemic control with minor weight gain.

## Health Services Research

**210. Electronic and personal health record adoption in pharmacy practice in Nebraska.** *Kevin T. Fuji, Pharm.D.,<sup>1</sup> Kimberly A. Galt, Pharm.D.,<sup>1</sup> Alexandra B. Serocca, B.A.,<sup>2</sup>; (1)Creighton Health Services Research Program, Creighton University School of Pharmacy and Health Professions, Omaha, Nebraska, USA; (2)Creighton University School of Pharmacy and Health Professions, Omaha, Nebraska, USA.*

**OBJECTIVES:** The practice of pharmacy is complex, partly due to the emergence of health information technologies that support pharmacists and patients. The use of electronic health records (EHRs) and personal health records (PHRs) to maintain and exchange health information can potentially facilitate care delivery and impact patient outcomes. This study describes adoption and use of EHRs and PHRs in community outpatient pharmacy practice.

**METHODS:** An explanatory mixed methods design is used, combining two data collection Methods. A written survey and qualitative interviews. The survey was sent to all 2,195 licensed pharmacists. Responses to selected questions were used to identify the interview sample of pharmacists. Descriptive analysis of survey responses, theme analysis of interviews, and comparison of results is planned. Survey analysis is complete. Interviews will be analyzed for readiness to use and experience with EHRs and PHRs in pharmacy practice. Pharmacists' perceptions of the impact EHRs and PHRs have on patient safety and care will be learned.

**RESULTS:** The survey was completed by 535 pharmacists (25% response rate). Of the respondents, 312 practice in community outpatient settings. Pharmacists report most (90%) patients keep track of personal health information in writing (90% keep a list of medications, and 50% keep a list of conditions/disease states), while 14% of patients access a PHR online. Most pharmacists cannot transfer information between the pharmacy system and patients' PHRs. Only 6% of pharmacists have prior experience and 3% currently use an EHR. Only 3% currently have access to patients' EHRs created by other providers, though 78% believe they should have access.

**CONCLUSIONS:** Pharmacists' readiness to participate in EHR and PHR health information exchange lags behind their beliefs about EHR access. Implementation strategies and patient safety perceptions will be described. Completion is planned by January 2009.

## Hematology/Anticoagulation

**211. Characterization of a 24-hour pharmacist managed direct thrombin inhibitor (DTI) program.** *T. Michael Farley, Pharm.D., George A. Davis, Pharm.D., BCPS, Daniel A. Lewis, Pharm.D., BCPS; University of Kentucky HealthCare, Lexington, Kentucky, USA.*

**OBJECTIVES:** Direct thrombin inhibitors (DTIs) play a key role in the treatment of patients with heparin induced thrombocytopenia (HIT). This study characterizes a program for managing the use of DTIs with a 24-hour-a-day pharmacist run service.

**METHODS:** A retrospective review of patient data from October 2008–November 2008 is being conducted. Patients who received either argatroban or bivalirudin were eligible for inclusion in the study. Seventy-eight patients have been identified for inclusion with twelve patients having been analyzed to date. Full analysis is expected over the

next two months. The primary endpoint is time to achieve therapeutic partial thromboplastin time (aPTT). Additional endpoints include frequency of laboratory monitoring for baseline liver function tests and coagulation studies, pharmacist response time following aPTT result, and bleeding complications defined by the thrombosis in myocardial infarction (TIMI) bleeding criteria.

**RESULTS:** Of the patients identified, 51.3% were treated with bivalirudin and 48.7% were treated with argatroban. Baseline monitoring of liver function tests and coagulation studies were completed in 100% of patients. The median time to a target therapeutic range of 50–70 seconds was 7.6 hours, with a median response time to an out of range aPTT of 34 minutes from lab value report to dose change. Minor bleeding (>6% drop in hematocrit from baseline) was seen in 8.4% of analyzed patients with no major bleeding (>15% decrease in hematocrit) detected.

**CONCLUSIONS:** A pharmacist managed direct thrombin inhibitor program provides effective monitoring and achieves therapeutic anticoagulation for patients being treated with DTIs in a timely manner without undue adverse events.

**212. Drug use evaluation of protamine and phytonadione: are the doses appropriate?** Teena Abraham, B.S., M.S., Pharm.D., BCPS, Nasser Saad, B.S., Pharm.D., Fabienne Vastey, B.S., Pharm.D., Eric Balmir, B.S., M.S., Amy Wang, Pharm.D., M.B.A.; New York Methodist Hospital, Brooklyn, New York, USA.

**OBJECTIVES:** This study is conducted to evaluate the use of protamine and phytonadione at an urban city hospital.

**METHODS:** This study is a retrospective chart review on patients who received either protamine or phytonadione. Information such as dose, routes of administration, indications for use, laboratory values, and signs and symptoms of bleeding are collected from the chart and the institution's computer system. Appropriateness of dosing for protamine and phytonadione will be evaluated based on dosing recommendations from package labeling and the 2008 Chest guideline.

**RESULTS:** The study included 22 patients who received protamine and 29 patients who received phytonadione. Patients in the protamine group were underdosed, dosed appropriately, and overdosed in 18.2%, 36.4%, and 45.4% of the cases, respectively. No significant correlations were identified between doses of heparin received and doses of protamine prescribed ( $r^2 = 0.6302$ ). Common indications for utilization of protamine were reverse effects of heparin post-surgery (46.7%) or post-cath (40%), and bleeding (13.3%). Bleeding events varied in degree of severity.

As for the phytonadione treatment group, common indications for usage included supratherapeutic INR (40%), reverse effects of warfarin for surgical procedures (28.6%), bleeding (20%), and other (11.4%). International normalized ratio was  $5.8 \pm 9.42$  prior to and  $4.9 \pm 11.61$  after phytonadione administration. Based on the INR and patients' clinical status, doses of phytonadione given were low, appropriate, and high in 1.82%, 30.9%, and 63.6% of the cases, respectively. Routes of administration were oral (45.5%), subcutaneous (23.6%), intravenous (20%), and intramuscular (10.9%). Bleeding events varied in degree of severity.

**CONCLUSIONS:** Utilization of protamine was mostly appropriate. Further education sessions should be provided for the physicians and nursing staff on dosing phytonadione in accordance to current guidelines. Moreover, utilizing the oral forms of phytonadione should be further encouraged, and utilization of the intramuscular dosage forms should be avoided.

**213. Evaluation of a weight-based heparin dosing protocol in obese patients.** A. Kendall Gross, Pharm.D.,<sup>1</sup> Tracy E. Macaulay, Pharm.D., BCPS,<sup>1</sup> Douglas T. Steinke, Ph.D.,<sup>2</sup> Daniel A. Lewis, Pharm.D., BCPS<sup>1</sup>; (1)University of Kentucky HealthCare, Pharmacy Services, Lexington, Kentucky, USA; (2)University of Kentucky College of Pharmacy, Lexington, Kentucky, USA.

**OBJECTIVES:** Although studies have demonstrated the utility of weight-based heparin dosing, the optimal strategy for obese patients has not been defined. Weight-based dosing results in faster achievement of therapeutic anticoagulation, fewer complications, and decreased costs; however, most studies included insufficient numbers of obese patients

to evaluate this population. Studies suggest weight-based dosing may yield higher activated partial thromboplastin time (aPTT) values in obese patients, but whether an initial dose cap or dosage adjustment should be employed remains unknown. The purpose of this study is to determine if a weight-based strategy with dose capping results in appropriate time to therapeutic anticoagulation in obese patients.

**METHODS:** Patients receiving heparin continuous infusions from July 2006 through October 2008 were randomized to non-obese (BMI <30 kg/m<sup>2</sup>) and obese (BMI ≥30 kg/m<sup>2</sup>) groups. A sample size of 170 is needed to achieve a power of 80% to detect a 6 hour difference in time to therapeutic aPTT ( $\alpha < 0.05$ ). Retrospective review was conducted for patients receiving heparin per institutional protocols. Primary endpoint is time to first therapeutic aPTT in obese and non-obese patients. Secondary endpoints are dosage associated with therapeutic aPTT and bleeding incidence, defined by thrombosis in myocardial infarction (TIMI) bleeding criteria.

**RESULTS:** To date, 30 patients have met inclusion criteria (16 non-obese, 14 obese). Final analysis, to be complete at the time of presentation, will include 170 patients. Mean time to therapeutic aPTT is 27 hours and 23 hours in the obese and non-obese groups, respectively. Dosage required to achieve therapeutic aPTT is 15.8 units/kg/hr in both groups. Incidence of minor bleeding is 12.5% in non-obese and 0% in obese subjects; no major bleeding events were reported.

**CONCLUSIONS:** Preliminary analysis reveals a similar time to therapeutic anticoagulation between groups. Safety data indicates no increased bleeding risk in obese patients utilizing current dosing strategies.

## Infectious Diseases

**214. Risk factors associated with the conversion of methicillin-resistant *Staphylococcus aureus* colonization to infection in hospitalized patients.** Lisa M. Harinstein, Pharm.D., Jason J. Schafer, Pharm.D., Frank D'Amico, Ph.D.; University of Pennsylvania Medical Center St. Margaret, Pittsburgh, Pennsylvania, USA.

**OBJECTIVES:** A retrospective cohort study was performed to determine risk factors for health-care associated methicillin-resistant *Staphylococcus aureus* (MRSA) infections in patients with MRSA colonization. Previous studies have investigated risk factors for MRSA colonization; however few have studied characteristics associated with the progression to infection. Identification of these characteristics is essential to prevent or help minimize the risk of MRSA infections in colonized patients.

**METHODS:** Study patients were included if they were ≥18 years of age and had a positive nares culture for MRSA between January 1, 2005 and August 1, 2008 at UPMC St. Margaret. Patients with a documented MRSA infection in the year preceding colonization were excluded. A chart review was performed for patients meeting inclusion criteria. Data collection began with a patient's index colonization and continued until the development of infection or for a maximum of 60 days. Data collected included: patient demographics, co-morbid conditions, medication use, presence of invasive devices, presence of wounds or other infections, nutritional status, and time to the development of infection.

**RESULTS:** Forty-one patients met inclusion criteria and progressed to MRSA infection. The majority of these patients developed pneumonia (51%), followed by bacteremia (22%), wound infections (17%), and urinary tract infections (10%). Data collected from these patients will be compared to 82 randomly selected control patients that met inclusion criteria but did not develop infection.

**CONCLUSIONS:** Pending data collection and analysis. Expected completion: Spring 2009.

**215. Etiology and outcomes for pneumonia patients admitted from a skilled-nursing facility (SNF): implications for empiric antibiotic therapy.** Russell T. Attridge, Pharm.D., Christopher R. Frei, Pharm.D., M.Sc., BCPS; The University of Texas at Austin and The University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA.

**OBJECTIVES:** Healthcare-associated pneumonia (HCAP) criteria are broad, encompassing ~50% of patients traditionally categorized as community-acquired pneumonia (CAP). Patients admitted from skilled-nursing facilities (SNF) are newly-regarded as HCAP; but it is unclear if

SNF patients present with different pneumonia etiology or experience worse health outcomes.

**METHODS:** Hospital admissions with a principal ICD9 code for pneumonia (481–486) were extracted from the 1996–2006 National Hospital Discharge Survey. Patients <18 years of age and those hospitalized  $\leq 1$  day were excluded. Patients were considered to be admitted from home (non-SNF patients) if they were admitted through the emergency room or by clinic, physician, or HMO referral. SNF patients were those transferred directly from a SNF facility to the hospital. Chi-square and Student's t-tests were used to compare baseline demographics, bacterial pathogens, mortality, and hospital length-of-stay (LOS) in SNF and non-SNF groups. Weighted data were used to derive population-based estimates.

**RESULTS:** Overall, 5.5 million adults (2.4% transferred from a SNF) met study criteria. The mean age was 70 years with 53.2% being female. All comparisons were statistically significant with  $p < 0.0001$ . Compared to patients admitted from home, those admitted from a SNF were more likely to be culture-positive (15.4% vs. 12.7%), have *S. aureus* (7.4% vs. 3.0%), *P. aeruginosa* (3.6% vs. 2.0%), and anaerobes (0.3% vs. 0.1%). Conversely, patients from home had a higher incidence of *S. pneumoniae* (2.8% vs. 0.9%), *Legionella* spp. (0.2% vs. 0), *H. influenzae* (1.0% vs. 0.2%), and *Proteus/Serratia* spp. (1.4% vs. 1.1%). Furthermore, SNF patients experienced greater mortality (12.9% vs. 4.7%) and had a higher proportion of patients hospitalized 7 or more days (40.3% vs. 27.8%).

**CONCLUSIONS:** SNF patients presented with different pneumonia etiology and experienced worse health outcomes than patients admitted from home. These data suggest that recent guidelines have appropriately categorized SNF patients with pneumonia as HCAP and empiric *S. aureus* coverage is warranted.

**216. Acquisition of resistance in urinary tract organisms infecting patients with spinal cord injury.** Young R. Lee, Pharm.D.,<sup>1</sup> Sara D. Brouse, Pharm.D., BCPS,<sup>1</sup> Susan Duquaine, Pharm.D., BCPS,<sup>2</sup> Roger Bedimo, M.D., M.S.,<sup>3</sup> Lance L. Goetz, M.D.<sup>3</sup>; (1)Texas Tech University Health Sciences Center and the Dallas Veterans Affairs Medical Center, Dallas, Texas, USA; (2)VA North Texas Health Care System, Dallas, Texas, USA; (3)The University of Texas Southwestern Medical Center, Dallas, Texas, USA and the Dallas Veterans Affairs Medical Center, Dallas, Texas, USA.

**OBJECTIVES:** This is a retrospective, observational study of patients with spinal cord injury (SCI) infected with urinary tract pathogens to 1) identify the incidence of resistant isolates, and 2) evaluate the impact of antibiotic usage patterns on the acquisition of resistance.

**METHODS:** Records for male or female adult patients admitted to the Veterans Affairs North Texas Healthcare System SCI unit for at least 3 months between 7/1/03 and 6/30/08 were reviewed. Patients with two positive urine cultures isolating the same organism were included. Exclusion criteria were a diagnosis of epididymitis, prostatitis, or pregnancy. The computerized patient record system was used to collect the following data: age, gender, duration of hospitalization in the SCI unit, neurologic level of injury and completeness, microbiology, urinalysis, antibiotic history, presence of comorbidities, concomitant drug therapy, and indwelling catheter.

**RESULTS:** Ninety-seven patients admitted to the SCI unit for at least 3 months during the study period were identified. Thirty-six charts have been reviewed to date and twenty-three patients met inclusion criteria. Preliminary analysis revealed that urinary pathogens in ten patients (43%, resistant group) developed resistance during their hospital stay and those in thirteen patients (57%, non-resistant group) did not. The mean duration of hospital stay was longer in the resistant group versus the non-resistant group (230 days vs. 176 days). More patients in the resistant group had an indwelling urinary catheter, history of hospitalization, and antibiotic usage as compared to the non-resistant group but this was not statistically significant. Age, neurologic level of injury and completeness or comorbidities such as diabetes and genitourinary tract disorder were not associated with increasing antibiotic resistance.

**CONCLUSIONS:** Preliminary results do not demonstrate the impact of antibiotic pressure on the acquisition of resistance in the urinary tract organisms infecting patients with SCI. However, additional data are required to confirm these results.

## Managed Care

**217. Aspirin prescriptions at discharge: a strategy to increase the percentage of cardiovascular patients receiving aspirin.** Vanessa J. Taylor, Pharm.D.,<sup>1</sup> Marcia L. Brackbill, Pharm.D.,<sup>2</sup> Christine Sytsma, R.N., M.S.N.,<sup>3</sup>; (1)Winchester Medical Center, Shenandoah University School of Pharmacy, Winchester, Virginia, USA; (2)Shenandoah University School of Pharmacy, Winchester, Virginia, USA; (3)Winchester Medical Center, Winchester, Virginia, USA

**OBJECTIVES:** An "aspirin prescription" similar in appearance to other prescriptions could potentially increase compliance with quality indicators. It would prompt nurses to include aspirin on discharge medication sheets and may also elevate patient awareness of the importance of aspirin. This pilot was designed to evaluate if an aspirin prescription would help achieve 100% compliance with patients prescribed aspirin at discharge.

**METHODS:** This is a single center prospective pilot study. All patients admitted to the hospital in the first quarter of 2009 for acute coronary syndrome or cardiac surgery will be included. Exclusion criteria include age <18 years old, aspirin allergy, contraindications to aspirin use, or valve-only surgery patients. Pre-printed aspirin prescriptions will be placed in charts of eligible patients upon admission and completed by the physician. This prescription (with other prescriptions) will be used by the nurse to create a discharge medication list and passed along to the patient at discharge. December will be used as an education month. Compliance data from Sept–Nov 2008 will be used as control data to determine if a change in compliance occurred as a result of the pilot.

**RESULTS:** Data collection regarding aspirin at discharge for the historical control group is currently in progress. Historical data available at this time demonstrates that the quality indicator was met in 95% of cardiac surgery patients (n=59) and 98% of acute coronary syndrome patients (n=114). The change in mean number of patients who meet the quality indicator after the pilot study will be determined and data analysis will occur in the first week of April. All heart center personnel have been educated about the pilot.

**CONCLUSIONS:** It is anticipated this pilot will find that the addition of a physical "aspirin prescription" will result in 100% compliance with the prescription of aspirin discharge for post-ACS and post-CABG patients.

## Medical Informatics

**218. Impact of an electronic risk factor assessment and medication order set on contrast induced nephropathy.** Megan A. McKee, Pharm.D., Pamela R. Maxwell, Pharm.D., Kay Green, R.Ph., Darrel W. Hughes, Pharm.D., Colleen Barthol, Pharm.D.; University Health System, San Antonio, Texas, USA.

**OBJECTIVES:** To evaluate the impact of an order set in a computerized prescriber order entry system (CPOE) on the incidence of contrast induced nephropathy (CIN).

**METHODS:** An evidence based CIN risk factor assessment tool and medication order set was developed and implemented on November 1, 2008. Electronic medical records of adult in-patients who received contrast-enhanced computed tomography exams between January 1 and October 31, 2008 were reviewed as retrospective controls. Baseline demographics, CIN risk factors, and prophylactic measures were documented. The primary outcome, CIN, was defined as an increase in serum creatinine  $\geq 0.5$  mg/dL or 25% from baseline within 48 hours following contrast exposure. Similar data are being collected prospectively as the treatment group since implementation of the order set and compared to the control.

**RESULTS:** A total of 201 (149 control, 52 treatment) patients have been reviewed to date. Overall, the median age was 48, with 57% males. Baseline characteristics were similar between groups, except the treatment group had a median of 2 risk factors versus 1 in the control group. The incidence of CIN was 22.15% in the control group and 13.46% in the treatment group ( $p=0.17$ ). Appropriate hydration was ordered in 62% of the control group versus 90% in the treatment group ( $p < 0.0006$ ). N-acetylcysteine was utilized in 7% of the control group versus 39% in the treatment group ( $p < 0.0001$ ).

**CONCLUSIONS:** An electronic order set in a CPOE system is a useful and efficient method to assist providers in identifying CIN risk factors and implementing prophylactic measures. The order set has improved

the prescribing of appropriate prophylactic measures in patients at risk for CIN.

### Medication Safety

**219. What is the evidence for the FDA warning for intravenous haloperidol and QT interval prolongation?** *Carla Meyer-Massetti, M.Sc., Christine M Cheng, Pharm.D., B Joseph Guglielmo, Pharm.D.; University of California San Francisco, San Francisco, California, USA.*

**OBJECTIVES:** In September 2007 the FDA strengthened label warnings for intravenous (IV) haloperidol associated QT prolongation (HQTP) and Torsades de Pointes (TdP), specifically requiring ECG monitoring. The minimum dose leading to HQTP has not been specified. Since IV haloperidol is widely used to treat acute delirium, this warning has been associated with controversy. An evidence-based review was conducted to evaluate the evidence associated with the warnings.

**METHODS:** Pubmed (1966–11/2008) and Embase (1972–11/2008) were searched using the terms “IV haloperidol”, “QT prolongation”, “TdP” and “cardiac arrest”. Additionally, the FDA MedWatch system was used to identify all haloperidol-associated ADEs from 11/1997–4/2008.

**RESULTS:** Using the PubMed and Embase databases, 38 published cases of HQTP and/or TdP were identified. These 38 cases included 17 females and 21 males (19–86 years). The cumulative dose of IV haloperidol at the time of the HQTP or TdP ranged from 2 mg to 1700 mg. Twentythree patients (cumulative dose range 9–1700mg) experienced both QT prolongation and TdP; 8 patients (lowest cumulative dose 2mg) experienced only HQTP, and 5 patients (cumulative dose range 10–175 mg) had only TdP. Twenty-three patients were receiving concomitant agents known to prolong QT. Two deaths were reported. In review of the 5994 MedWatch haloperidol-associated ADEs, 36 cases of HQTP and TdP were reported involving intravenous haloperidol, including 10 females and 25 males (18–82 years). The cumulative dose at the time of the ADE ranged from 2 mg–1700 mg. Five deaths were reported.

**CONCLUSIONS:** QT prolongation and/or TdP have not been documented with single doses of IV haloperidol of <2 mg. Many reports of QT prolongation and/or TdP were confounded by other risk factors (pre-existing rhythm disturbances, electrolyte imbalance, concomitant pro-arrhythmic drugs, critical illness). Despite the FDA warnings, it may be safe to administer intravenous haloperidol in doses <2 mg.

**220. Evaluation of an anticoagulation clinic medication reconciliation process.** *Kade T. Birkeland, Pharm.D., Lori Spellman, Pharm.D., David Parra, Pharm.D., BCPS; The Department of Veterans Affairs Medical Center, West Palm Beach, Florida, USA.*

**OBJECTIVES:** Evaluate local anticoagulation clinic medication reconciliation processes of medications patients obtain outside of the Veterans Affairs (VA) medical system.

**METHODS:** Anticoagulation clinic patients' electronic medical record listing of active Non-VA medications will be compared to a self-reported active Non-VA medications list. Two hundred-fifty anticoagulation clinic patients will be selected to complete an assessment form. Completed assessment forms will identify patients who have discrepancies in their electronic medical record listing of active Non-VA medications. Data collected includes: total number of patients, total number patients identified to have an accurate electronic medical record listing of active Non-VA medications, active Non-VA medications (total and per patient), percent of active Non-VA medications accurately reconciled, nature of inaccuracy in the electronic medical record listing of active Non-VA medications, active Non-VA medications with potential to interact with warfarin (total and per patient), and active Non-VA medications inaccurately reconciled with potential to interact with warfarin (total and per patient). Data will be analyzed and reported using descriptive statistical measures.

**RESULTS:** Comparison of anticoagulation patients' electronic medical record listing of active Non-VA medications to a self-reported active Non-VA medications list was initiated December 15, 2008. Preliminary findings showed that patients reported on average taking three or more Non-VA medications. Of 23 patients evaluated, only 5 had a completely accurate electronic medical record listing of active Non-VA medications. Fifty-seven percent of patient reported active Non-VA medications were inaccurately reconciled, 45% of which may directly interact with or

precipitate an adverse drug event when used concomitantly with warfarin. Underreporting of active Non-VA medications was the most frequently encountered documentation error.

**CONCLUSIONS:** Further interpretation of the data will assist in quantification and description of Non-VA medication use and reconciliation processes in this patient population. Full results will be available for presentation.

**221. Drug use evaluation of fondaparinux at a community teaching hospital.** *Rachelle M. Busby, Pharm.D., Ronald J. Campbell, Pharm.D., BCPS; UPMC St. Margaret, Pittsburgh, Pennsylvania, USA*

**OBJECTIVES:** A retrospective drug use evaluation of fondaparinux was performed to: (1) evaluate prescribing patterns according to indications, contraindications, and appropriateness of use; and (2) assess the occurrence of major bleeding events.

**METHODS:** Patients chosen for review were all patients ordered fondaparinux from 1/1/08 to 6/30/08 identified through the electronic medical record. Electronic medical records were reviewed and the following data was recorded for each patient: weight, creatinine clearance, indication, dose, duration, presence of contraindications or warnings, active bleeding, platelet levels, and prescribing physician service (i.e., hematology).

**RESULTS:** After review of 75 patients, 96% were prescribed fondaparinux for deep vein thrombosis prophylaxis. According to FDA approved indications, fondaparinux was prescribed off label in 63% of patients. At initiation of therapy, 16% of patients had a calculated creatinine clearance (Cockcroft-Gault) less than 30 ml/min. In addition, 8% of patients weighed less than 50 kg and received fondaparinux as deep vein thrombosis prophylaxis. In terms of appropriateness of use; a platelet count less than  $100,000 \times 10^6/L$  at initiation occurred in 12% of patients. Two patients had a major bleed (as defined in the fondaparinux prescribing information) while on fondaparinux therapy.

**CONCLUSIONS:** Fondaparinux is prescribed commonly off label and occasionally inappropriately. The results of this drug use evaluation will be used to develop policies and procedures to improve patient safety at our institution.

**REFERENCES:** 1. Arixtra Prescribing Information. Research Triangle Park, North Carolina, USA: GlaxoSmithKline; 2005 Oct.

### Oncology

**222. Medication use evaluation of megestrol acetate in cancer patients.** *Stephanie V. Phan, Pharm.D., Patricia Rhee, Pharm.D.; West Palm Beach VA Medical Center, West Palm Beach, Florida, USA.*

**OBJECTIVES:** Objectives of this retrospective chart review include assessment of the effectiveness and safety of megestrol acetate therapy for cancer-related anorexia and cachexia in cancer patients.

**METHODS:** Medical records of 100 cancer patients receiving a prescription for megestrol acetate suspension from July 2006 to July 2008 at the West Palm Beach Veteran Affairs Medical Center will be reviewed. Patients' cancer-related history including chemotherapy and/or radiation therapy and diagnosis will be documented in addition to megestrol acetate use and concurrent weight at baseline, two weeks, one, three, six and every six months thereafter. Adverse effects causing discontinuation of therapy will be recorded.

**RESULTS:** To date, data on 38 male patients have been collected. Average weight at two weeks and one month increased from baseline by 0.29% (0.20 kg;  $p=0.59$ ) and 0.57% (0.39 kg;  $p=0.65$ ) respectively. The average daily dose of megestrol acetate suspension was 1011mg/day (range of 800 to 1600 mg/day). Of the patients receiving chemotherapy, 7.89% received chemotherapy with high emetic risk, 50% with moderate risk, 5.26% with low risk, and 15.79% with minimal risk; 21.1% of patients received no chemotherapy. Sub-group analysis based on chemotherapy emetogenicity did not reveal statistically significant weight gain among groups. No megestrol acetate prescriptions were discontinued due to adverse events although 47.4% of patients had megestrol acetate prescriptions discontinued due to patient death; the remaining prescriptions were active or expired. Other possible etiologies for anorexia or cachexia (i.e., GI obstruction, COPD, etc.) were absent in 21.1% of patients. Eighteen patients reviewed filled megestrol acetate suspension one time only. Final results will include medication compliance analysis and patient demographics.

**CONCLUSIONS:** Based on a preliminary data analysis, megestrol acetate does not significantly contribute to weight gain in cancer-related anorexia and cachexia. Further evaluation of megestrol acetate use is pending completion of data collection.

## Pediatrics

**223. Evaluation of antimicrobial prophylaxis in pediatric surgical patients.** *Pratish C. Patel, Pharm.D.,<sup>1</sup> Kelley Lee, Pharm.D., BCPS,<sup>2</sup> Sandra Arnold, M.D., FRCPC<sup>1</sup>; (1)University of Tennessee/Le Bonheur Children's Medical Center, Memphis, Tennessee, USA; (2)LeBonheur Children's Medical Center, Memphis, Tennessee, USA*

**OBJECTIVES:** Surgical site infections (SSI) comprise approximately 38% of all nosocomial infections, leading to increased morbidity, mortality, costs, and length of stay. The objective of this project is to evaluate the appropriateness and effectiveness of antimicrobial prophylaxis in our pediatric patients undergoing surgical procedures.

**METHODS:** The subjects included in this retrospective data review include patients admitted to our 225-bed pediatric hospital and had a surgical intervention performed in the first week of every month for one year from November 2007. Data collected includes patient demographics, drug allergies, pre-existing diagnoses of infectious nature, duration of pre-surgery stay, American Society of Anesthesiologists physical status classification, type of surgery performed, duration of surgery, antibiotic(s) used (including dose, timing, and interval), markers for infection (temperature, WBC, neutrophils, CRP, and cultures), type of surgical site infection, and readmission to the hospital within 30 days of surgery.

**RESULTS:** Approximately 300 charts were reviewed for inclusion in the data review. Patients having surgery performed on an outpatient basis and for ear, nose, and throat related indications were excluded. Outcome measures examined in this chart review were surgical site infection rate (stratified by antibiotic used and type of surgery performed), severity of infection, readmission rate, and adherence to hospital SSI antimicrobial prophylaxis policy.

**CONCLUSIONS:** To be determined after data review is completed and information is analyzed.

**224. Survey of pediatric hospitals adoption of once daily aminoglycoside dosing.** *Dianna K. Proulx, Pharm.D., Melissa O'Neill, Pharm.D., Lindsay Lester, Pharm.D.; Huntsville Hospital, Huntsville, Alabama, USA.*

**OBJECTIVES:** The objective of this survey is to assess pediatric hospitals in the United States adoption of once daily aminoglycosides. For the pediatric hospitals that are using once daily aminoglycosides, this survey will determine how dosing is recommended, clinical services that monitor and adjust therapy, how therapy is monitored, contraindications to therapy, and clinician's attitudes toward once daily aminoglycosides in the pediatric population.

**Purpose:** The purpose of the survey is to describe how once daily aminoglycosides have been adopted in the pediatric populations. Currently, there are two published surveys evaluating the adoption of once daily aminoglycosides in acute care hospitals with the focus of the surveys being adult medicine. There has been no published information assessing the same information in the pediatric population.

**METHODS:** A survey was sent to pediatric practitioners using the American College of Clinical Pharmacy's Pediatric listserve and the Pediatric Pharmacy Advocacy Group's general pediatrics, critical care, and infectious disease listservices. The survey will be resent to the listservices in March. Paper copies of the survey will be sent to large pediatric hospitals to increase the response rate.

**RESULTS:** Surveys are being collected now.

**CONCLUSIONS:** Surveys are being collected now.

**225. Evaluation of therapeutic monitoring of once-daily gentamicin in preterm neonates based on serum creatinine concentrations.** *Andrea R. Chamberlain, Pharm.D., Kendra C. Bosley, Pharm.D., Brian C. Yarbey, Pharm.D.; Kosair Children's Hospital, Louisville, Kentucky, USA.*

**OBJECTIVES:** The primary objective is to determine a correlation between measured serum creatinine levels and serum gentamicin troughs with a goal of identifying a serum creatinine, stratified by gestational age and birth weight, at which 95% of patients have a

gentamicin trough <2 µg/mL to potentially reduce the number of gentamicin troughs obtained and healthcare costs associated with those levels.

**METHODS:** The health system's electronic medical record system is being used to identify 175 preterm neonates (<38 weeks gestation) who were treated in the neonatal intensive care unit at Kosair Children's Hospital in Louisville, Kentucky from January 2006–December 2008 who received gentamicin in the first 24 hours of life for at least 5 days. Patients are being randomized based on gestational age and birth weight with serum creatinine concentrations and serum gentamicin troughs being the primary measures evaluated. Other demographic data being collected includes: gender, use of concomitant nephrotoxic agents, presence of confirmed infection by culture, congenital renal and/or cardiac anomalies, and history of maternal drug abuse.

**RESULTS:** Using the inclusion and exclusion criteria established prior to commencement of data collection, there have been no suprathreshold gentamicin troughs (≥2 µg/ml) identified thus far despite presence of concomitant nephrotoxic agents and congenital anomalies. Once data collection is complete, patient data will be retrospectively evaluated using Pearson's correlation coefficient.

**CONCLUSIONS:** This is a study in progress, so conclusions will be made once data collection and evaluation are complete.

## Pharmacoeconomics/Outcomes

**226. Organizational and financial impact of centralized preparation of antineoplastic monoclonal antibodies in a French hospital.** *Baptiste Quélenec, Pharmacist, Resident, Christelle Lemarignier, Pharmacist, Michèle Ancel, Pharmacist, Daniel Roncalez, Pharmacist; Hôpitaux Civils de Colmar, Colmar, France.*

The number of monoclonal antibodies therapeutic indications is increasing. Placing antibodies preparation under pharmacists' responsibility will improve patient's security, optimize nursing time and expensive drugs management. Moreover, this should correspond to the French recommendations on drugs good use.

**OBJECTIVES:** This study aims at assessing the organizational and financial impacts of the centralized reconstitution of monoclonal antibodies within a cytotoxic drugs reconstitution unit (CDRU).

**METHODS:** A retrospective statement of anticancer monoclonal antibodies dispensations was made from July 2007 to June 2008. The collected data included date, care unit, patient's initials, prescribed and exempted quantities. Drugs returned for non administration were listed.

**RESULTS:** There were 1458 antibodies dispensations. Activity increased by over 11.6%. Exempted antibodies surpluses amounted to 31 319 euros. 43 treatments, representing 2.9% of dispensations and 54 776 euros, were returned to CDRU for non administration. Reminders The current management process has led to 31 319 euros losses. With a centralized preparation of antibodies the losses due to unusable remainders would amount to 16 849 euros and the total theoretical losses due to non administration should be added to this sum. Consequently, centralization would generate 71,625 euros theoretical losses. The necessary improvement directions are two fold: (1) share of returned drugs should fall to 1 % (21,000 euros); and (2) remainders quantities should be reduced. Practices should be reorganized in partnership with care units.

**CONCLUSIONS:** The financial side shouldn't lead to discredit centralization, which holds three major assets concerning patient's safety: (1) to the harmonization of preparation techniques, drugs will be prepared by a qualified personnel; (2) quality assurance program will guarantee traceability; (3) will lead to nursing time redeployment towards patients' benefit .

**227. Hospital Costs Associated with a Pharmacodynamic Based Clinical Pathway for Empiric Antibiotic Choice in Patients Infected with Ventilator Associated Pneumonia.** *Anthony M. Nicasio, Pharm.D.,<sup>1</sup> Kathryn J. Eagey, M.P.H.,<sup>1</sup> Effie L. Kutu, Pharm.D.,<sup>2</sup> David P. Nicolau, Pharm.D., FCCP, FIDSA,<sup>1</sup> Joseph L. Kutu, Pharm.D.<sup>1</sup>; (1)Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, Connecticut, USA; (2)University of Connecticut, School of Pharmacy, Storrs, Connecticut, USA*

**OBJECTIVES:** Ventilator associated pneumonia (VAP) increases mortality, length of stay (LOS) in intensive care units (ICUs), and

hospitalization costs. After implementing a clinical pathway (CP) consisting of a three-drug antibiotic regimen [vancomycin, tobramycin, and high-dose cefepime 2g q8h (3h infusion) or meropenem 2g q8h (3h infusion)] derived from pharmacodynamic modeling and ICU-specific resistance data, we found a significant reduction in infection related mortality (21.6% to 8.5%). Because costly high-dose antibiotic regimens were empirically prescribed, we sought to determine if such costs were offset by the improved outcomes.

**METHODS:** A retrospective cost analysis was conducted in two cohorts of adult patients infected with VAP at Hartford Hospital: those treated with CP between 2006–2007 and those of a historic control group treated for VAP before CP implementation (2003–2005). Hospital costs were derived from the discharge billing data and inflated to 2007 values using the consumer price index for medical care. The two cohorts were compared for infection-related LOS (IR-LOS) and total and daily hospitalization costs during therapy for VAP.

**RESULTS:** Of 166 total patients, similar patient demographics (age, comorbid conditions, and APACHE II scores) between CP (n=93) and historic (n=73) cohorts were observed. During the treatment for CP versus historic VAP, respectively, daily hospitalization costs were similar between both cohorts (\$3,470 versus \$3,527,  $p=0.742$ ). Total VAP hospitalization costs were highly correlated with IR-LOS ( $r^2=0.95$ ,  $p<0.001$ ). Despite more costly empiric antibiotic therapy, CP patients had a shorter IR-LOS (11 vs. 25 days,  $p<0.001$ ) and reduced total hospitalization costs compared with the historic control group (median [25th–75th percentile]; \$35,841 [22,288–56,351] vs. \$75,270 [44,791–138,454],  $p<0.001$ ).

**CONCLUSIONS:** Although higher cost antibiotic therapy was empirically used to treat VAP during CP, this approach resulted in improved clinical outcomes, a reduction in IR-LOS, and lower total hospitalization costs.

## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**228. Tigecycline penetration into the epithelial lining fluid of infected and uninfected murine lungs.** Jared L. Crandon, Pharm.D., BCPS, Aryun Kim, Pharm.D., David P. Nicolau, Pharm.D., FCCP, FIDSA; Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, Connecticut, USA.

**OBJECTIVES:** When evaluating the pharmacodynamics of antimicrobials, assumptions are often made relative to their pharmacokinetics. One example of this is applying tissue penetration results of uninfected hosts to those displaying a targeted illness. As tigecycline evolves into a potential treatment option for pneumonia, we determined whether the presence of a lung infection affected the penetration of the drug into the epithelial lining fluid (ELF).

**METHODS:** Single doses of tigecycline 50 and 25 mg/kg were administered to neutropenic ICR mice with or without the presence of a lung infection. Serum samples were gathered at time points ranging from 0.5–24h after tigecycline administration; additionally, bronchoalveolar lavage (BAL) was conducted at 1, 1.5, 4, and 8h. Tigecycline concentrations in serum and BAL fluid were determined by a validated HPLC method, urea correction was used to calculate the tigecycline concentrations in ELF. Comparisons of ELF penetration in infected and uninfected lungs were based on the ratios of the 8 hour area under the concentration time curve ( $AUC_{0-8}$ ) in ELF and the free  $AUC_{0-8}$  in serum. In both instances, AUC was calculated by the trapezoidal rule.

**RESULTS:** Serum pharmacokinetics of tigecycline were best described by a 2-compartment model with first-order input and elimination. The uninfected group displayed an ELF penetration ratio of 8.1 and 6.2 for the 50 and 25 mg/kg doses, respectively. The respective penetration ratios in the infected lungs were 23.3 and 12.9.

**CONCLUSIONS:** While tigecycline exhibits excellent ELF penetration in healthy and infected murine lungs, the presence of infection greatly enhances penetration. Moreover, increased systemic exposures of tigecycline result in greater ELF penetration, regardless of infection status. When future tigecycline clinical trials for the treatment pneumonia are considered, escalated doses may reap greater than expected benefits towards achieving adequate pharmacodynamic indexes within the lungs.

**229. Cockcroft-Gault (CG) using ideal body weight (IBW) versus adjusted body weight (AdjBW) in obese patients.** Marco R. Scipione, Pharm.D., Polina Lerner, Pharm.D., Boris Nogid, Pharm.D., BCPS, Robert DiGregorio, Pharm.D.; The Brooklyn Hospital Center, Brooklyn, New York, USA.

**OBJECTIVES:** To compare how patient specific aminoglycoside/vancomycin clearance will correlate with glomerular filtration rate (GFR) as estimated by either Cockcroft-Gault using ideal body weight (IBW) or adjusted body weight (AdjBW) in obese patients.

**METHODS:** This is a retrospective review of obese patients (BMI  $\geq 30m^2$ ),  $\geq 18$  years old, with CrCl  $\geq 30$  ml/min, on vancomycin or an aminoglycoside. Patient-specific elimination rate constant (Ke) and volume of distribution ( $V_d$ ) were calculated based on  $C_{max}$  and  $C_{min}$  of vancomycin or aminoglycoside. Using these two variables the patient-specific drug clearance was calculated. Estimated drug clearances were obtained from CG-IBW and CG-AdjBW equations and compared to calculated patient-specific drug clearance. Statistics will be analyzed using the Pearson correlation coefficient.

**RESULTS:** Nine patients on vancomycin were evaluated. The CG-IBW equation shows a higher level of correlation with patient-specific drug clearance compared to the CG-AdjBW equation ( $R^2 = 0.3557$  vs.  $R^2 = 0.2905$ ). Although CG-IBW shows a higher correlation compared to CG-AdjBW, neither calculation demonstrated a strong correlation to patient-specific drug clearance in obese patients.

**CONCLUSIONS:** Data collection is ongoing. Preliminary results show a weak correlation between the CG-IBW and CG-AdjBW equations in estimating patient-specific drug clearance in obese patients.

**230. A comparison of gentamicin dosing strategies in neonates  $\leq 29$  weeks gestation.** Keliana L. O'Mara, Pharm.D., BCPS,<sup>1</sup> Peter Gal, Pharm.D., BCPS,<sup>2</sup> Christopher C. McPherson, Pharm.D.<sup>1</sup>; (1)Women's Hospital of Greensboro, Greensboro, North Carolina, USA; (2)Greensboro Area Health Center, Greensboro, North Carolina, USA

**OBJECTIVES:** It is unknown whether gentamicin dosing strategies recommended in Neofax (N), Pediatric Dosing Handbook (P), and Redbook (R) are appropriate for neonates  $\leq 29$  weeks gestation in the first week of life. By using gentamicin drug concentrations drawn post-loading dose to calculate pharmacokinetic parameters, various dosing regimens were compared to determine which strategy best optimizes pharmacokinetic and pharmacodynamic principles in extremely preterm neonates.

**METHODS:** This was a retrospective analysis of neonates up to 29 weeks gestation born at Women's Hospital of Greensboro. Gentamicin was administered on day one. One-compartment model pharmacokinetic (PK) parameters and an individualized dosing regimen were calculated for each neonate to use as the dosing standard for comparison. Following recommendations from commonly-used texts, maintenance dose, interval, and expected peak and trough serum concentrations were determined with each patient's PK data. Peak plasma concentration ( $C_{max}$ )/mean inhibitory concentration (MIC) and intensity index-72 (II-72) were also calculated to evaluate pharmacodynamic appropriateness.

**RESULTS:** There were 203 evaluable neonates. Based on trends in mean PK parameters, patients were divided into two groups: 23 to 26 weeks gestation (G1) and 27 to 29 weeks gestation (G2). Percentages within the therapeutically-acceptable ranges were determined for each regimen. Using peak serum concentrations of 6–12  $\mu g/mL$ , G1 N=95%, P=95%, and R=21%, and G2 N=90%, P=83%, and R=35%. Using serum trough concentrations  $\leq 2 \mu g/mL$ , G1 N=95%, P=69%, R=82% and G2 N=100%, P=85%, R=74%. The target  $C_{max}/MIC$  was 10–12. For this parameter, G1 N=22%, P=14%, and R=1% and G2 N=31%, P=6%, R=0.9%. II-72 was considered acceptable if greater than 400; results were N=82%, P=83%, and R=46% in G1 and N=50%, P=53%, and R=82% in G2.

**CONCLUSIONS:** None of the dosing regimens recommended in standard neonatal reference books optimize both pharmacokinetics and pharmacodynamics to ensure appropriate treatment of presumed sepsis in neonates  $\leq 29$  weeks gestation.

**231. An in vitro pharmacodynamic model of a human simulated high dose, prolonged infusion meropenem regimen against *Klebsiella* spp.-producing KPC carbapenemase.** Catharine C. Bulik, Pharm.D., Henry

Christensen, B.S., Peng Li, B.S.(Pharm.), David P. Nicolau, Pharm.D., FCCP, FIDSA, Joseph L. Kuti, Pharm.D.; Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, Connecticut, USA.

**OBJECTIVES:** *Klebsiella* spp. that produce the KPC carbapenemase can have varying meropenem minimum inhibitory concentrations (MIC), but the majority are above the susceptibility breakpoint (4 µg/ml), thus rendering standard dosage regimens ineffective. The objective of this study was to assess the performance of an optimized high-dose meropenem regimen against KPC isolates using an in vitro pharmacodynamic model.

**METHODS:** A human simulated meropenem regimen (2g q8h as a 3-hour infusion) was replicated for the purpose of obtaining 40% free drug time above the MIC ( $fT>MIC$ ) at MICs up to 16 µg/ml. A one compartment in vitro pharmacodynamic model was employed to assess the reduction in bacterial density over 24 hours against *Klebsiella* isolates known to produce the KPC enzyme. Distinct isolates with meropenem MICs of 6 µg/ml (n=1), 8 µg/ml (n=3), 16 µg/ml (n=3), 32 µg/ml (n=1), and 64 µg/ml (n=1) were included. Bacterial density was assessed in duplicate at 0, 3, 6, 8, 11, 16, 19, and 24 hours after dosing. Meropenem concentrations were simultaneously collected to verify targeted exposure.

**RESULTS:** Meropenem achieved a rapid  $\geq 3$  log reduction in CFU against all organisms within 4–6 hours. No regrowth was observed for the isolate with an MIC of 6 µg/ml. All other isolates grew back to control ( $10^8$  CFU/ml) by 16–19 hours. Targeted meropenem concentrations were achieved in organism-free models (drug alone) and against the isolate with an MIC of 6 µg/ml. However, meropenem was rapidly degraded by 8–16 hours in all other experimental models, thereby resulting in suboptimal  $fT>MIC$  exposures.

**CONCLUSIONS:** Regardless of MIC, a human simulated high-dose meropenem regimen achieved rapid bactericidal activity against these KPC producing isolates, followed by regrowth in all but the isolate with the lowest MIC. In this in vitro model, meropenem was efficiently hydrolyzed by the KPC enzyme, thereby resulting in lower than effective concentrations over the 24-hour experiment.

## Transplant/Immunology

**232. Evaluation of the effect of a transplant specialty pharmacy service line on renal allograft rejection.** *Nicole Kenyon, Pharm.D., Crystal Truax, Pharm.D., Sabrina Lee, Pharm.D., Michael Kelly, R.Ph., Lonn Smith, Pharm.D.*; University of Utah Hospitals and Clinics, Salt Lake City, Utah, USA.

**BACKGROUND:** Despite the effectiveness of immunosuppressive medications, medication non-compliance continues, leading to graft rejection and loss. A major factor contributing to medication non-compliance is cost. Our transplant specialty pharmacy provides detailed and thorough billing and reimbursement expertise for patients to minimize this burden. At hospital discharge, patients may choose to receive a month-supply of medications from the specialty pharmacy; approximately 325 patients continue this service post-transplant. The pharmacy provides eligibility, reimbursement, and accounts receivable services, increasing patient accountability and compliance. The pharmacy can bill many out-of-state Medicaid providers and small PBM s, increasing medication access. Additionally, patient assistance and charity programs provide assistance for qualified patients. Coordination between the billing and transplant departments ensures all patients receive medications and/or appropriate follow-up if barriers to dispensing exist.

**OBJECTIVES:** The purpose of this study is to determine if utilization of our transplant specialty pharmacy services leads to decreased incidence of graft rejection.

**METHODS:** All renal transplant recipients from 1/2000 to 11/2007 were evaluated. Billing records were reviewed to determine length of participation in the service line. Patients were then grouped according to length of time they used pharmacy services. Episodes of rejection were compared between groups ( $\chi^2$ ).

**RESULTS:** 583 patients were included in this study. 173 patients left the system within 1 year; 49 patients left 1–3 years post-transplant; 49 patients left after 3 years; 110 patients left then returned at least once post-transplant. Of patients who left within 1 year, 60 used our system

only upon discharge and experienced 19 episodes of rejection. These patients had a rejection rate of 23% compared with 15% if they left our system after 1 year ( $p<0.05$ ).

**CONCLUSIONS:** A more detailed evaluation of risk factors must be undertaken, but it appears a transplant specialty pharmacy service may contribute to a decreased incidence of rejection.

## Women's Health

**233. Valproate use in women of childbearing potential.** *Christine D. Lee, Pharm.D., Rex Force, Pharm.D., Brooke Pugmire, Pharm.D.*; Departments of Family Medicine and Pharmacy Practice, Idaho State University, Pocatello, Idaho, USA.

**OBJECTIVES:** Valproate use in women of childbearing age is concerning because it has been assigned FDA pregnancy category D. While the use of valproate may be necessary in women with seizure disorders, use for other indications (bipolar, migraine prophylaxis, etc.) may be inappropriate in women of childbearing potential. To characterize this problem, we analyzed longitudinal paid pharmacy and medical claims in this at-risk population.

**METHODS:** Idaho Medicaid claims were queried from January 1, 1997–December 31, 2007 to identify women age 14–45 (*at-risk women*). Prescription claims for at least one fill of valproate were identified to evaluate prescribing trends. For every valproate claim, concurrent contraception was identified. Exposed pregnancies were determined by using CPT procedure and/or ICD-9 delivery codes (index date). Patients with at least one fill of valproate within the 280 days prior to delivery were identified and categorized by trimester exposed. Indications for valproate use will be identified.

**RESULTS:** Of 26,061 at-risk women in 1997, 720 (2.76%) had at least one claim for valproate. At-risk women has been trending down to a total of 670 women exposed of 41,550 (1.61%) in 2007. Contraceptive coverage increased from 30.61% in 1997 to 38.02% in 2001, but has fallen to 27.99% in 2007. There were 96,985 pregnancies during the study period, 157 of which were linked with one or more claims for valproate. Most of the exposures occurred in the first trimester. The annual rate of exposure did not change over the study period.

**CONCLUSIONS:** In the preliminary analysis, valproate use in at-risk women has decreased, contraception was not detected in a majority of women despite knowledge of fetal risk, and pregnancies continue to be exposed. Completed analysis, including valproate use by indication will be available at the time of presentation.

## STUDENT SUBMISSIONS

### ADR/Drug Interactions

**234. INR elevation associated with maitake extract in combination with warfarin.** *Michele R. Hanselin, Pharm.D., Candidate, Joseph P. Vande Griend, Pharm.D., Sunny A. Linnebur, Pharm.D.*; University of Colorado Denver School of Pharmacy, Aurora, Colorado, USA.

**OBJECTIVES:** To introduce a possible drug-interaction between maitake (Grifon®-Pro Maitake D-fraction® Tincture, Maitake Products, Inc.) and warfarin resulting in elevated international normalized ratio (INR).

**METHODS:** We present the case of a 79-year-old man with a history of hyperlipidemia, diastolic heart failure, metastatic carcinoma of the lungs, bladder, and humerus, atrial fibrillation, mitral valve regurgitation, BPH, and hypertension. His medications included diltiazem, tamsulosin, eszopiclone, simvastatin, hydromorphone, warfarin, prednisolone ophthalmic suspension, vitamin E, and an omega-3 supplement, none of which were recently changed. The patient was taking warfarin 5 mg twice weekly and 2.5 mg five times weekly. His INR was therapeutic (2.0–3.0) for four consecutive visits over a period of six weeks prior to starting maitake. He self-initiated maitake 25 drops orally three times daily for alternative cancer treatment. Two weeks after initiation of maitake, his INR elevated to 5.1. The patient did not experience any bleeding associated with the increased INR. Warfarin was held for two doses (7.5 mg) and his INR two days later was 3.0. The patient continued taking maitake. To prevent his INR from increasing further, another 2.5 mg of warfarin was held, and his dose was reduced by 2.5 mg weekly. After one week at the reduced dose, the patient's INR was slightly low at 1.8. He took an extra 2.5 mg warfarin and maintained

the reduced weekly dose. Other than the maitake, there was no explanation for the patient's significantly elevated INR.

**RESULTS:** This patient had consistently therapeutic INRs until the introduction of maitake. A "probable interaction" exists between maitake and warfarin according to the Naranjo ADR Probability Scale (score of six). The mechanism of interaction is unknown; protein binding displacement may play a role.

**CONCLUSIONS:** An elevated INR was noted after the addition of maitake to chronic warfarin therapy. We are unaware of other reports of this potential drug-interaction.

**235. Polymedication in hospitalized elderly patients: a prospective analysis of drug prescription.** *Corinne The, Junior Pharmacist, Julia Dessault, Junior Pharmacist, Mélanie Robin, Junior Pharmacist, Carole Frances, Pharmacist, Bertrand Gourdiér, Pharmacist; Department of Pharmacy - Reims University Hospital, Reims, France.*

**OBJECTIVES:** An inappropriate prescribing is frequently encountered in geriatrics and pharmacokinetic and pharmacodynamic age-related modifications may increase the adverse drugs reaction (ADR) in the elderly patients. The aim of this prospective study was to assess the requirement of pharmaceutical analysis of prescriptions in an elderly unit at the Reims University Hospital.

**METHODS:** In order to give the best pharmaceutical advice, a daily analysis of drug prescriptions is dispensed to the elderly unit (142 patients) as follows: evaluation of the drug interaction thanks to a French data base "theriaque", drug switch, dose adaptation.

**RESULTS:** A total of 126 prescriptions were analyzed. The population of patient was on average age 84.3 years old (63–100) and the male/female ratio was 0.4. These patients lived in this institution for an average of 3 years (one month–19 years). These results pointed out the polymedication observed in elderly patients. The results showed at least that all the patients used regularly some pharmacological therapy. Their distribution was: less than 5 drugs/day: 12 (10%), between 5 to 10 drugs/day: 54 (53%), more than 10 drugs/day: 60 (47%). The mean daily drug consumption was 9 drugs (1–18). Among these prescriptions occurred some drug interactions: 103 presented potentially more than one drug interaction. Drug-drug interactions have been also analysed and classified; 56 were precaution use (44%), 89 were interaction demanding clinical attention (71%). No contra-indication has been found. The most drugs prescribed were the cardiovascular system drugs (92, 73%), pain medications (71, 57%), and nervous system drugs (110, 87%).

**CONCLUSIONS:** Polypathologic conditions sometimes justify polymedication which needs a close attention to prevent ADR. Our experience has been helpful (1) to elaborate a prescriber information support; (2) to determine in a geriatric unit the role of the pharmacist student; and (3) to optimise the safety of the medications and decrease iatrogenic events.

**236. Description of Adverse drug events (ADE) linked to health products: pharmaceutical students in the service of a public health mission.** *Florence Ollivier, Pharm.D., Ph.D., student, Nathalie Asseray, M.D, Ph.D., Françoise Ballereau, Pharm.D, Ph.D.; UPRES EA 3826 Faculté de Médecine, Nantes, France*

**OBJECTIVES:** Iatrogenic risk reduction is one of the priorities of the French Public Health Act issued on August 9, 2004, and integrates the hospital risk gestion program. In the University Hospital of Nantes, 5th year Pharmacy students are trained to track and report adverse drug events linked to health products during their training courses in care units.

**METHODS:** Pharmacy students acquire an adverse effect detection and analysis approach during their clinical pharmacy module, which takes place in collaboration with a clinician. Adverse effect description is done using the *Drug Errors Declaration* form, proposed by the SFPC (Société Française de Pharmacie Clinique) and the analysis refers to the National Coordinating Council for Medication Errors Reporting and Prevention (NCCP-MERP) taxonomy: the therapeutic process stages concerned by errors, nature of errors, the root cause, and the gravity level of the error have been characterized.

**RESULTS:** Since September 2005, 218 adverse effects have been identified by students: 3 events without error, 114 errors without injury,

82 errors with injury and no death. The main stages concerned in the pharmaceutical life cycle are prescription (34%), administration (30%), and dispensation (21%). 14% of the events concern antibiotics, 9% anti-thrombotics and 8% opioid analgesics.

**CONCLUSIONS:** The pharmacist plays a major role in the health-linked risks gestion approach. The collection of adverse effects by Pharmacy students in hospitals has aroused an institutional reflection (pharmacists / doctors / direction) and has incited the risks gestion cell and the drugs committee (COMEDIMS) to get involved in a medication error review approach, to secure the patient therapeutic care.

## Ambulatory Care

**237. Impact of pharmacist-directed diabetes education programs in a Veteran's Administration Medical Center.** *Valerie M. Prost, B.S.,<sup>1</sup> Cynthia M. Phillips, Pharm.D., CDE,<sup>2</sup> James W. Hardin, Ph.D.<sup>3</sup>; (1)University of South Carolina, College of Pharmacy, Columbia, South Carolina, USA; (2)South Carolina College of Pharmacy, USC campus, Columbia, South Carolina, USA; (3)University of South Carolina, Biostatistics Collaborative Unit, Columbia, South Carolina, USA*

**OBJECTIVES:** This study evaluated patients who were referred for diabetes education at a Veteran's Administration Medical Center (n=129). The primary purpose was to test the hypothesis that clinical outcomes are associated with a pharmacist-directed diabetes education program. The secondary purpose was to test the hypothesis that clinical outcomes are associated with a medication therapy management component added to the diabetes education program.

**METHODS:** Medical records of three groups were reviewed: patients who participated in a longitudinal diabetes education program with integrated medication therapy management; patients who participated in a one-time 4-hour diabetes education program; or patients who declined to participate in either program and only received standard care. Patient's disease states, medications, hemoglobin HbA1c, cholesterol levels, blood pressure, and body mass index (BMI) were documented at six months prior and post to their attendance or scheduled attendance for one of the two programs. Statistical analyses were conducted on an intention-to-treat basis and patients served as their own control for within patient comparisons. Data is presented as means, standard deviations, and percentages. A  $\chi^2$  test and student's *t* test were used to analyze categorical and continuous data for significance, respectively.

**RESULTS:** Of the 129 patients evaluated, 13% attended the longitudinal program, 62% attended the 4-hour program, and 25% declined to participate. Clinical variables across the three groups were comparable at baseline. Hemoglobin HbA1c significantly decreased from baseline in the longitudinal program ( $9.0 \pm 2.1$  vs.  $7.9 \pm 1.6$ ;  $p=0.003$ ) and 4-hour program ( $8.0 \pm 2.2$  vs.  $7.2 \pm 1.6$ ;  $p=0.00018$ ) participants. Cholesterol levels and BMI were also decreased in those who participated in either education program compared to those who declined education.

**CONCLUSIONS:** Preliminary data confirms that pharmacist-directed diabetes education improves clinical outcomes at six months, especially hemoglobin HbA1c levels. Patients who received standard care showed no improvements in clinical outcomes.

**238. Asthma: A breathing experience.** *Acaysia Webster, High, School, Student,<sup>1</sup> Kenneth Rush, High School Student,<sup>1</sup> Miranda Lucas, High School Student,<sup>1</sup> Daniela Lobo, M.D.,<sup>2</sup> Kristal L. Williams, Pharm.D., CDE<sup>3</sup>; (1)Crispus Attucks Medical Magnet High School, Indianapolis, Indiana, USA; (2)Indiana University Methodist Family Practice Center, Indianapolis, IN Indiana, USA (3)Butler University College of Pharmacy and Health Sciences/Indiana University Methodist Family Practice Center, Indianapolis, Indiana, USA*

**OBJECTIVES:** To optimize asthma-related care during school hours and school-related activities by increasing asthma awareness and knowledge among school employees (SE) and to increase asthma awareness and self-management among students with asthma (SwA) and their guardian(s).

**STUDY GOALS:** To increase the overall control of asthma among school-aged children; to decreased the number of asthma-related missed days from school or work; and to decrease the number of health professional contacts secondary to the presence of uncontrolled asthma symptoms.

**METHODS:** This multi-phase study will incorporate the use of

investigator-designed quizzes, surveys, and/or interactive presentations to assess the asthma awareness among SE and asthma awareness and self-management skills among SwA and their guardians. The study will be conducted at Crispus Attucks, a medical magnet school. Audience-specific interactive presentations on asthma will be given to the SE, SwA, and their guardians. Pre- and post-test to assess asthma knowledge will be given to each participant. Knowledge scores will be analyzed to determine learning. SwA will complete a 25-item asthma-related demographic survey. Self-management techniques will be assessed by having the SwA demonstrate, via a placebo-device, the use of their inhalers and, if prescribed, peak-flow monitor. Immediately after the demonstration of each, the guardian will be asked to comment on the accuracy of the student's technique. If warranted, specific one-on-one education on proper device technique will be provided and the student will repeat the exercise. The accuracy of the students' device technique will be categorized as excellent, very good, or poor using the inhaler grade sheet. Student-specific peak flow readings will be compared to population-averages, their test and device technique scores and survey responses. SwA will be provided with educational resources, spacers, peak flow meters. An exempt IRB application has been submitted and data collection is scheduled to begin in January 2009.

**RESULTS:** To be presented.

**CONCLUSIONS:** To be presented.

### Cardiovascular.

**239. Retrospective review of warfarin use in patients with low ejection fraction and no established indication for anticoagulation.** *Jessica Starr, Pharm.D., BCPS,<sup>1</sup> Jessica L. Golden, Pharm.D. Candidate,<sup>2</sup> Amy K. Pennington, Pharm.D. Candidate<sup>3</sup>;* (1)Auburn University Harrison School of Pharmacy, Birmingham, Alabama, USA; (2)Auburn University, Homewood, Alabama, USA; (3)Auburn University, Birmingham, Alabama, USA

Patients with systolic heart failure are at an increased risk for thromboembolic events due to the pooling of blood in the left ventricle of the heart. While warfarin is an appropriate anti-coagulant for proven indications, the benefits of its use in lone systolic heart failure may not outweigh the risks associated with its use. Prescribers frequently initiate anti-coagulation in these patients without well designed clinical trials to substantiate this practice.

To determine the incidence of warfarin initiation in patients with decreased ejection fraction who have no established indication for anticoagulation.

**METHODS:** Retrospective chart review of patients at Princeton Baptist Medical Center between January 2008 and December 2008 who were prescribed warfarin therapy as a component of heart failure treatment. Patients included had ejection fractions  $\leq 40\%$  and were excluded if they had concomitant atrial fibrillation, mechanical prosthetic heart valves, or a history of DVT, PE, or stroke.

**RESULTS:** In progress; data collection and analysis to end February 2009.

**CONCLUSIONS:** Results will help direct the selection of appropriate usage of anti-coagulant therapy for patients with heart failure. The results will also confirm the need for a well designed clinical trial to provide evidence based recommendations on this subject.

### Clinical Administration

**240. Relation between the route of administration of drugs and the feeding mode of patients in a French teaching hospital.** *Amina Benmani, Pharmacy Student,<sup>1</sup> Olivier Bourneton, Pharmacy Student,<sup>1</sup> Catherine Stiebert, Pharmacy Student,<sup>1</sup> Marie Czekala, Pharmacy Student,<sup>1</sup> Morgane Ethgen-Bonnet, Pharmacist,<sup>1</sup> Laurence Beretz, Pharmacist,<sup>1</sup> Philippe Wolf, M.D.<sup>2</sup>;* (1)Pôle de pharmacie-pharmacologie, Hôpital de Hautepierre, Strasbourg, France; (2)Pôle des pathologies digestives, hépatiques et de la transplantation, Hôpital de Hautepierre, Strasbourg, France.

**OBJECTIVES:** Parenteral drugs are generally more expensive than their oral forms; regarding fluoroquinolones antibacterial agents, proton pump inhibitors, analgesic drugs, the cost of the injectable forms may be 10 fold higher. The main objective of this study was to analyze the relation between the feeding mode of patients hospitalized in a digestive diseases unit and the medication administration route. The secondary

objective was to estimate the potential additional cost of drugs given by the parenteral route in patients fed orally.

**METHODS:** The pharmaceutical team generated a standardized data collection form. At a given day, we collected data including patient's characteristics, the feeding mode and the treatment administered (drugs such as proton pump inhibitors, antibiotics, antifungal agents, analgesics, antispasmodic and antiemetic drugs, the doses and the route of administration).

**RESULTS:** We included 138 patients. Among 101 patients fed orally, 62% received medications by the parenteral route and 37% orally. Furthermore, 19 (46%) of 34 fasting patients were administered their treatment orally. We noticed that treatments considered inappropriate (ie, treatment administered orally in fasting patients and parenteral drugs given in patients fed orally) concerned 59% of the population. Injectable drugs of concern mostly were analgesics, antibiotics (ciprofloxacin, amoxicilline/clavulanic acid), antifungal agents (fluconazole, metronidazole), antiemetics (ondansetron) and antispasmodic drugs (metoclopramide). In this study, the daily total cost of the injectable forms in patients fed orally was € 253.5. Thus, the daily total additional cost was € 216.7 compared to the oral administration considered feasible (€ 36.8 per day).

**CONCLUSIONS:** In our study, the route of administration of drugs was related to the feeding mode in a minority of patients. Consequently, it is necessary to revise these practices and to insure a regular follow up of the prescriptions in wards in order to optimize the use of expensive injectable drugs.

### Community Pharmacy Practice

**241. Contributing pharmaceutical services with the U.S. naval hospital ship Mercy through the Pacific Partnership 2008 in Vietnam and Timor-Leste.** *Amie Phuc Nguyen, Pharm.D. Candidate, Julie Ha Nguyen, Pharm.D. Candidate; University of California, San Diego, La Jolla, California, USA.*

**OBJECTIVES:** To examine pharmacy operations on the U.S. Naval Hospital Ship Mercy throughout humanitarian services in Vietnam and Timor-Leste between June 19 and July 25, 2008.

**METHODS:** Two pharmacy students spent six weeks living on the U.S. Naval Hospital Ship Mercy and participated in medical humanitarian missions in Vietnam and Timor-Leste that were 10 and 13 days in length, respectively. Data collected included: the number of patients seen aboard the Mercy and onshore medical clinics, the quantity of prescriptions filled, therapeutic classes of medications dispensed, those most commonly used, hours of operation, staffing, workload, and infrastructure of the Mercy pharmacy department.

**RESULTS:** The average workload while underway and during the mission was 77 hours per week for all pharmacy personnel. Pharmacy staff included five pharmacists, 15 technicians, and two student pharmacists. The pharmacy was approximately 2,412 square feet composed of a storage area, a compounding or IV room, and an outpatient area. Medications dispensed during both missions ranging from analgesics to antibiotics dermatological agents, and others. The most commonly used drugs were doxycycline 100mg and acetaminophen 325 mg while underway, and adult multivitamins and Ibuprofen 800 mg during the mission, in both countries.

**CONCLUSIONS:** The workload during the two humanitarian missions in Vietnam and Timor Leste on the U.S. Naval Hospital Ship Mercy was heavier than normal pharmacy operations in the US, as it required longer working hours for the pharmacy personnel. Differences were identified in the medications dispensed aboard the Mercy and at onshore medical clinics. Although these differences were identified between traditional pharmacy practice and that of a humanitarian mission aboard the USNS Mercy, two successful humanitarian missions were carried out in Vietnam and Timor Leste that helped thousands of people.

**242. Illinois Prescription Monitoring Program Utilization by Community Pharmacist.** *Christopher Herndon, Pharm.D., BCPS,<sup>1</sup> Andrew Brand, Pharm.D. Candidate,<sup>2</sup> Matthew Layman, Pharm.D. Candidate<sup>3</sup>;* (1)Southern Illinois University at Edwardsville, Edwardsville, Illinois, USA; (2)Southern Illinois University at Edwardsville, Waterloo, Illinois, USA; (3)Southern Illinois University at Edwardsville, Glen Carbon, Illinois, USA

**OBJECTIVES:** A growing problem in the United States is the abuse of prescription drugs including opioids, depressants, and stimulants, along with many others. Prescriptions drugs as a whole are one of the most commonly abused substances among Americans. In 2005, the National All Schedules Prescription Electronic Reporting Act (or NASPER) bill was signed, which was developed by the American Society of Interventional Pain Physicians. The bill was developed to clinically improve overall patient control as well as controlling the abuse and trafficking of controlled medications. The bill made it each states' responsibility to design individual prescription monitoring programs, but it provided much federal funding for the design and development. In January 2008, the Illinois Prescription Monitoring Program was expanded to include all controlled substances dispensed in retail pharmacies. The purpose of our research includes the following. With the Illinois Prescription Monitoring Program being effective for approximately 6 months now, we feel that researching how the program is being used by retail pharmacists in Illinois could help develop recommendation on how the program could be improved. We also feel that we can increase the awareness of a program that is currently underutilized by Illinois pharmacists.

**METHODS:** We plan to survey 1,000 community pharmacists that are licensed in Illinois. The list of licensed pharmacists was obtained by the State of Illinois Pharmacy Register and 1,000 pharmacists were randomized to be included in the study. Questions included in the survey are: demographic information about the pharmacist, whether the pharmacist uses the Illinois Prescription Monitoring Program or not, which employee in the pharmacy submits data to the program, and any recommendations or suggestions the pharmacist has regarding the program. Based on the responses, a summary of recommendations will be compiled.

**RESULTS:** Not yet compiled.

**CONCLUSIONS:** Conclusions will be made upon receiving results.

**243. Patient counseling efforts in U.S. community pharmacies: associations to pharmacy and personnel attributes.** *Stephan Linden, B.S.Pharm.,<sup>1</sup> Almut G. Winterstein, Ph.D.,<sup>2</sup> Carole Kimberlin, Ph.D.,<sup>3</sup>* (1)University of Florida, Dept. of Pharmaceutical Outcomes & Policy, Gainesville, Florida, USA; (2)Department of Pharmacy Health Care Administration, University of Florida, Gainesville, Florida, USA; (3)University of Florida College of Pharmacy, Gainesville, Florida, USA

**OBJECTIVES:** This observational, cross-sectional study portrays oral patient counseling in continental U.S. community pharmacies as a follow up to the 2003 BL Svarstad et. al study. Additionally the association of the quantity and quality of oral counseling with adjoining factors such as pharmacy characteristics and pharmacy personnel will be examined.

**METHODS:** Trained professional shoppers were sent as patients to 365 randomly selected community pharmacies to fill first time prescriptions for Lisinopril and Metformin between January 28 and March 31, 2008. Immediately upon visiting the pharmacies, the shoppers documented receipt of oral and written information as well as pharmacy and pharmacy personnel characteristics in a 40 item protocol. The protocol is organized in six sections: shopper demographics, contact person demographics, general counseling, specific counseling for each drug and pharmacy characteristics.

**RESULTS:** (preliminary) Oral counseling in at least one of the 24 counseling items was received by 71% of the shoppers. Oral counseling varied significantly with a mean of 5.4 items and a standard deviation of 6.8 items. The type of pharmacy and the busyness (assessed as patients waiting in the pick-up area) was not associated to the amount of counseling. Shoppers in contact with a younger pharmacist (below 35yrs.) were more likely to be counseled on at least one item and receive more general information counseling.

**CONCLUSIONS:** While these results are preliminary, they already provide an impression that oral counseling still shows immense diversity in quantity and quality. The complete results at the ACCP International Congress in April 2009 will be indicators for state boards of pharmacy, pharmacy associations, pharmacy managers, and practitioners to identify persisting quality deficits and accordingly will help improve pharmaceutical care.

## Critical Care

**244. Automated dispensing system in a medical intensive care unit: impact on medication errors and users' satisfaction.** *Claire Chapuis, Student,<sup>1</sup> Pierrick Bedouch, Pharm.D., Ph.D.,<sup>1</sup> Matthieu Roustit, Pharm.D.,<sup>2</sup> Carole Schwebel, M.D., Ph.D.,<sup>3</sup> Jean-François Timsit, M.D., Ph.D.,<sup>3</sup> Pascal Pansu, Ph.D.,<sup>4</sup> Jean-Luc Bosson, M.D., Ph.D.,<sup>2</sup> Jean Calop, Pharm.D., Ph.D.,<sup>5</sup> Benoît Allenet, Pharm.D., Ph.D.<sup>1</sup>;* (1)Department of Pharmacy, ThEMAS TIMC-IMAG UMR CNRS 5525 UJF, University Hospital, Grenoble, France; (2)Centre of Clinical Investigations, INSERM CHU Grenoble, University Hospital, Grenoble, France; (3)Medical Intensive Care Unit, University Hospital, Grenoble, France; (4)LSE-EA-602, UPMF, Grenoble, France; (5)Department of Pharmacy, University Hospital, Grenoble, France.

**OBJECTIVES:** Automated dispensing systems (ADS) allow a reduction of medication errors and improvement of drug distribution in clinical wards. The objective of this study was to assess the impact of an ADS (1) on medication errors, and (2) on user's perception.

**METHODS:** We conducted a prospective controlled study in a medical intensive care unit. Nurses were observed by a pharmacist using the technique as described by the American Society of Health-System Pharmacists, in an 8-bed studied unit and in a 10-bed controlled unit, 2 months before and 2 months after the implementation of an ADS (OmniRx, Omnicell™, USA). We observed picking, preparation and administration of drugs. Clinical significance of errors was judged by a multidisciplinary group (2 physicians and 2 pharmacists), using the NCC-MERP method. Nurses' perception was evaluated through questionnaires 2 weeks before, 6 weeks after and 8 months after ADS implementation.

**RESULTS:** The study involved 104 patients, 66 nurses and 22 prescribers. Out of the 9600 opportunities for error observed, 4700 occurred before implementation, and 4800 afterwards. A total of 64 questionnaires assessing nurses' satisfaction toward the new system were filled-out at the 3 different times. Contributing factors and effects on working conditions were taken into account to explain satisfaction scores. Statistical analysis is currently being performed (we will be able to deliver the results by the time of the congress).

**CONCLUSIONS:** We expect a reduction in medication errors, by facilitation of the drugs selection. Economic impact and improvement of the ward pharmacy management were showed previously<sup>1</sup>. Moreover, nurses favour this system. ADS enhance medication distribution while allowing pharmacists and nurses to focus on tasks depending on their own domain of expertise.

**REFERENCE:** Kheniene F, Bedouch P, et al. Economic impact of an automated dispensing system in an intensive care unit. *Ann Fr Anesth Reanim.* 2008;27:208-15.

## Drug Abuse and Treatment

**245. Evaluation of therapeutic adherence and withdrawal management in methadone maintenance treatment program in Penang Malaysia.** *Wasif S. Gillani, M.Clin., Pharm., Azhar S. Sulaiman, Pharm. D;* Universiti Sains Malaysia (USM), Malaysia, Pulau Pinang, Malaysia.

**OBJECTIVES:** The objectives cover; 1) therapeutic adherence of patients to the MMT program, 2) National protocol comparison with that of active practices by practitioners.

**METHODS:** Medical records of all the patients from Jan 2007 to May 2008 were reviewed. A year's retrospective and six months' prospective study was done. Exclusion was made for the defaulted out-patients. Medical records were reviewed from all the Government registered methadone clinics of Penang.

**RESULTS:** A total of 283 patients were registered, 97.5% were males and 2.5% females. Only 215 patients' records were reviewed in study. Majority of defaulted cases were untraceable (70.1%) and these drop-outs were found among the Chinese. Only 1 case was successfully treated. 54.0% were well adhered to the therapy and stay over a year of treatment. 99 patients restarted the methadone treatment after an interval of 1-7 months. Withdrawal symptoms were observed among 57.3% of patients, while 89.8% out-patients had medical complications during the methadone therapy with: musculo-skeletal problems (48.2%), Neurological disorders (41.5%) etc. Dose management showed that 69.4% patients were on ineffective therapeutic comfort dose. 60.0% had positive urine analysis (>14 times) during 6 months of treatment,

while a negative correlation ( $r=-0.492$ ) was found between counseling and positive urine analysis with 24.2% shared variance. Regression modeling identified ( $R^2=0.793$ ) 79.3% functional change in the adherence to therapy with  $p<0.001$  and CI 95%.

**CONCLUSIONS:** High rate of defaulted cases were observed as compared to the therapeutic adherence to MMT program. Inconsistent practices were found although the practices were inconsistent to National Protocol but it was found that is a strong need to review the National Guidelines on present evidence-based therapeutic approach. To control the positive urine analysis further research is needed to identify the social stigma among the patients during the treatment paradigm.

## Drug Information

**246. Improvement of drug administration in patient with swallowing problems and feeding tubes.** *Jocelyn Jezequel, Interne, Chloé Rousselière, Pharmacist, Isabelle Carpentier, Pharmacist; Pharmacy Department, Lens Hospital, France, Lens, France.*

**OBJECTIVES:** Drug administration in patient with swallowing problems and feeding tubes is a common practice in hospital. However studies have shown that this administration requires specific care because of not adapted galenic form and that medical staff had very limited knowledge of the appropriate best practice. So correct administration is a challenge for pharmacy.

**METHODS:** It is made a review of literature in several databases (PubMed, Science Direct, John Libbey Eurotext, etc.), data-gathering from suppliers and a survey to know practice met in clinical ward.

**RESULTS:** In January 2008, the pharmacy drew up:

- A list of oral drugs: Brand name, generic name, possibility of substitution by liquid medication, possibility of dissolution, possibility of crushing and substitute solution are given for all drugs held at the pharmacy.
- Guides to help administration of drugs Pharmacy bought also manual crushers to crush tablets.

A list of oral drugs, guides and crushers were given to staff on three wards (intensive care unit, neurology, internal medicine) in August 2008 and two wards (pediatric emergency service, otorhinolaryngology) in September. At beginning meeting is organised with staff to explain this work. It followed by continuous cooperation with pharmacy.

In October 2008 a questionnaire was developed to know the impact of this pharmacy intervention. It was appreciated by all wards but there are differences between them. Intensive care and pediatric emergency unit use crushers but fewer list and guides. Neurology use list but fewer guides and crushers. Otorhinolaryngology and internal medicine use crushers and list but fewer guides.

**CONCLUSIONS:** Pharmacy has promoted the correct administration in five services (66 beds) and optimised quality of patient care. This education program will be extended to geriatric and gastroenterology and then to all ward. But it will be adapted to practice of each ward.

## Education/Training

**247. Retrospective analysis of albumin utilization pre- and post-introduction of an albumin order sheet.** *Megan E. Kavanaugh, Pharm.D.Candidate, B.S., Rebecca S. Pettit, Pharm.D.Candidate, MBA, Tammy L. Burns, Pharm.D., Lee E. Morrow, M.D., Mark A. Malesker, Pharm.D.; Creighton University, Omaha, Nebraska, USA.*

**OBJECTIVES:** Albumin is utilized for a variety of indications, but has unpredictable accessibility and cost. The purpose of this study was to assess whether introduction of an evidence-based albumin order sheet resulted in: (1) decreased overall use of albumin; and (2) an increased percentage of appropriate use.

**METHODS:** A retrospective chart review was conducted on patients who received albumin nine months before and three months after implementation of an albumin order sheet at an academic medical center. Data collected included baseline demographics, indication for albumin, service ordering and use of albumin order sheet.

**RESULTS:** A total of 656 records meeting criteria were reviewed (468 pre and 188 .

**CONCLUSIONS:** Data suggests little change in utilization three months post study; however, at one year post implementation usage has decreased. The implementation of a required order form has succeeded

in reducing albumin use; however, it is unclear whether this is due to an increased awareness of appropriate indications for use of albumin or the hassle factor of using a required order form.

Presented at the ASHP Midyear Clinical Meeting, Orlando, FL, December 7–11, 2008.

**248. A global interprofessional clinical rotation in pharmacy and nursing: partnership for sustainability of care.** *Brianna Riley, 2009 Pharm.D. Candidate,<sup>1</sup> Crystal Obering, Pharm.D., M.B.A.,<sup>2</sup> Thad Wilson, AP.R.N., B.C., Ph.D.<sup>3</sup>; (1)University of Missouri Kansas City School of Pharmacy, Kansas City, Missouri, USA; (2)Kansas City VA Medical Center, Kansas City, Missouri, USA; (3)University of Missouri Kansas City School of Nursing, Kansas City, Missouri, USA*

**OBJECTIVES:** An objective of this Advanced Pharmacy Practice Experience (APPE) was to provide quality healthcare to citizens in areas of Honduras with limited access to healthcare while establishing a long term partnership with material resources to continue quality medical care in those areas served. Additionally, the experience provides a well rounded clinical pharmacy and nursing experience in diagnosing and treating common disease conditions with the ultimate goal of increasing awareness of global health issues to students in their respective schools.

**METHODS:** A group of five pharmacy and eight nursing students aided in the care provided at Clinica La Buena Fe in Honduras. Pre-trip planning included finding a means to supply the clinic with medication and keep a continual supply going to the clinic after the students had left Honduras. Teams of pharmacy and nursing students, paired with a translator, worked together to communicate, diagnose, and treat each patient with the limited resources available at the clinic.

**RESULTS:** While providing a very unique opportunity in clinical education for pharmacy and nursing students, the experience provided quality medical interventions as well as patient education to an area of underserved people in Honduras. Students were able to gain leadership experiences and develop their own programs to keep a continual supply of medications and other necessary resources to maintain the clinic's function, as well as promoting a broader understanding of global health to other students to sustain the program in the future years.

**CONCLUSIONS:** The experience provided the team with an understanding of the legalities in transporting medications across borders and a realization of the resources available for future mission trips. The experience also gave students the means to continue sponsorship of health and human services through other students in their respective schools and increase the awareness of global health issues in poverty stricken countries.

**249. Clinical pharmacy consultations provided by American and Kenyan pharmacy students during an acute care advanced pharmacy practice experience in western Kenya.** *Sarah E. Lyons, Pharm.D. Candidate,<sup>1</sup> Evelyne Kamau, B.Pharm. Candidate,<sup>2</sup> Shauna Santare, Pharm.D. Candidate,<sup>1</sup> Sonak D. Pastakia, Pharm.D., M.P.H.,<sup>3</sup> Ellen M. Schellhase, Pharm.D.,<sup>3</sup> William R. Vincent III, Pharm.D.<sup>4</sup>; (1)Purdue University, West Lafayette, Indiana, USA; (2)University of Nairobi, Eldoret, Kenya; (3)Purdue University School of Pharmacy, West Lafayette, Indiana, USA; (4)Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University, Brooklyn, New York, USA.*

**OBJECTIVES:** Although there have been considerable advancements in the provision of clinical pharmacy services in the U.S., clinical pharmacy services have not been widely implemented in resource-constrained areas. Similarly, the role of students assisting in the provision of clinical pharmacy services in resource-constrained settings has not been well characterized. Documentation of pharmacy consultations can be used to identify areas that need improvement to increase the overall quality of health care. This investigation was conducted to characterize the provision of clinical pharmacy consultations by American and Kenyan pharmacy students in a unique practice setting.

**METHODS:** Retrospective analysis of consultations provided by pharmacy students from the Purdue University School of Pharmacy and Pharmaceutical Sciences and University of Nairobi School of Pharmacy. Students participated in interdisciplinary patient care rounds on the adult internal medicine wards at Moi University Teaching and Referral Hospital. Beginning in August 2008, either during or following daily

patient care rounds, students self reported physician accepted interventions using a documentation tool modeled after Clini-Doc (Gold Standard; Tampa, FL). Documentation included the provision of medical information, drug therapy review, and proper dosing and administration. Students also noted specific drug classes included in consultations and the amount of time spent on consultations. The study will continue for a six month period and will include consultations provided by 24 students.

**RESULTS and CONCLUSIONS:** During the first month, 4 American and 4 Kenyan pharmacy students reported over 100 hours of consultations. Medication administration record reconciliation (43%), chart review (24%), and physician education (7%) were the most common areas of consultation. Data collection will continue until March 2009 and the results will be used to advocate for further institutional support of acute care pharmacy services. Final results and analysis to be presented.

**250. Could physician education of pharmacokinetic principals improve gentamicin levels in neonates?** *Katherine C. Han, Pharm.D. Candidate,<sup>1</sup> Gladys El-Chaar, Pharm.D.,<sup>2</sup> Susana Castro-Alcaraz, M.D.,<sup>3</sup>; (1)St. John's University College of Pharmacy and Allied Health Professions, Brooklyn, New York, USA; (2)St. John's University College of Pharmacy and Allied Health Professions, Queens, New York, USA; (3)Schneider Children's Hospital, New Hyde Park, New York, USA*

**OBJECTIVES:** Basic principals of therapeutic drug monitoring (TDM) should be integrated into the training of physicians, pharmacists and nurses in order to improve patient care. TDM in neonates is especially important because of significant physiological differences and maturational changes. Neonatal pharmacists assist in TDM; however, if not available, the house staff may or may not apply patient-specific pharmacokinetic calculations to change dosages when needed. In our neonatal intensive care unit (NICU), gentamicin serum trough levels were elevated 51% of the time. A change in sampling guidelines was implemented in June 2006, as well as education of NICU attending physicians and fellows of pharmacokinetic principals via didactic teaching workshops and supplemental one-on-one demonstrations.

**METHODS:** A list of 60 neonates who were prescribed gentamicin in the NICU will be obtained, prior to and following pharmacokinetic education and application. Patients without documented gentamicin dosage and levels will be excluded. Patient medical records will be reviewed to document patient demographics, gentamicin dosages and serum concentrations, any dosage changes, adverse effects related to gentamicin and patient outcomes. Evidence of learning and calculations of pharmacokinetic by the housestaff will entail comparison of the physician- vs. pharmacist-derived pharmacokinetic parameters and dosage changes. Only one pharmacist (author) educated the medical team. An anonymous survey will be distributed to the neonatal staff, including physicians, nurses, and pharmacists to identify barriers to this implementation. Statistical testing will include the student's T test for continuous data, and the Fisher's Exact test for outcomes data.

**RESULTS:** Pending.

**CONCLUSIONS:** Pending.

**251. Cadaver anatomy - clinical correlations for pharmacy students.** *Mary Liddelow, BS, MS, David A Apgar, Pharm.D.; University of Arizona, Tucson, Arizona, USA.*

**OBJECTIVES:** To evaluate a pilot cadaver anatomy course in which therapeutics, pharmacology and clinical medicine are related to human body dissections. This class is a unique interdisciplinary team based teaching effort that includes the Colleges of Medicine and Pharmacy.

**METHODS:** Four self-selected second year pharmacy students who had already completed basic courses in anatomy and physiology meet for 5 hours a week. Three objectives will be evaluated regarding their participation in the course: (1) Specific correlations between the human body and disease states commonly encountered by the practicing pharmacist. (2) The effectiveness of cadaver and team based interdisciplinary learning as related to clinical pharmacy. (3) Perceived prior learning to the cadaver and team based approach.

**RESULTS:** All students will complete a retrospective pre-test/post-test questionnaire, provide reflections, and participate in a focus group on completion of the course. An example of clinical learning was our

resection of the large colon after finding ship between medicine and pharmacy using anatomy has been integral to our course. Initial reflections provided positive feedback for the course, for example: "It is my opinion that health science students should know 'how really are/look/feel' in order to make them better professionals and to ultimately aid in decision making that help others get better or live a healthier life."

**CONCLUSIONS:** We are confident that future inclusion of this course as an elective can aid students' interpretation and treatment of disease states, particularly chronic states such as cerebrovascular disease, diabetes mellitus, chronic obstructive pulmonary disease and coronary artery disease. All data will be collected and analyzed prior to the conference.

**252. Advanced practice pharmacy experiences (APPE) students' impact and contribution in a medication therapy management (MTM) program in an independent-community pharmacy.** *Kristin E. Vaughan, Pharm.D. Candidate, Tracy Tran, Pharm.D. Candidate, Armin Hariri, Pharm.D. Candidate, Anh-Vuong Ly, Pharm.D.; Loma Linda University, Loma Linda, California, USA.*

**INTRODUCTION:** Accreditation standards emphasize that professional pharmacy programs should promote student's knowledge, skills, abilities, attitudes, and values necessary to the provision of pharmaceutical care for the general practice of pharmacy in any institutional settings. Upon student's professional fourth year, APPE students should have the knowledge, skills and training to implement and manage MTM services at community pharmacies. Participating students will assure an understanding of pharmaceutical care and become proficient in MTM procedures, which they will be able to utilize in their future careers.

**OBJECTIVES:** (1) Describe students' roles in the implementation and management of the MTM program; (2) Determine students' long-term assessment in clinical skills in current practice after completion of MTM Community Pharmacy APPE rotation.

**METHODS:** Describe the implementation (approximately 1 year) and all aspects of clinical services provided through the student-managed MTM program at an independent community pharmacy. The clinical services provided include: (1) comprehensive medication review (CMR); (2) prescriber consultation; (3) patient consultation; (4) patient education and monitoring; (5) patient compliance consultations. A student survey will be given to each post-graduated students who completed the APPE Community Pharmacy MTM site. The survey will incorporate the magnitude (25%, 50%, 75%, 100%) and types of clinical services utilized in current pharmacy position (s).

**RESULTS:** Students' roles in the MTM implementation and management will be summarized. The magnitude and types of clinical services currently utilized in past APPE students will be measured.

**CONCLUSIONS:** Students will be able to expand future community pharmacy innovations and improve patient outcomes and reduce healthcare expenditures.

**253. Improving patient perception about medication adherence.** *Shannon B. Rosier, Pharm.D. Candidate,<sup>1</sup> Theresa S. Tilden, Pharm.D. Candidate,<sup>1</sup> Leslie A. Sengel, Pharm.D.,<sup>2</sup> Kimberly R. Schnacky, Pharm.D.<sup>2</sup>; (1)University of Florida College of Pharmacy, Gainesville, Florida, USA; (2)Orlando VA Medical Center, Orlando, Florida, USA.*

**OBJECTIVES:** Research demonstrates that non-adherence to chronic medications is associated with negative health outcomes, including hospitalization, adverse drug events, and death. This poster focuses on development of strategies to increase patient perception and adherence to medications, based on outcomes of a related patient survey.

**METHODS:** An 11-item questionnaire focusing on the importance of medication adherence, including self-reported level of adherence, perception of knowledge about medications and source of medication information, was administered by pharmacy students at a VA outpatient clinic. Evaluation of survey outcomes allowed pharmacy services to strategize methods for improving concerning areas.

**RESULTS:** Evaluation of 106 completed surveys revealed several opportunities for pharmacists to target to improve adherence. 1 in 10 patients surveyed selected "it is ok to miss doses sometimes" (such as once a week), while 1 in 20 chose "it is ok to miss often" (as much as 2

or 3 times a week). Over half miss medications because they “just forget,” 6% miss because they don't like the side effects, and 4% miss because they don't like taking a lot of pills. 81% have some method to help them remember to take their medication. Among those, the majority listed using a pillbox, keeping their medication out in their line of vision, or at the reminder of their spouse. Survey results for this VA population will be compared to those in the published medical literature. Limitations and confounders of the results will be discussed. Several strategies implemented by pharmacy services will be presented, including publication of the survey results in “RX Updates: Patient Edition Newsletter,” changes to counseling methods, and strategies to remind patients to take their medications.

**CONCLUSIONS:** Pharmacists have a great opportunity to enhance VA patient perception and adherence to medications, particularly regarding the importance of taking each dose and reducing unintentional non-adherence.

## Endocrinology

**254. Safety and efficacy of sitagliptin added to insulin in Type 2 Diabetes.** *Benjamin Dropkin, Pre-Med,<sup>1</sup> Andrea N. Traina, Pharm.D.,<sup>2</sup> Michael P. Kane, Pharm.D.,<sup>2</sup> Robert S. Busch, M.D.,<sup>3</sup> Gary Bakst, M.D.,<sup>3</sup> Jill M. Abelseth, M.D.,<sup>3</sup> Robert A. Hamilton, Pharm.D.<sup>2</sup>; (1)Hamilton College, Clinton, New York, USA; (2)Albany College of Pharmacy and Health Sciences, Albany, New York, USA; (3)The Endocrine Group, LLP, Albany, New York, USA.*

**OBJECTIVES:** To evaluate the off-label safety and efficacy of sitagliptin in type 2 diabetes patients already receiving insulin therapy.

**METHODS:** This retrospective study was approved by the Albany College of Pharmacy Institutional Review Board. Review of electronic medical records (EMRs) of three private-practice endocrinologists was conducted using the search terms sitagliptin OR Januvia. Study population included diabetes patients receiving insulin in whom sitagliptin was initiated at least 12 months previously. Safety was evaluated by review of documented reports of side effects and drug discontinuations. Efficacy was evaluated by comparing baseline HBA1C and weight with data after a minimum one year of sitagliptin-insulin therapy. Paired *t*-tests were performed to compare baseline and follow-up data. Data are reported as mean (SD).

**RESULTS:** EMR review identified 136 patients who met inclusion criteria. Thirty patients discontinued therapy prior to one year because of lack of efficacy (25), cost (2), side effect (2) or undocumented reason (1); 15 patients had not returned for one-year follow-up visits; 91 patients received combination therapy for at least one year. Demographics of the 91 completers included: age 65 years ( $\pm 12$ ), 64.8% male, BMI 33.5 ( $\pm 10.6$ ), diabetes duration 13 years ( $\pm 7$ ), baseline HBA1C 8.05% ( $\pm 1.73$ ). Sitagliptin added to insulin resulted in a significant HBA1C reduction of 0.35% ( $p=0.019$ ) despite a significant reduction of meglitinide use ( $p<0.002$ ). Sulfonylurea use, pre-meal insulin use, total daily insulin dose, or number of daily insulin injections did not change significantly. An HBA1C of  $<7\%$  was attained by 36.3% of patients compared to 24.2% at baseline ( $p=0.076$ ). Sitagliptin use was associated with a nonsignificant 1.7 pound weight loss ( $p=0.479$ ). Hypoglycemic episodes were reported by three patients (no severe hypoglycemia was reported).

**CONCLUSIONS:** Sitagliptin added to insulin was associated with statistically significant HBA1C lowering and was overall well tolerated.

## Geriatrics

**255. Assessment of inappropriate medication use and dosage in elderly patients.** *Yurhee Hong, M.S. Candidate, Sukhyang Lee, Pharm.D.;* Sookmyung University, Graduate School of Clinical Pharmacy, Seoul, South Korea.

**OBJECTIVES:** To evaluate the patterns of inappropriate medication use and to assess inappropriate dosage use in elderly patients in Korea.

**METHODS:** A retrospective study was performed for 65 years or older who admitted from January 2007 to December 2007 in a medical center, Seoul, Korea. Potentially inappropriate medication (PIM) use in the elderly was evaluated using Beers criteria. Eighteen drugs out of Beers criteria were included in the formulary of the institute. Inappropriate dosage was set using Beers criteria, CMS (the Centers for Medicare and

Medicaid Services) guideline, Geriatric Dosage Handbook (Lexi-Comp). **RESULTS:** The patients with PIM were 2,172 during the study period. The commonly used inappropriate medications were Nervous system ( $n=1237$ , 44.78%), Alimentary System ( $n=663$ , 24.54%) and Cardiovascular system ( $n=494$ , 18.28%). Among the elderly, the prevalence of inappropriate dosage was 10%. The commonly inappropriate dosage drug was digoxin ( $n=75$ , 27.27%), diazepam ( $n=70$ , 22.55%) and ferrous sulfate ( $n=66$ , 24.00%). Logistic regression analysis showed the number of PIM, days of hospital treatment as predictors related to inappropriate dosage use.

**CONCLUSIONS:** CNS drug was frequently prescribed as PIM. Older patients are particularly vulnerable to drug-related illness. It is needed to develop a device of decreasing adverse drug events in elderly.

**256. Assessment of adverse drug events related to potentially inappropriate medications in elderly patients.** *SunYoung Kim, M.S. Candidate, Sukhyang Lee, Pharm.D.;* Sookmyung University, Graduate School of Clinical Pharmacy, Seoul, South Korea.

**OBJECTIVES:** The goal of this study was to determine the prevalence of potentially inappropriate medication (PIM) use, analyze the adverse drug events (ADEs) caused by inappropriate drug use and evaluate if inappropriate medication prescribing is associated with the occurrence of ADEs in older hospitalized adults.

**METHODS:** We performed a retrospective study for patients aged 65 years or older admitted to a hospital for 1 month, January 2008 by collecting data on general demographics and the prescribed drug from the order communication system. Data were collected for all the medications during and prior to admission. PIMs were identified on the basis of the 2003 Beers criteria (BC). We reviewed the medical chart of patients BC medications prescribed to identify adverse drug events.

**RESULTS:** Total 317 patients were assessed during the study period. Patients with PIM were 43.6% during hospitalization. ADEs presented in 19.5% of patients with PIM. Patients with medications prior to admission were taking PIM in 22.3% and ADEs presented in 28.6% of them. The principal risk factor of PIM was the number of medications. The most common PIM was diazepam (45, 19.2%) as long-acting benzodiazepines, followed by hydroxyzine (41, 17.5%), bisacodyl (25, 10.7%), flurazepam (22, 9.4%) and piroxicam (22, 9.4%). The drugs with high proportions of adverse drug events during hospitalization were piroxicam (7/18), amiodarone (3/8), digoxin (2/3). The ADEs with PIM prior to admission occurred more due to nifedipine (1/1), amitriptyline (4/8), hydroxyzine (2/5). The most common ADE was dizziness, followed by falls, abdominal pain, diarrhea, and nausea/vomiting.

**CONCLUSIONS:** The PIM was taken considerably in the elderly patients. ADEs were related to PIM. The clinically significant ADEs were falls and dizziness. The drugs causing falls and fractures such as benzodiazepines should be used carefully.

**257. Vascular risk factors and Alzheimer's disease: the role of medications.** *Stephanie M. Seaton, Pharm.D. Candidate,<sup>1</sup> Catherine M. Roe, B.A., M.S., Ph.D.,<sup>2</sup> John C. Morris, M.D.,<sup>2</sup> Monique M. Williams, M.D.,<sup>2</sup>;* (1)St. Louis College of Pharmacy, St. Louis, Missouri, USA; (2)School of Medicine, Washington University in St. Louis, St. Louis, Missouri, USA.

**OBJECTIVES:** Vascular risk factors (hypertension, diabetes, obesity, atherosclerosis, and hyperlipidemia) may also be Alzheimer's disease (AD) risk factors. The goal of this study was to determine whether the use of medications to treat vascular risk factors was associated with prevalent AD.

**METHODS:** In this secondary analysis of a longitudinal prospective study, we evaluated 1650 community-dwelling older adults aged 65 years and older with no dementia (Clinical Dementia Rating [CDR] 0,  $n=538$ ) and very mild (CDR 0.5,  $n=652$ ), or mild dementia (CDR 1.0,  $n=654$ ) at the baseline clinical assessment at the Washington University Alzheimer's Disease Research Center. Medication histories and other demographic data were also obtained at the initial visit.  $\chi^2$  and logistic regression analyses were used to test whether baseline use of medications for vascular risk factors was associated with risk of prevalent AD.

**RESULTS:** Baseline demographics for the sample were: mean age of 78.3

$\pm 7.6$  years, 38.2% male, 13.9% African American, mean duration of education of  $13.5 \pm 3.5$  years, and a mean systolic blood pressure  $141.2 \pm 20.3$  mmHg. The majority of participants (69%) used at least one medication for vascular risk factors at baseline, and 45.3% of the participants had at least one apolipoprotein 4 allele (Apo E4). Participants who had vascular risk factors and used medications to treat vascular risk factors had a significantly lower prevalence of AD ( $p=0.008$ ; OR 0.74, 95% CI 0.57–0.97).

**CONCLUSIONS:** For older adults with vascular risk factors, the use of medications to treat those vascular risk factors is associated with decreased risk of prevalent AD. These findings warrant further investigation to determine whether a causal relationship exists.

## Health Services Research

**258. Impact of the medical home on the safety and quality of health care in Canada.** *Andrea C. Scobie, MHSA,<sup>1</sup> Neil J. MacKinnon, Ph.D., FCSHP,<sup>1</sup> Sean D. Higgins, B.Sc.,<sup>1</sup> Holly Etchegary, Ph.D.,<sup>2</sup> Rhonda Church, M.D.<sup>3</sup>; (1)Dalhousie University, Halifax, Nova Scotia Canada; (2)IWK Health Centre, Halifax, Nova Scotia Canada; (3)Gateway Family Practice, Bridgewater, Nova Scotia Canada.*

**OBJECTIVES:** To examine the relation between medical homes and the safety and quality of health care in Canada.

**METHODS:** As part of a seven-country health policy survey, the Commonwealth Fund surveyed a sample of 3003 people 18 years and older in Canada's 10 provinces and 3 territories between 6 March and 7 May 2007. We examined the Canadian data with a particular focus on the presence of a medical home. We explored the effect of having a medical home on a number of outcome variables using  $\chi^2$  tests for categorical variables and Mann–Whitney  $U$  tests for ordinal variables.

**RESULTS:** Of Canadians surveyed, 51% did not have a medical home. Based on the 2006 census, this extrapolates to nearly 13 million adult Canadians. Overall, the presence of a medical home was associated with self-reported improved access to health care services, coordination of the services received, confidence in the services received and provider knowledge. Self-reported medical and medication error rates were higher among those without a medical home. However, emergency department use patterns were similar among those with and without a medical home.

**CONCLUSIONS:** The presence of a medical home is associated with perceived safer and higher-quality patient care. Ensuring that Canadians have a medical home through primary health care reform may be an effective means to mitigate medical and medication errors while increasing patient satisfaction and strengthening patient–provider relationships.

**259. Health service challenges in chronic illness management: the views of Australian pharmacists.** *Elin C. Lehnborn, B.Sc.Pharm., M.Pharm.Sc., M.Clin.Pharm., Jo-anne E. Brien, BPharm, B.S.(Pharm), Pharm.D.; Faculty of Pharmacy, Sydney, Australia.*

**OBJECTIVES:** The Serious and Continuing Illness Policy and Practice Study (SCIPPS) is a large Australian funded multidisciplinary, multisite study examining health services and management of chronic heart failure, chronic obstructive pulmonary disease and diabetes from patients', carers', and health professionals' perspectives. The aim of the study reported here was to explore pharmacists' perspectives of enablers and barriers to providing care for people with chronic illness.

**METHODS:** Data were collected through interviews with community and hospital pharmacists working in western Sydney. Interviews were audio recorded, transcribed, and analysed for emerging themes.

**RESULTS:** The analysis identified lack of continuity of care, lack of communication between different health professionals and with patients, and lack of teamwork as perceived barriers to providing optimal care. Pharmacists were also concerned about high medication costs and the effect on adherence. Community pharmacists raised business-related aspects, specifically the lack of reimbursement for some pharmacy services. Suggested solutions included multidisciplinary practice, more liaison pharmacists, remuneration for counselling, better communication and systems for sharing patient information among all health professionals involved. Interviews with other health professionals have revealed similar themes: lack of coordinated care, adherence challenges, and a need to change behaviours and attitudes of health

professionals to improve the dysfunctional health care system.

**CONCLUSIONS:** Health care systems are designed differently around the world and this study provides insight to the perspectives of pharmacists, along with other health professionals and patients, regarding future implementation of health services and policy in Australia. It can also be used by pharmacists in other countries to compare and reflect on their local policy and practice. This project provides a model for pharmacist involvement in research in health policy development.

**260. Cost-shifting and timeliness of drug formulary decisions in Atlantic Canada.** *Andrea C. Scobie, MHSA, Neil J. MacKinnon, Ph.D., FCSHP; Dalhousie University, Halifax, Nova Scotia, Canada.*

**OBJECTIVES:** Our objectives were to investigate the timeliness of adoption of Common Drug Review (CDR) recommendations by Atlantic Canadian provincial public drug plans and to determine the degree of public-private cost-shifting in Atlantic Canada with the largest benefits carrier in the region.

**METHODS:** Information from Atlantic provincial drug plan formularies and utilization analyses from an Atlantic Canada-based private drug benefits carrier were used.

**RESULTS:** The average time period between the issuance of a Notice of Compliance (NOC) and the addition of a drug to an Atlantic provincial drug formulary was 86.8 weeks. The CDR review process itself has increased from 20.6 to 26.8 weeks over the past three years. Financial impacts on private benefits carriers were minimal.

**CONCLUSIONS:** Our results indicate that the CDR has not increased the timeliness of drug review in nor has it reduced variation in provincial drug formulary listings. To become a truly efficient process, the CDR must ensure the support of all provinces and truly advocate for the timely submission of drugs and uptake of recommendations.

## Herbal/Complementary Medicine

**261. Evaluation of Antidiabetic activity of Momordica cymbalaria in streptozotocin induced diabetic rats.** *Henis J. Patel Jr., B.Pharm., Kamal Modh, B.Pharm., M.Pharm., I.S. Anand, B.Sci.(medicine), M.Pharm., Ph.D, C.N. Patel, B.Pharm., M.Pharm., Ph.D.; Shri Sarvajani Pharmacy College, Mehsana, Mehsana, India.*

*Momordica cymbalaria* Fenzl (Cucurbitaceae) widely distributed in the western parts of India and used ethnically by tribal people of India for controlling blood sugar. This prompted us to undertake a study to examine the possible antidiabetic activity of aqueous extract of the roots by glucose tolerance test in normal and streptozotocin induced diabetes in Wistar albino female rats. Oral glucose tolerance test was performed in normal rats after receiving glucose orally (10 g/kg). Diabetes mellitus was induced with streptozotocin (65 mg/kg, i.p.) and graded doses of the aqueous root extracts were then administered orally to experimental diabetic rats for 30 days. Fasting serum glucose levels, serum lipid profiles, liver glycogen, peripheral glucose uptake, changes in body weight and liver weight were evaluated. Oral glucose tolerance test clearly indicate that aqueous extract (250 mg/kg, p.o.) and (500 mg/kg, p.o.) improves the glucose tolerance by 54.3% and 113.8 % and glibenclamide does so by 224.39% at 30 min. In diabetic rats, treatments with aqueous extract (250 mg/kg, p.o.) and (500 mg/kg, p.o.) resulted in a significant reduction in serum glucose, serum cholesterol and serum triglycerides and significant elevation in serum HDL cholesterol, liver glycogen and body weight but no significant change in liver weight and in-vitro glucose uptake comparable with that of glibenclamide (500  $\mu$ g/kg, p.o.). The results of our study clearly show that aqueous extract of roots of *Momordica cymbalaria* Fenzl exhibits a potent antidiabetic activity in streptozotocin induced diabetic rats.

**262. Assessment of complementary and alternative medicine utilization in cancer patients at Moores UCSD Cancer Center.** *Rebecca Lau, B.S., Trang Tran, Pharm.D., Beatriz Batarse, Pharm.D., Felicity Shen, Pharm.D., James Gonzales, Pharm.D., Susan Wilson, Pharm.D., Linda Barnachea, Pharm.D., BCOP, Eunice Tang, Pharm.D., BCOP, Meghana Trivedi, Pharm.D., Ph.D.; Moores UCSD Cancer Center, La Jolla, California, USA.*

**OBJECTIVES:** The use of complementary and alternative medicines

(CAM) has increased significantly, especially among cancer patients, in the last decade. Because CAM utilization is not assessed when obtaining medication history, healthcare professionals are often unable to provide effective patient care. The primary objective of this study is to assess the current use of CAM in patients with cancer at Moores UCSD Cancer Center. The secondary objectives are to compare the characteristics of patients that chose to use CAM with those who do not, evaluate the usage patterns and reasons for using CAM, examine processes used by patients to gather information about CAM, and develop a database of drug interaction studies for frequently utilized CAM.

**METHODS:** This study is a prospective survey-based analysis of utilization of CAM in patients at Moores UCSD Cancer Center. The goal is to enroll patients until at least 200 evaluable surveys are collected. Patients who are at least 18 years of age, receiving active cancer treatment at Moores UCSD Cancer Center, able to speak and understand English, and able to read, understand and sign the informed consent are included in the study. We are obtaining accurate medication histories including the dose, duration and frequency for each medication, including CAM. In addition, demographic information is being assessed to help describe the patient population more likely to be using these products. Other information being evaluated include CAM-specific questions such as type of CAM used, reasons for using CAM, source of information, and whether patients have informed any healthcare professional of their CAM use.

**RESULTS:** To date (12/11/08), we have enrolled 149 patients in the study. The estimated time for completion of enrollment and data analysis is March 2009.

**CONCLUSIONS:** Complete study results will be presented at the 2009 ACCP Spring Practice and Research Forum.

## Infectious Diseases

**263. Evaluation of the use of three antifungal agents for the treatment of fungal infections at a community hospital.** Whitney K. Deal, Pharm.D., *Candidate*,<sup>1</sup> Vanthida Huang, Pharm.D., BSPHM,<sup>2</sup> NaaDede Badger, Pharm.D., BCPS,<sup>3</sup> Todd Parker, Pharm.D.<sup>3</sup>; (1)Mercer University, Atlanta, Georgia, USA; (2)Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia, USA; (3)Piedmont Hospital, Atlanta, Georgia, USA

**OBJECTIVES:** Fungal infections continue to be associated with high morbidity and mortality rates despite the availability of a myriad of antifungal agents. Conflicting evidence and adverse events associated with antifungal agents may influence the choice used in the management of fungal infections. Our objective was to evaluate the safety and efficacy of three antifungal agents used at a community hospital.

**METHODS:** This is a single-center prospective descriptive investigation of patients receiving fluconazole, amphotericin B (liposomal and traditional), or micafungin between September and December 2008. Patients were identified by a daily computer-generated census of patients receiving one of the three target agents. Charts were reviewed to collect pertinent data. The primary outcome was to determine efficacy of each agent with success defined as microbiological success and/or clinical improvement. Secondary outcomes include adverse events, site of infections, risk factors, and microbiological isolation. Statistical analysis employed Pearson's  $\chi^2$  test and multiple regression with significance defined as a p-value <0.05.

**RESULTS:** 107 patients were identified. There was no difference between agents in regards to the primary outcome of microbiological success and/or clinical improvement. Patients are more likely to experience adverse events with amphotericin B (p<0.05). Patients with diabetes were more likely to be on fluconazole. Patients with HIV/AIDS were more likely to be on amphotericin B (p<0.05). Of the 107 patients identified, 75 had positive cultures identified in urine (44%), lungs (27%), blood (13%), CSF (5.0%), abdomen (6.7%) and eye (2.6%). The most commonly isolated fungal species was *Candida albicans* (46%).

**CONCLUSIONS:** Fluconazole and micafungin are safe and effective in the treatment of fungal infections. Risks versus benefits should be examined before a patient is selected for amphotericin B because of adverse effects. Current literature suggests that *Candida albicans* is the most common species isolated in fungal infections and this was observed in the study.

**264. Risk factors associated with metronidazole failure in treating patients with *Clostridium difficile*-associated disease in a community hospital.** Nadeje Aurubin, Pharm.D. *Candidate*,<sup>1</sup> Vanthida Huang, Pharm.D., BSPHM,<sup>2</sup> NaaDede Badger, Pharm.D., BCPS,<sup>3</sup> Todd Parker, Pharm.D.<sup>3</sup>; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia, USA; (2)Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia, USA; (3)Piedmont Hospital, Atlanta, Georgia, USA

**OBJECTIVES:** The emergence of the hypervirulent NAP1/B1/027 strain has played a significant role in the ever increasing incidence and virulence of *Clostridium difficile* associated disease (CDAD). This atypical strain has been associated with failure of metronidazole as first line therapy. The objective of this study is to survey risk factors associated with treatment failure in managing CDAD in patients treated with metronidazole.

**METHODS:** A medical record review of hospitalized patients from June 2007 to November 2008 was conducted to identify patients with risk factors which predispose to metronidazole failure for the treatment of CDAD. Risk factors included recent antibiotic exposure, hypoalbuminemia, community-associated CDAD and proton pump inhibitors. The secondary outcome was to evaluate disease severity and to compare failure rates to that found in the U.S. Logistic regression was used to compare the outcomes related to the specific risk factors. A p value of <0.05 was considered significant.

**RESULTS:** Of the 100 patients included in the study, 73% responded to metronidazole as initial therapy with 27% failing initial treatment. Risk factors identified were prior antibiotic exposure (p=0.53), hypoalbuminemia (p=0.09), community-associated CDAD (p=0.12); and proton pump inhibitors (p=0.66) were not significantly associated with negative treatment outcomes. Disease severity was found to be associated with treatment failure (p=0.04). Nationally, metronidazole failure rates reported to be 18.2% in October 2008 compared to the 27% of non-responders found in the study.

**CONCLUSIONS:** Pre-existing data reports factors significantly associated with metronidazole failure. Despite the data outcome in this particular study which may not accurately reflect such a correlation, identifying risk factors to treatment failure may potentially improve the likelihood of treatment success and preclude the need for second line therapy. Further research is warranted to investigate whether correcting or modifying specific risk factors provides supporting data.

**265. Policies for the use of antibiotics in 54 Western French hospitals in 2007.** Florence Ollivier, Pharm.D., Ph.D. *Student*,<sup>1</sup> Nathalie Asseray, M.D., Ph.D.,<sup>1</sup> Sonia Thibaut, Ph.D.,<sup>2</sup> Gilles Potel, M.D., Ph.D.,<sup>1</sup> Françoise Ballereau, Pharm.D., Ph.D.<sup>1</sup>; (1)UPRES EA 3826 Faculté de Médecine, Nantes, France; (2)MedQual CHU de Nantes, Nantes, France.

**OBJECTIVES:** In 2007 the French Health Ministry renewed the "Plan to preserve the effectiveness of antibiotics". The increasing antimicrobial resistance in bacteria is a major problem and requires the implementation of rigorous policies to optimize the use of antibiotics.

**METHODS:** In 2007, the author, Ph.D. student of the MedQual Center: "a Network for the good use of antibiotics in the Pays de la Loire" conducted a study in 54 Western French hospitals, using a questionnaire to assess the implementation of policies for an appropriate use of antibiotics, according to the national guidelines issued by the French government in 2002.

**RESULTS:** In the public and private hospitals, the most frequent actions quoted by the 49 respondents (91% of participation) were: issuing of a list of available antibiotics (98%); issuing of information regarding the antibiotic's consumption (86%); expressed in DDD/1000 bed-days in 60% of hospitals; the bacterial resistance (81%); and control of antibiotics dispensation (60%). Local guidelines were available in 69% of hospitals for curative treatment and in 92% for surgery. antibioprophyllaxis. The evaluation of the use of antibiotics was practised in 63% of hospitals. Trainings about antibiotherapy and computer links between clinical settings, pharmacy and microbiology lab were the less widespread measures. The number and type of actions were related to hospital size and activity.

**CONCLUSIONS:** These findings support that policies for an appropriate use of antimicrobials should be reinforced by issuing treatment guidelines, specific tools for measuring, auditing and improving antimicrobial use and by educating prescribers with the rational use of antibiotics.

**266. Association between fluoroquinolone use and antimicrobial resistance.** Jiyeon Seo, M.S. Candidate, Sukhyang Lee, Pharm.D., Ph.D.; Graduate School of Clinical Pharmacy, Sookmyung Women's University, Seoul, South Korea.

**OBJECTIVES:** The purpose of this study was to assess the use of fluoroquinolone and its association to the prevalence of antimicrobial resistance.

**METHODS:** The study was carried out from October 2005 through June 2008 in a tertiary care hospital, Seoul, Korea. Data were collected for fluoroquinolone use from the pharmacy data and antimicrobial resistance profile were collected from the clinical laboratory data in electronic health record. Fluoroquinolones in the hospital formulary included ciprofloxacin, levofloxacin, moxifloxacin. The investigated pathogens were ciprofloxacin-resistant, methicillin-resistant *S.aureus* (MRSA), ciprofloxacin-resistant

**RESULTS:** Use of Fluoroquinolone increased by 25.9%, ciprofloxacin by 2.8%, and levofloxacin by 78.3% during the study period. Moxifloxacin use dropped by 13.6%. The prevalence of ciprofloxacin-resistance *P. aeruginosa* increased by 12.3%, and Ciprofloxacin-resistance *E. coli* by 21.6%. The prevalence of MRSA dropped by 6.2%. The fluoroquinolone use was not significantly correlated to the prevalence of antimicrobial resistance (ciprofloxacin-resistant *P. aeruginosa*:  $p=0.13$ , Ciprofloxacin-resistant *E. coli*:  $p=0.11$ , MRSA:  $p=0.74$ ). However, the ciprofloxacin use and the prevalence of ciprofloxacin-resistant *P. aeruginosa* showed significant correlation in the year of 2006 ( $r=0.95$ ,  $p=0.05$ ). The use of fluoroquinolone and the rate of ciprofloxacin-resistant *P. aeruginosa* showed significant correlation in 2006 ( $r=0.95$ ,  $p=0.050$ ). The Levofloxacin use and the rate of Ciprofloxacin-resistant *E. coli* showed significant correlation in 2007 and 2008 ( $R=0.812$ ,  $p=0.050$ ).

**CONCLUSIONS:** Total increase of fluoroquinolone was affected primarily by the increased use of levofloxacin. The use of Ciprofloxacin showed fluctuations during the study period. The use of levofloxacin replaced the use of ciprofloxacin. The increase of fluoroquinolone use was related to the antimicrobial resistance between ciprofloxacin and *P. aeruginosa*.

**267. Setting up of tools helping in the prescription of antibiotics in hospitals in the Pays de la Loire Region: Creation of a regional thesaurus of antibiotherapy protocols.** Florence Ollivier, Pharm.D., Ph.D. Student,<sup>1</sup> Sandra Bourdon, Pharm.D.,<sup>2</sup> Nathalie Asseray, M.D., Ph.D.,<sup>3</sup> David Feldman, Pharm.D.,<sup>4</sup> Gilles Potel, M.D., Ph.D.,<sup>1</sup> Francoise Ballereau, Pharm.D., Ph.D.,<sup>1</sup>; (1)UPRES EA 3826 Faculté de Médecine, Nantes, France; (2)CHD la Roche sur Yon, La Roche sur Yon, France; (3)UPRES EA 3826 Faculté de médecine, Nantes, France; (4)CRMDM-ARH Pays de la Loire, Nantes, France.

**OBJECTIVES:** The Region has 54 public and private hospitals, 27% of which do not have antibiotherapy frames of reference. Within the framework of the Regional Plan for the Good Use of Antibiotics, the objectives of the Region's Drug Committee (CRMDM) are: the improvement of the discernment of antibiotic therapeutics and the reduction of antimicrobial resistance; the distribution to all the Region's hospitals of local antibiotherapy recommendations validated and adapted to their medical and surgical practices.

**METHODS:** The regional antibiotherapy protocols thesaurus was elaborated in two times: centralisation of the hospitals' protocols at the MedQual Center, which is the master-builder of the project validation of these local reference frames by referring infectiologists members of the Antibiotics Commission of the CRMDM for the protocols which have not been validated internally by a referring doctor specialised in antibiotherapy (according to the circular of May 2<sup>nd</sup> 2002).

**RESULTS:** In November 2008, 179 protocols were collected from 19 hospitals among which 106 curative antibiotherapy protocols and 73 medical and surgical antibioprophyllaxy protocols. Among the clinical situations treated, urinary (18%), respiratory (15%) and intra-abdominal (13%) infections were mainly encountered. The most represented surgical prophylaxies are: gynecological and obstetrical (15%), urologic (12%), and digestive (11%). 82 protocols weren't validated, due to the absence of a local referring specialist: among those 82 protocols, 40 were validated, 7 were modified by the Antibiotics Commission, 8 weren't validated due to a lack of information (absence of directions for use, length of treatment) and 27 are currently being validated.

**CONCLUSIONS:**The approach consisting in the sharing of antibiotherapy

protocols was well accepted by healthcare workers. Online access to a wide range of validated protocols will allow doctors, pharmacists and bacteriologists in hospitals to adapt the antibiotic therapeutics to their local situation and if need be, to create their own antibiotherapy recommendations in order to encourage quality prescriptions.

**268. Evaluation of vancomycin MIC increase among clinical MRSA isolates at a private hospital.** Lida M. Valentine, Pharm.D. Candidate,<sup>1</sup> Douglas A. Prince, M.M.Sc.,<sup>2</sup> Vanthida Huang, Pharm.D., BSPHM<sup>1</sup>; (1)Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia, USA; (2)Piedmont Hospital, Atlanta, Georgia, USA

**OBJECTIVES:** Methicillin-resistant *Staphylococcus aureus* (MRSA) has been increasing at an alarming rate in both the community and hospital. Vancomycin is the treatment of choice; however, treatment failures have been reported due to increases in vancomycin minimum inhibitory concentrations (MIC). Piedmont Hospital (Atlanta, GA) is a 500-bed private hospital utilizing an automated susceptibility system which does not report MIC. Therefore, we sought to investigate the phenomena of vancomycin MIC increase utilized Etest and microbroth dilution method against clinical MRSA isolates.

**METHODS:** Three hundred twenty-four clinical isolates of MRSA from respiratory and blood were obtained between March 2007 to November 2008. MICs were determined using Etest and microbroth dilution methods with starting inoculum of 0.5 McFarland per Clinical and Laboratory Standards Institute (CLSI) guidelines. Vancomycin analytical powder (Sigma, St. Louis, MO) and vancomycin Etest strips (AB Biodisk North America, Piscataway, NJ) were utilized. ATCC 29213 was utilized as a control strain.

**RESULTS:** The average MICs for Etest and microbroth dilution were 1.12 and 0.81 µg/ml, respectively. The average Etest MICs for blood and respiratory isolates were 1.11 and 1.13 µg/ml, respectively. MIC<sub>50</sub> for Etest and microbroth dilution was 1.0 µg/ml. MIC<sub>90</sub> for Etest and microbroth dilution was 1.5 and 1.0 µg/ml, respectively. Thirty-two out of 324 isolates (9.9%) had MIC of ≥2.0 µg/ml using Etest method.

**CONCLUSIONS:** The alarming increase of MRSA in both community and hospital reported nationally has intensified the concern of potential vancomycin failure. This study demonstrated an increased trend of vancomycin MIC among MRSA isolates via Etest methods reinforcing data that show MRSA is becoming less susceptible to vancomycin. Reduced susceptibility may result in subtherapeutic response and treatment failure. This highlights the importance of performing MIC detection for MRSA isolates. Further investigation of increased vancomycin MIC among MRSA isolates is warranted.

## Managed Care

**269. Impact of levofloxacin prophylaxis utilization among neutropenic patients with haematologic malignancies.** Sophie Perriat, Resident, Emilie Talagrand, Resident, Jean Côme Meniane, Hematologist, Patrice Ceballos, Hematologist, Nathalie Fegueux, Hematologist; CHU Lapeyronie, Montpellier, France.

**OBJECTIVES:** Fluoroquinolone prophylaxis during neutropenia in patients with cancer has been associated with decreased incidence of gram-negative bacteremia and decreased incidence of mortality (ECIL 2). We have evaluated the impact of levofloxacin (LVF) antibioprophyllaxis (ABP) on the incidence of neutropenic febrile episodes and bacteremia among patients admitted to the bone marrow transplantation unit of Montpellier hospital.

**METHODS:** We realized a retrospective analysis of the incidence of fever, developed infections, and involving germs among neutropenic patients (allogenic stem cells transplantation (ASCT) and acute leukemia induction (IND)) before (LVF -) and after (LVF +) systematic instauration of levofloxacin antibioprophyllaxis when patient were admitted in the unit.

**RESULTS:** 41 patients have been included in this study: 20 patients with levofloxacin prophylaxis (LVF +) and 21 without levofloxacin antibioprophyllaxis (LVF -). 49 hospitalizations have been evaluated. In LVF - group, 3 patients presented lymphoma and 17 were treated by chemotherapy induction (IND) for acute leukemia while in LVF +, they were respectively 6 patients with lymphoma and 15 with acute leukemia.

	LVF- (n= 27)	LVF + (n=22)	p
Incidence of febrile episodes. in ASCT patients.			
Mean	3.8	2.3	
Median	3	2	0.0017
Incidence of febrile episodes. in IND patients.			
Mean	2.1	1.4	
Median	2	2	NS
Duration without fever in. ASCT patients (days)	5.2 (0–16)	13.8. (4–34)	0.01
Duration without fever in. IND patients (days)	4.3 (0–14)	7.7. (0–15)	NS

**CONCLUSIONS:** We have observed a reduction of febrile episode in ASCT patients who received levofloxacin prophylaxis ( $p=0.0017$ ). In this same population, febrile episode occurrence was evaluated about 5.2 days in LVF- patients and about 13.8 days in LVF + ( $p=0.01$ ). No significant difference in IND patients about these evaluation criteria. Moreover, levofloxacin prophylaxis seems to lead no resistant bacteria emergence in our population.

## Medical Device

**270. Efficacy of wound treatment by vacuum-assisted closure.** *Christelle Boczek, Student, Nathalie Martin, Pharm.D., Christelle Labrande, Pharm.D., Albert Darque, Pharm.D., Marie-Claude Bongrand, Pharm.D.; CHU Conception AP-HM, Marseille, France.*

**OBJECTIVES:** Vacuum Assisted Closure (VAC) therapy is a technique for wound healing using the application of a negative pressure on the surface of the wound. Data on the efficacy of this technique are sparse. This prospective study focused on VAC therapy received by patients having difficulties to heal in order to compare indications, and evaluate treatment efficiency.

**METHODS:** The medical records of 50 patients receiving VAC therapy and who did not respond favourably to an earlier treatment were analysed over a 12-month period.

**RESULTS:** VAC therapy was prescribed for: traumatic wound (17.3%), adjuvant of surgery (17.3 %) including vaginoplasty (7.7%), loss of substance (11.5%), acute eschar (11.5 %), burns (7.7%), and other indications (27 %). One-third of the patients received fat dressing (27%) or surgical sear (7.7%) as an initial therapy. The length of stay in hospital ranged from 10 days (vaginoplasty) to several weeks or several months (eschar). The majority of patients healed (25%), or were eligible for further skin graft (33%), and this repair of damaged skin was considered as a success (58%) The average cost of treatment per patient with VAC therapy has been estimated between 31 € (vaginoplasty) and 2164 € (surgery adjuvant).

**CONCLUSIONS:** VAC therapy was mostly used as adjuvant of surgery or for the treatment of traumatic wound. This therapy has led to good results after a few weeks of use, avoiding more costly therapies.

## Medication Safety

**271. Quality of prescription: an ambulatory dispensation experience in a teaching hospital.** *Fanny Oger, Junior Pharmacist, Anissa Poirer, Pharmacy Technician, Melanie Richard, Pharmacy Technician, Morgane Ethgen-Bonnet, Pharmacist, Bertrand Gourdiere, Pharmacist; Department of Pharmacy, Reims University Hospital, Reims, France.*

**OBJECTIVES:** Our study evaluated the appropriateness and conformity to ambulatory drugs' prescriptions in a teaching hospital.

**METHODS:** This retrospective study included all prescription delivered for external patients over a period of 3 months (July to September 2008). The pharmaceutical team generated a standardized data collection form. Before data extraction, as a calibration exercise, four members of the team independently evaluated a separate set of 10 prescriptions. We collected data on physicians (name, quality), on patients (name, sexe, age, weight), on drugs' prescriptions (date, dosage, galenic form, interval between doses, duration of treatment, specific instructions). The quality was evaluated in terms of proportions of

prescriptions in which any of the previously items deviated from the standards. The standards were based on recommendations in current official French texts. One point was given when the item was correct. Quality of prescription was adequate for score range 13 to 15, partially adequate for score range 10 to 12 and inadequate for score <10.

**RESULTS:** During the 3 months, 875 prescriptions were evaluated. Only 17.48% of prescriptions were adequate, 79.54% and 2.97% were respectively partially and inadequate. The items not conformed were dosage (non-indicated in 51.43%), galenic form of the drugs (33.77%) and the interval between dose (1.94%). The evaluated prescriptions concerned antiretroviral drugs in 32.0% of prescriptions, antalgic drugs in 8.5%, immunomodulators in 5.9%, ATU drugs in 5.5%, antibiotics in 3.3%, antifungal drugs in 1.4%, and other treatment (i.e., vitamins, corticoids, diet) in 40.6%. Specific instructions were only reported in 119 prescriptions (13.6%).

**CONCLUSIONS:** Our intervention highlights a lack of informations (i.e., interval between doses, specific instructions) in prescriptions which could decrease patient's observance. To remedy, pharmaceutical team decided to write specific information supports for each ambulatory dispensed drugs for providing an understandable and clear information to patients.

**272. Quality of the prescription: a retrospective analysis of pharmacist clinical interventions in computerized units.** *Fanny Oger, Junior Pharmacist, Corinne The, Junior Pharmacist, Julia Dessault, Junior Pharmacist, Morgane Ethgen-Bonnet, Pharmacist, Bertrand Gourdiere, Pharmacist; Department of Pharmacy, Reims University Hospital, Reims, France.*

**OBJECTIVES:** The clinical pharmacy associated to the computerized prescription is a growing activity in French hospital. Also, these prescriptions need a daily pharmaceutical evaluation. The pharmaceutical analysis includes the evaluation, the prevention and their solutions of the main identified problems. An intervention was defined as any recommendation made with the intent of changing drug treatment. The aim of this retrospective study was to assess the pharmaceutical intervention and their ending issue to improve medication safety in medicine units of Reims University Hospital.

**METHODS:** This retrospective study was realised between January 14, 2008 and April 30, 2008 on the overall pharmaceutical interventions in 8 medicine and 2 chirurgial units. For each intervention, the following data were collected: patient identification, drug-related problems, pharmaceutical intervention and their follow up, classification ATC drugs. The interventions were assessed with a questionnaire adapted on a computer tool developed by the French Clinical Pharmacist Society.

**RESULTS:** The population of patients (898) was on average age 64 years old (16–104) and the male/female ratio was 1.03. A total of 1624 interventions were analyzed (average 1.8 interventions per patients). The most commonly drug-related problems were inappropriate administration ( $n=491$  [30%]), nonconformity to guidelines ( $n=318$  [20%]) and suprathapeutic dose ( $n=288$  [18%]). The four main interventions were optimization of administration ( $n=383$  [24%]), change of administration route ( $n=352$  [22%]), drug switch ( $n=341$  [21%]) and drug discontinuation ( $n=286$  [18%]). The problems concerned nervous system drugs ( $n=462$  [29%]), cardiovascular system ( $n=398$  [25%]), alimentary tract and metabolism ( $n=220$  [14%]), anti-infective for systemic use ( $n=170$  [10%]). The rate of physicians' acceptance was 46% (20% refusals, 35% not assessable).

**CONCLUSIONS:** These data highlights that pharmacist intervention is important and should be extended in all units of the hospital. Clinical pharmacy contributes to rationalization of drug therapy and therefore increases medication safety.

**273. Effectiveness of medication dispensing machine.** *Erin E. Thatcher, B.A., Biochemistry, Karen Farris, Ph.D., Professor, Julie Lang, M.B.A., Research Assistant; University of Iowa, Iowa City, Iowa, USA.*

**OBJECTIVES:** Unintentional non-adherence is important among older adults with decreased cognition. The MD.2 machine is a timed medication-dispensing machine. The objective was to quantify the effectiveness of the MD.2 machine.

**METHODS:** *Design:* Prospective, randomized trial. *Subjects:* Subjects had  $\geq 2$  medication doses/day, required medication management, had someone to fill a dispensing machine, were in independent living, had a

phone and were expected to live 6 months. Subjects were excluded if they were blind and deaf or were eligible for hospice. **Data Collection:** Demographics, measures of functional status, cognitive ability (CLOX), adherence and number of ER and hospital visits were collected. Baseline data determining the characteristics of the subjects, and 3 and 6-month follow-up data were utilized. Analysis:  $\chi^2$  and *t*-tests were performed for all 92 enrolled subjects to compare groups at baseline.  $\chi^2$  test was performed to determine if there was a difference between ER visits/hospitalizations at follow-up. Logistic regression was also completed. The dependent variable was any ER/hospitalization visits during follow-up, and independent variables included age, sex, CLOX score and treatment/control group. The  $\chi^2$  test and logistic regression were performed for 53 subjects, due to loss to follow-up or withdrawal. **RESULTS:** Subjects' average age was 78.7, SD = 8.52 in the treatment group and 74.7, SD = 6.46 in the control group, and 75% were female in both groups. There was a significant difference in CLOX1 clock-drawing activity at baseline ( $t = 0.525$ ,  $p < 0.001$ ), but no differences for education, gender, age and sex. ER/hospitalizations at follow-up were not statistically significantly different by study group ( $X^2 = 2.80$ ,  $p = 0.094$ ) and treatment was not significant in the logistic regression ( $p = 0.07$ ). **CONCLUSIONS:** The two study groups were similar at baseline. The presence of ER/hospitalizations at follow-up was not significantly different between the MD.2 and control groups.

## Nephrology

274. **C-reactive protein changes in anemic non-dialysis chronic kidney disease patients receiving intravenous iron.** Harleen Guraya, Pharm.D. Candidate,<sup>1</sup> Naomi V. Dahl, Pharm.D.<sup>2</sup>; (1)Wilkes University, Wilkes-Barre, Pennsylvania, USA; (2)Watson Laboratories, Morristown, New Jersey, USA.

**OBJECTIVES:** High sensitivity C-reactive protein (hs-CRP), an inflammatory marker, is chronically elevated in chronic kidney disease (CKD), and correlated to cardiovascular and all-cause mortality. Our analysis evaluates the relationship between intravenous iron administration and changes in hs-CRP levels in these patients.

**METHODS:** Data were obtained from a prospective, randomized, controlled trial examining the effects of repeated doses of ferric gluconate (FG) and iron sucrose (IS) on proteinuria. Anemic patients with CKD (stages 3-4) and proteinuria were randomized to receive 5 doses (100 mg) of either FG or IS at weekly intervals. hs-CRP samples were drawn pre-infusion and at follow-up. Changes from baseline (CFB) in hs-CRP were compared at weekly intervals between treatments using a Mann-Whitney *U* Test. Multivariate analyses included demographic and medical history data to determine variables associated with baseline hs-CRP and with CFB in hs-CRP.

**RESULTS:** 63 participants were analyzed ( $65.4 \pm 15$  years, 65.1% female, 63.5% White, baseline hs-CRP  $5.69 \pm 8.06$  mg/L). In the multivariate analysis of baseline hs-CRP, White ( $7.02 \pm 9.54$  mg/L;  $p = 0.011$ ) and Black/AA patients ( $4.23 \pm 3.53$  mg/L;  $p = 0.020$ ) had higher levels than Asian patients ( $1.81 \pm 3.40$  mg/L). Asthma/COPD/emphysema ( $12.69 \pm 15.06$  mg/L vs.  $4.53 \pm 5.67$  mg/L;  $p = 0.027$ ), and hypothyroidism ( $10.6 \pm 13.75$  mg/L vs.  $4.54 \pm 5.65$  mg/L;  $p = 0.033$ ) were also associated with higher hs-CRP levels. FG was associated with a mean decrease in CRP, while IS was associated with a mean increase in CRP at visits 2 ( $-1.58 \pm 9.22$  vs.  $1.85 \pm 6.25$ ;  $p = 0.005$ ) and 3 ( $-1.84 \pm 7.43$  vs.  $0.98 \pm 4.87$ ;  $p = 0.012$ ). This association remained robust in multivariate analysis. This trend continued at later time points although it was no longer statistically significant.

**CONCLUSIONS:** In anemic ND-CKD patients FG appears to be associated with a decrease in hs-CRP levels during the first two weeks of treatment initiation, while IS appears to increase levels. Additional potential confounders (e.g., medications, smoking status, renal function) should be evaluated.

## Neurology

275. **Survey of risk factors for osteoporosis among epilepsy patients.** Marianna Fedorenko, Student,<sup>1</sup> Mary L. Wagner, M.S., Pharm.D.,<sup>1</sup> Brenda Y. Wu, M.D., Ph.D.<sup>2</sup>; (1)Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey, Piscataway, New Jersey, USA; (2)UMDNJ-Robert Wood Johnson Medical School, New Brunswick, New Jersey, USA

**OBJECTIVES:** Patients with epilepsy have a two-fold risk of sustaining a fracture compared to the general population. Use of anti-epileptic medications can cause bone loss. This study aims to assess: (1) high risk behaviors and characteristics for developing osteoporosis; (2) patients' awareness of their risk.

**METHODS:** Patients attending the Epilepsy Clinic at the UMDNJ-Robert Wood Johnson Medical School were asked to complete a survey tool. The survey included questions regarding: patient demographics, fracture history, frequency of exercise, dietary intake of calcium, supplement intake, frequency and duration of sunlight exposure, antiepileptic medication use, DXA Scan result, and perception of bone health.

**RESULTS:** To date, 67 (F=38, M=29, average age = 44.6, 51% White, 25% Black, 10% Hispanic, 6% Asian, 7% Other) out of 200 patients completed the survey. Of these, 65.7% of the patients obtain less than three servings of calcium-rich foods daily (<900 mg), 48% had a prior bone fracture, 36% take calcium supplements (with or without Vitamin D), 27% engage in weight bearing exercise at least three times per week, 23% indicated a family history of osteoporosis, and 19% smoked. Patients perceived their bone health as a little better than average (3.38 out of 5 points). Half completed a DXA scan and 30% of these had low bone density (T-score less than -1.5 SD). Most patients (82%) had been previously exposed to an antiepileptic drug (AED) that might be associated with bone mass reduction (carbamazepine, phenytoin, oxcarbazepine, divalproate).

**CONCLUSIONS:** The lifestyles and nutrition in patients with epilepsy are not maximized to prevent bone mass loss. Complete data analysis will be available by the beginning of April, 2009.

## Nutrition

276. **What product attributes influence dieters on the selection of weight loss food items.** Kari L. Vavra, Pharm.D. Candidate,<sup>1</sup> Evie E. Slagh, Pharm.D. Candidate,<sup>2</sup> Allison Bernknopf, Pharm.D., BCPS,<sup>3</sup> Gregory Wellman, Ph.D.<sup>4</sup>; (1)Ferris State University College of Pharmacy, Davison, Michigan, USA; (2)Ferris State University College of Pharmacy, Holland, Michigan, USA; (3)Ferris State University College of Pharmacy, Kalamazoo, Michigan, USA; (4)Ferris State University College of Pharmacy, Grand Rapids, Michigan, USA.

**OBJECTIVES:** To determine the most important product attributes that dieters consider when choosing frozen food products, in particular frozen entrees and ice cream.

**METHODS:** 258 Ferris State University College of Pharmacy students and faculty completed a two-part survey consisting of fictional nutrition labels with attributes (entrée type or flavor of ice cream, calories, fat grams, carbohydrate grams, fiber grams, and cost) of different numeric value. Participants were asked to evaluate the nutrition labels in each question (four per question) and to select the one item that he/she would most likely buy if he/she were on a diet. Selections were compiled and the degree of importance placed on each attribute was determined.

**RESULTS:** With regard to frozen entrees, the importance scores for each attribute were reported as follows: fat grams (20.55%), calories (17.61%), entrée type (17.10%), cost (12.84%), carbohydrate grams (12.00%), fiber grams (10.03%), and brand name (9.88%). For ice cream, the importance scores for each attribute were reported as follows: calories (26.34%), fat grams (21.11%), flavor (18.59%), brand name (11.21%), cost (8.99%), fiber grams (7.50%), and carbohydrate grams (6.26%).

**CONCLUSIONS:** Fat grams and calories were ranked the highest overall with fat grams being the highest for frozen entrees and calories being the highest for ice cream. Despite these findings, there were other noteworthy differences within the importance rank of the remaining attributes, specifically brand name, cost, and carbohydrate grams.

## Oncology

277. **Use of dexrazoxane in breast cancer: does it systematically use dexrazoxane with epirubicin in adjuvant or neo-adjuvant?** Jonathan Finzi, Pharmacist, Resident,<sup>1</sup> Karine Morand, Pharmacist, Doctor,<sup>1</sup> Jean Chidiac, Medecine Doctor,<sup>2</sup> Marie L. Brandely, Pharmacist, Doctor,<sup>1</sup> Francois Chast, Pharmacist, Professor<sup>1</sup>; (1)Pharmacy Department, Hotel Dieu Hospital, Paris, France; (2)Oncology Department, Hotel Dieu Hospital, Paris, France.

**OBJECTIVES:** Dexrazoxane is indicated for "prevention of chronic

cumulative of in patients having already received anthracyclines." We've listed other uses in treatment of breast cancer.

**METHODS:** Prescriptions of in treatment of breast cancer, made for 14 months in Hotel-Dieu, were reviewed.

**RESULTS:** Twenty-six patients aged 49 years on average (31.6–65.6 years) were studied. For all, the left ventricular ejection fraction (LVEF) was normal (mean LVEF = 71% (56–86%), Normal = 65% ± 10). Twenty-five patients received only (cumulative dose 379 mg/m<sup>2</sup> [75–752 mg/m<sup>2</sup>]), 1 patient received successively (450 mg/m<sup>2</sup>), doxorubicin (200 mg/m<sup>2</sup>) and liposomal doxorubicin (90 mg/m<sup>2</sup>). Two patients (7.7%) were treated according to the official indication. Four patients (15.4%) received because they had a risk factor increasing the anthracycline's cardiotoxicity. For 18, dexrazoxane was used in combination with adjuvant (n=4–15.4%) or neo-adjuvant treatment (n=14–53.8%). For 17 of them (46 years on average, SBR grade II-III, 76% with HER2 negative status), the chemotherapy protocol used was a SIM (Day one: 1200 mg/m<sup>2</sup>, 75 mg/m<sup>2</sup>, cycle of 15 days, 6 cycles). Two medical records weren't found.

**CONCLUSIONS:** At the Hotel-Dieu, to treat breast cancer, dexrazoxane is mainly used in first line, combined with a SIM. Epirubicin is used in "dose-dense" although cumulative dose is below the toxic level (800 mg/m<sup>2</sup>). Furthermore, in adjuvant or neo-adjuvant, patients will receive other cardiotoxic therapies (taxanes, trastuzumab, thoracic radiation, anthracyclines again in case of relapse). The both incite clinicians to use systematically dexrazoxane combined with SIM for young women. In 2004, American Society of Clinical Oncology recommended not to use dexrazoxane in adjuvant outside clinical trials. To date, it's a widespread practice, probably consistent but not validated by scientific data. Use of dexrazoxane means to be safe but it's necessary to evaluate the "cost-efficacy" of this indication.

**278. Intentional and unintentional nonadherence to imatinib in patients with chronic myeloid leukaemia.** *Lina L. Eliasson, B.Sc. (Hons), Nick Barber, B.Pharm., Ph.D., M.R.Pharm.S., FRSM, Sarah Clifford, BA, M.Sc., Ph.D., C.Psychol.; The School of Pharmacy, University of London, London, United Kingdom.*

The average non-adherence rate in cancer patients is 21% (DiMatteo 2004). Self-administered oral anticancer regimens are becoming more commonly prescribed and entail reduced clinical monitoring of the patient's medication usage. Therefore, non-adherence within oncology is likely to become more of an issue than it already is. To intervene and facilitate patients' use of anticancer drugs we need to understand both intentional and unintentional reasons patients have for not adhering as prescribed. The current study uses Reason's behavioural model (Reason, 1990) as a conceptual framework for investigating non-adherence. The framework allows for focus on the whole process of medicine usage, from health services to individual patients' behaviour.

**OBJECTIVES:** The aim of this study is to better understand the causes of non-adherence to imatinib in adult patients with chronic myeloid leukaemia (CML). To reach this aim the following objectives are set up: 1) To explore factors associated with unintentional non-adherence to imatinib; 2) To explore factors associated with intentional non-adherence to imatinib; 3) To explore factors associated with achieved adherence to imatinib; 4) To assess the usefulness of Reason's behavioural framework in understanding non-adherence to imatinib.

**METHODS:** Design: Qualitative study using in-depth face-to-face patient interviews at a haematology department specialising in treating CML. Participants: Adult patients with CML having been treated with imatinib as first line therapy will be selected in accordance with existing adherence data emanating from an ongoing clinical trial.

**RESULTS:** Interviews were initiated December 2008, and preliminary results are expected to be ready for presentation by April 2009.

**CONCLUSIONS:** The knowledge gained may further adherence research and intervention development.

**279. Effects of iron treatment on serum phosphate levels in anemic cancer patients undergoing chemotherapy.** *Kara Avila, Pharm.D., Candidate<sup>1</sup>, Naomi V. Dahl, Pharm.D.<sup>2</sup>; (1)Wilkes University, Wilkes-Barre, Pennsylvania, USA; (2)Watson Laboratories, Morristown, New Jersey, USA.*

**OBJECTIVES:** Some intravenous iron preparations have been associated

with hypophosphatemia, possibly through a mechanism of acute renal tubular toxicity. The objective of this study was to explore the effects of IV iron treatment on changes in serum phosphate levels in anemic cancer patients.

**METHODS:** Data were obtained from a prospective, randomized, controlled trial which compared the effects of IV ferric gluconate (FG), oral iron, and no iron on hemoglobin response to epoetin in anemic cancer patients receiving chemotherapy. All patients with baseline and end-of-study phosphate levels and who had received study drug were included in this post-hoc retrospective analysis. To control for potential confounders, multivariate regression analyses included the following covariates: treatment group, age, race, gender, baseline phosphate, estimated glomerular filtration rate (eGFR) and pertinent concomitant medications (e.g., bisphosphonates, renal tubular toxins). Change from baseline (CFB) in phosphate was analyzed with ANCOVA. Likelihood of experiencing a decrease of at least 0.5 mg/dl in phosphate was analyzed by logistic regression.

**RESULTS:** Data were available for 165 patients (114 female, 27 African-American, baseline phosphate 3.4 ± 0.7 mg/dL, eGFR 97.4 ± 36.5 mL/min). There was no association between treatment group and CFB phosphate level in either of the models. The only parameters independently associated with a ≥0.5 mg/dl decrease in phosphate were age >55 (OR 6.3, 95% CI 1.5–26.6) (p=0.012) and African-American race (OR 4.9, 95% CI 1.4–17.1) p=0.014. Independent associations with overall CFB in phosphate included: age (0.009 mg/dl decrease in phosphate per year, p=0.022), baseline eGFR (0.317 mg/dl greater decrease in phosphate with stages 3 and 4 than stage 2, p=0.038), and change in eGFR (0.005 mg/dl increase in phosphate per 1% decrease, p=0.008).

**CONCLUSIONS:** While this study found several factors independently associated with decreases in serum phosphate, treatment with IV ferric gluconate was not associated with any changes in phosphate levels in this patient population.

## Pediatrics

**280. Current treatment practices of pediatric oncologists management of depression and anxiety disorders in 9 institutions across the United States.** *Lalymar T. Fernandez, MS, Pharm.D. Candidate<sup>1</sup>, Robert B. Noll, Ph.D.<sup>2</sup>, Sean Phipps, Ph.D.<sup>3</sup>, Lori Wiener, Ph.D.<sup>4</sup>, Avi Madan-Swain, Ph.D.<sup>5</sup>, Heather Huzti, Ph.D.<sup>6</sup>, Nicole Vincent, Ph.D.<sup>6</sup>, Mary J. Kupst, Ph.D.<sup>7</sup>, Larry L. Mullins, Ph.D.<sup>8</sup>, Rhonda Robert, Ph.D.<sup>9</sup>, Robert J. Wells, M.D.<sup>9</sup>, Olle J. Sahler, M.D.<sup>1</sup>, Ty Ridenour, Ph.D.<sup>11</sup>; (1)Duchesne University School of Pharmacy, Pittsburgh, Pennsylvania, USA; (2)Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania, USA; (3)St. Jude Children's Research Hospital, Memphis, Tennessee, USA; (4)National Cancer Institute, Bethesda, Maryland, USA; (5)Children's Hospital Birmingham, Birmingham, Alabama, USA; (6)Children's Hospital of Orange County, Orange, California, USA; (7)Medical College of Wisconsin, Milwaukee, Wisconsin, USA; (8)Oklahoma State University, Stillwater, Oklahoma, USA; (9)University of Texas M.D. Anderson Cancer Center, Houston, Texas, USA; (10)University of Rochester, Rochester, New York, USA; (11)University of Pittsburgh, Pittsburgh, Pennsylvania, USA.*

**OBJECTIVES:** Our objective is to examine whether pediatric oncologists and fellows who see children with cancer who may have co-morbid depressive or anxiety disorders prescribe SSRIs; to determine why medications are initiated; and analyze how the FDA black box warning is monitored. We hypothesized that a majority of oncologists prescribe SSRIs for a minority of their patients. No hypothesis was generated regarding following the FDA black box warning.

**METHODS:** Nine institutions participated representing many regions of the US, including large teaching pediatric hospitals and smaller teaching hospitals. The 17-item questionnaire targets the use of SSRIs and mixed mechanism agents used to treat depressive and/or anxiety disorders. All of the medications carry the black label warning from the FDA.

**RESULTS:** To date, we have obtained data from 153 physicians from 9 institutions. 68% of pediatric oncologists reported prescribing antidepressants to children with cancer. Of those, 54% state that the FDA black label warning has not affected their prescribing practice. Analyses are ongoing examining reasons for initiation of treatment and decision making about ending psychotropic drug therapy.

**CONCLUSIONS:** Preliminary analyses suggest that the FDA black box

warning has not changed the prescribing practices of pediatric oncologists or their procedures for patient monitoring. Social policy implications are discussed.

**281. Intravenous immunoglobulin, high-dose corticosteroids, and infliximab in the treatment of refractory Kawasaki disease: A retrospective review.** *Amanda J. Worshum, Student,<sup>1</sup> Paula Thompson, M.S., Pharm.D., BCPS,<sup>1</sup> Mary Worthington, Pharm.D., BCPS,<sup>1</sup> Sean King, M.S., Ph.D.,<sup>1</sup> Walter H. Johnson Jr., M.D.<sup>2</sup>; (1)Samford University, Birmingham, Alabama, USA; (2)University of Alabama at Birmingham, Birmingham, Alabama, USA.*

**OBJECTIVES:** The objective of this study is to describe the incidence of refractory Kawasaki disease (KD) at the Children's Hospital of Alabama and evaluate the use and outcomes of repeat intravenous immunoglobulin (IVIG), high-dose corticosteroids, and infliximab in the treatment of refractory KD.

**METHODS:** All cases of diagnosed KD at Children's Hospital over a ten-year period will be retrospectively reviewed. For each identified case, it will be determined whether the patient responded to initial treatment with IVIG. These data will then be utilized to assess the incidence of refractory KD for the period under study. For these patients a standardized data collection form will be used to document therapy with repeat doses of IVIG, high-dose corticosteroids, and infliximab. Outcomes associated with each patient's treatment will be reported.

**RESULTS:** The expected date of completion of this study is January 2009. Early estimations indicate that approximately 500 cases of KD have been diagnosed at Children's Hospital in the ten-year period under study. Current literature supports the prediction that at least ten percent of these cases are refractory KD. Preliminary information also indicates that a majority of patients who received infliximab also received high-dose corticosteroids.

**CONCLUSIONS:** The results of this retrospective chart review will provide institution-specific information for the Children's Hospital of Alabama to utilize when selecting treatment options in future KD patients. Although the results may not necessarily be extrapolated beyond Children's Hospital, they may be utilized to develop a treatment algorithm for cases of refractory KD and to inspire other institutions to analyze similar data.

**283. Discovery of HIV infection in a 10 years old girl in a paediatric hospital: case report.** *Duval Stéphanie, Student,<sup>1</sup> Marchand Sophie, M.D.,<sup>2</sup> Schar Karin, M.D.,<sup>1</sup> Senon Géraldine, M.D.,<sup>1</sup> Provot Stéphanie, M.D.,<sup>1</sup> Meunier Philippe, M.D.<sup>1</sup>; (1)Pharmacy Department; Paediatric Hospital de Clocheville, Tours, France; (2)Paediatric Department; Paediatric Hospital de Clocheville, Tours, France.*

**OBJECTIVES:** L., a 10-year-old girl, 35 kg, is hospitalized for suspicion of chronic autoimmune hepatitis. Clinical and biological signs are: persistent asthenia, anorexia, hepatosplenomegaly with cytolysis, pancytopenia and inflammatory syndrome. A corticotherapy is initiated with prednisone and ursodesoxycholic acid: hepatosplenomegaly decreases. After two months, lymphopenia, cytolysis and inflammatory syndrome persist. L. presents a persistent irritative cough and a buccal candidiasis resistant to amphotericin B and ketoconazole, treated by fluconazole and miconazole. An immunodepression syndrome is suspected.

**METHODS:** Further tests are made and a HIV infection is diagnosed (positive antiHIV1 serology) with CD4 decreased (13/mm<sup>3</sup>) and an important HIV viral load (6.3 copy/mL). The mother's serology is positive antiHIV1 and was unknown so far. HIV infection by maternofetal transmission is supposed. This case is studied in pluridisciplinary commission to determine the antiretroviral therapy with hospital pharmacy whose dispenses treatment (according to Yeni's Recommendations 2008).

**RESULTS:** A tritherapy is adopted: zidovudine (250 mg x 2/d), lamivudine (150 mg x 2/d) and lopinavir/ritonavir syrup (280 mg x 2/d), associated with sulfamethoxazole/trimethoprim (prevention of pneumocystis infection), hydrocortisone and miconazole. After initialization of treatment, L. presents fever, rash with pruritus (treated by ursodesoxycholic acid) and leucopenia (zidovudine dosage is reduced during hospitalization) whose the cause is probably an immune restoration. Prednisone is restored and azathioprine is prescribed due to

persistent inflammatory syndrome. During the first month, abacavir 300 mg x 2/d replaces zidovudine because of anemia and four months later, lopinavir/ritonavir tablets replaces lopinavir/ritonavir syrup, which allows to change treatment by actual antiretroviral therapy: abacavir/lamivudine 600/300 mg/d and lopinavir/ritonavir tablets (600 mg/d).

**CONCLUSIONS:** Ten months after starting treatment, inflammatory syndrome decreased, the HIV viral load is undetectable (1.75 copy/mL) and the increase of CD4 (698/mm<sup>3</sup>) allowed to stop sulfamethoxazole/trimethoprim. MC is in good health and side effects disappeared. The role of hospital pharmacist is important in this case in terms of confidentiality and pharmaceutical advices to L. and her parents.

## Pharmacoeconomics/Outcomes

**284. An analysis of computer alerts suggesting oral medication use during computerized order entry of intravenous (IV) medications.** *William L. Galanter, M.D., Ph.D., Xiaoping (Frank) Liu, M.S., Bruce Lambert, Ph.D.; University of Illinois at Chicago, Chicago, IL.*

**OBJECTIVES:** To identify factors associated with compliance with computer alerts suggesting switching from IV to oral medications, in order to improve the design and performance of this and similar interventions that promote less costly inpatient medication use.

**METHODS:** A clinical decision support system was developed to suggest using oral medications during IV medication ordering in patients receiving oral diets. Medications were selected due to equivalent oral and IV efficacy; clindamycin, dexamethasone, famotidine, fluconazole, levofloxacin, levetiracetam, linezolid, metronidazole, methylprednisolone, phosphenytoin, rifampin and trimethoprim/sulfamethoxazole. The alerts were studied at a university teaching hospital for 13 months. A variety of potential factors were analyzed for their association with alert compliance, which was defined as switching from the IV to oral medication.

**RESULTS:** There were 3919 alerts. The overall compliance rate was 18.7 ± 0.6%. The compliance varied among the medications; methylprednisolone had the lowest compliance and famotidine the highest, 8.5% vs. 32.0% (p<0.05). Compliance varied only slightly by the time of day. Nurses were the most compliant type of clinician, while pharmacists were the least, 34.6% vs. 10.3% (p<0.05). Housestaff, 19.0%, and faculty, 21.2%, had similar compliance which was between that of the nurses and pharmacists. Compliance was related to location, with adult ICU's having lower compliance than med/surg wards 14.9% vs. 20.6% (p<0.05).

**CONCLUSIONS:** While computer alerts suggesting switching an IV medication to oral had some effectiveness, the compliance was relatively low. The compliance varied by medication, location, type of ordering clinician, and time of day. This information should provide useful for further modifications of alert based interventions designed to decrease medication costs through increased use of oral medications.

## Pharmacoepidemiology

**285. The use of PEG-interferon in four Piedmont's Public Local Sanitary Companies (ASL) during years 2006/2007 as therapy for patients with B- and non-A/non-B hepatitis.** *Elena Mittone, Doctor,<sup>1</sup> Michelangela Pozzetto, Doctor,<sup>2</sup> Lucia Bagnasco, Doctor,<sup>1</sup> Elisa Sciorsci, Doctor,<sup>1</sup> Daniela Piccioni, Doctor,<sup>3</sup> Vera Pastore, Doctor,<sup>3</sup> Andreina Bramardi, Doctor,<sup>4</sup> Lorenza Ferraro, Doctor,<sup>2</sup> Maurizia Mazengo, Doctor,<sup>5</sup>; (1)Turin-School of Hospital Pharmacy, Torino, Italy; (2)Turin-Territorial Pharmaceutical Service ASL TO2, Torino, Italy; (3)Turin-Pharmaceutical Service, Hospital Martini ASL 2, Torino, Italy; (4)Mondovi-Ceva-Pharmaceutical Service ASL16, Mondovi, Italy; (5)Turin-Pharmaceutical Service, Hospital Maria Victoria and Amedeo of Savoia ASL 3, Torino, Italy.*

**OBJECTIVES:** B and non-A/non-B type hepatitis are serious infectious diseases with incidence rates (x 100,000-inhabitants) respectively to 1.6 and 0.5 in Piedmont during 2006. Among the used treatments there are peg-interferon and ribavirin, they are distributed exclusively by the ASL to their patients. Disease's criticality has suggested the possibility of an analysis to describe population and consumption differences in realities of some Piedmont's ASLs. Main purpose are: peg-interferons' and

ribavirin's consumption-treated population characteristics with analysis of appropriateness.

**METHODS:** Peg-interferons prescriptions in the years 2006 and 2007 of ASL2 (235,222 inhabitants) ASL3 (218,447 inhabitants) ASL4 (193,453 inhabitants) and ASL16 (86,689 inhabitants) were analysed using direct distribution's data. Patients were separated by gender and age.

**RESULTS:** Patients treated between 2006 and 2007, with peg-interferons were 156 in ASL2, 80 in ASL3, 152 in ASL4 and 51 in ASL16. 63.6% of patients are male, 26.3% aged between 18–40 years, 61% between 41–64 and 12.8% over 65 years with differences between the percentages of treaties in ASLs. In the period under review 9197 peg-interferons packs were distributed: 38.9% peg-interferon alfa-2a-180 µg, 27.8% peg-interferon-alfa-2b 80 µg, 19.8% peg-interferon-alfa-2b 100 µg. Patients treated with ribavirin instead were 164 in ASL2, 80 in ASL3, 133 in ASL4 and 48 in ASL16. The 65.9% of patients are male. 27.5% of the total aged 18–40 years, 59.9% between 41–64 years and 12.7% over 65 years. In total, were distributed 238,878 units dosing of ribavirin.

**CONCLUSIONS:** We discovered a uniform distribution between patients and the used active substances comparing different realities. This work brings out the relatively high percentage of over 65 patients treated when, from the main guidelines, patients less than 40 years are more responsive to treatment. Special attention was also paid to the identification of ribavirin's monotherapy, that is contraindicated in summaries of product characteristics.

### Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**286. Atenolol pharmacokinetics and excretion in breast milk during the first 6-8 months postpartum.** Joong D. Kim, B.S.,<sup>1</sup> Gail D. Anderson, Ph.D.,<sup>1</sup> Megan L. Buchanan, B.S.,<sup>1</sup> Jinny K. Eun, B.A.,<sup>1</sup> Debra A. Brateng, R.N.,<sup>2</sup> Darcy B. Carr, M.D.,<sup>2</sup> David K. Blough, Ph.D.,<sup>1</sup> David E. Woodrum, M.D.,<sup>3</sup> Thomas R. Easterling, M.D.,<sup>2</sup> Mary F. Hebert, Pharm.D., FCCP<sup>4</sup>; (1)University of Washington Department of Pharmacy, Seattle, Washington, USA; (2)University of Washington Department of Obstetrics and Gynecology, Seattle, Washington, USA (3)University of Washington Department of Pediatrics, Seattle, Washington, USA; (4)University of Washington Departments of Pharmacy and Obstetrics & Gynecology, Seattle, Washington, USA

**OBJECTIVES:** The objectives of this study were to determine maternal steady-state atenolol pharmacokinetics (PK) in lactating women 2–4 weeks, 3–4 months and 6–8 months postpartum and the plasma concentration of atenolol in 3–4 month old nursing infants whose mothers were taking atenolol.

**METHODS:** Serial blood, urine and breast milk samples were collected in 24 lactating women 2–4 weeks, 3–4 months and 6–8 months postpartum over 1 atenolol dosing interval. Eleven women completed all 3 study days. A single blood sample was collected from 15 nursing infants of the mothers participating in the study. Plasma atenolol concentrations were measured using a validated HPLC method. Standard noncompartmental analysis was utilized to estimate steady-state atenolol PK parameters. All results are reported as mean ± SD.

**RESULTS:** Creatinine clearance increased 6–8 months postpartum ( $145 \pm 29$  mL/min) as compared to 2–4 weeks ( $133 \pm 21$  mL/min,  $p=0.01$ ) and 3–4 months postpartum ( $129 \pm 30$  mL/min,  $p=0.003$ ), but this did not translate into any significant changes in atenolol PK. Atenolol concentrates in the breast milk (breast milk/plasma atenolol AUC ratios were 2–4 weeks:  $6.0 \pm 0.6$ , 3–4 months:  $5.0 \pm 0.9$  and 6–8 months:  $4.4 \pm 1.3$ ), although average actual infant exposure was <1% of the maternal dose. Times to maximum atenolol concentration in the breast milk were  $4.9 \pm 1.9$  hours,  $4.9 \pm 2.0$  hours and  $5.2 \pm 1.9$  hours post-atenolol dosing 2–4 weeks, 3–4 months and 6–8 months postpartum, respectively. Atenolol concentrations were below assay quantification limits (<10 ng/mL) in the plasma of all 3–4 month old infants studied.

**CONCLUSIONS:** Atenolol exposure through breast milk is not expected to have any pharmacologic effect on normal healthy nursing infants, but pre-mature infants and those with kidney impairment require further study. Current guidelines from the American Academy of Pediatrics regarding timing of medication dosing relative to nursing will not decrease infant exposure to atenolol through the breast milk and may increase exposure.

**287. Population pharmacokinetic methods to establish bioequivalence between two formulations of injectable sodium ferric gluconate complex in sucrose.** Corinne Seng Yue, B.Pharm., M.Sc.,<sup>1</sup> Philippe Colucci, M.Sc.,<sup>1</sup> Martin A. Joyce, Ph.D.,<sup>2</sup> Vincent P. Andolina, B.S.,<sup>2</sup> Deepen M. Patel, M.D.,<sup>3</sup> Murray P. Ducharme, Pharm.D.<sup>3</sup>; (1)Universite de Montreal, Montreal, Quebec Canada; (2)Generamedix, Liberty Corner, New Jersey, USA; (3)Cetero Research, Cary, North Carolina, USA.

**OBJECTIVES:** Exogenous iron administered intravenously presents a unique clinical pharmacology challenge as it is only eliminated by plasma sampling, it cannot be measured directly and it possesses non-linear pharmacokinetic (PK) characteristics. Taking all of this into account, this study aims to present an accurate and novel way of assessing the relative bioavailability of 2 different formulations of sodium ferric gluconate complex (SFGC).

**METHODS:** This was an open label, randomized, single dose, two-period crossover study. Subjects with low but normal iron levels were infused 62.5 mg SFGC in sucrose by GeneraMedix Inc. and Ferlecit<sup>®</sup> Injection (Watson Laboratories Inc.) IV over 30 minutes. Samples were assayed for total iron (TI) and transferrin-bound iron (TBI) over 72 hours. Population PK analyses were conducted using ADAPT-V<sup>®</sup> (n=29). The model best describing the PK of TI and TBI was selected using standard discrimination techniques. It was then used to predict SFGC area-under-the-curve ( $AUC_{pred}$ ) and maximal concentration ( $C_{maxpred}$ ). An ANOVA was performed using ln-transformed  $AUC_{pred}$  and  $C_{maxpred}$ ; ratios of means and 90% confidence intervals (CIs) were estimated. Bioequivalence was declared if SFGC ratios and 90% CIs were within 80–125%.

**RESULTS:** The final PK model accounted for serum iron, iron bound to transporters (transferrin and non-transferrin), and stores in the reticuloendothelial system and bone marrow (red blood cells). The model also took into consideration the iron lost during blood sampling. Overall, it explained the data very well, with residual variabilities of 23.0% and 17.2% for TI and TBI, respectively. Ratios (90% CI) for SFGC  $AUC_{pred}$  and  $C_{maxpred}$  were 89.7% (85.7; 93.9) and 89.9% (85.9; 94.0), respectively.

**CONCLUSIONS:** Based on population PK modeling results, SFGC in sucrose injection by GeneraMedix Inc. met the bioequivalence criteria compared with the reference formulation (Ferlecit<sup>®</sup> Injection). This demonstrates the applicability and precision of this innovative approach for establishing bioequivalence between iron products.

**288. Bioequivalence potential of a new extended-release formulation determined by clinical trial simulations.** Philippe Colucci, M.Sc.,<sup>1</sup> Jacques Turgeon, B.Pharm, Ph.D.,<sup>2</sup> Murray P. Ducharme, Pharm.D.<sup>3</sup>; (1)Universite de Montreal, Montreal, Quebec Canada; (2)Centre Hospitalier de l'Université de Montréal (Research Center), Montreal, Quebec Canada; (3)Cetero Research, Cary, North Carolina, USA.

**OBJECTIVES:** To determine the development potential of a new formulation based on a pilot study.

**METHODS:** In a single-dose crossover study in 12 adults, relative bioavailability of a test extended-release NSAID suspension (12-hour fast; twice the reference strength) was compared to a reference suspension given twice 6 hours apart (first dose: 12-hour fast, second dose: 2 hours after lunch). Compartmental modeling and simulations in ADAPT-V<sup>®</sup> were performed to determine the two formulations' pharmacokinetics, the food-effect and to assess bioequivalence potential in simulated studies removing the food effect and/or steady-state studies. Noncompartmental parameters were calculated (pilot and simulated studies). Bioequivalence was determined using FDA guidelines. To prove bioequivalence, fasting and fed single-dose studies and a fasting steady-state study would be required.

**RESULTS:** Drug pharmacokinetics was described by a 2-compartment model with 3 absorption phases. A reduction in bioavailability (15–25%) for the second reference dose was required (potential food-effect). The estimated compartmental  $AUC_{0-t}$  and  $C_{max}$  ratios (pilot study) were similar to the noncompartmental analysis (approximately 100%). However, the test formulation's bioavailability (125%) was slightly higher than the calculated  $AUC_{inf}$  ratio (112%). This difference resides in a long third absorption half-life for the test product (16.1 hours) with approximately 20% still being absorbed after 24 hours (end of collection). Simulation results suggest that the products could be

bioequivalent under true fasting conditions (single-dose and steady-state), but bioequivalence may be difficult to prove under fed conditions and under fast/fed steady-state conditions.

**CONCLUSIONS:** Simulations suggest that the test formulation should be modified to increase chances of meeting bioequivalence. This study illustrates the usefulness of modeling and simulations in the decision-making for the optimization of bioequivalence products.

**289. Evaluating the effects of population based volume of distribution models on the elimination rate constant ( $K_e$ ) in predicting target vancomycin concentrations.** Vishal S. Shah, B.S., Pharm.D. Candidate, S. Scott Sutton, Pharm.D.; College of Pharmacy, University of South Carolina, Columbia, South Carolina, USA.

**OBJECTIVES:** To evaluate the effects of population based volume of distribution models on the elimination rate constant ( $K_e$ ) and target vancomycin concentration.

**METHODS:** The elimination rate constant ( $k_e$ ) for vancomycin will be calculated using glomerular filtration and population based volume of distribution ( $V_d$ ) models Ambrose, Bauer, Matzke variation, Moellering, and Winter [ $k_e = Cl/V_d$ ]. The glomerular filtration rate used to calculate  $k_e$  will be estimated using Cockcroft-gault. The estimated  $k_e$  will be used to predict target vancomycin concentrations. These estimated concentrations will be compared to vancomycin trough values obtained for each patient analyzed, in efforts to predict which calculation of  $k_e$  correlates with actual vancomycin trough levels.

**RESULTS:** Results are pending. Data collection and analysis is currently ongoing. All data collection and analysis will be complete by February 2009 and be ready to present at the 2009 ACCP/ESCP International Congress on Clinical Pharmacy.

**CONCLUSIONS:** Volume of Distribution ( $V_d$ ) is a critical pharmacokinetic parameter because it determines the maintenance dose (MD) that is required to obtain a given steady-state concentration. This evaluation will compare methods of calculation for  $k_e$  and its ability to predict target vancomycin trough concentrations.

## PHARMACY ADMINISTRATION

**290. Evaluation of beneficial effect dibotermine alpha in patients operated for a spine surgery.** Lemachatti J. Jihane, Pharmacy Intern, Gourieux Bénédicte, P.H., Steib Jean Paul, P.H., Beretz Laurence, P.H.; University Teaching Hospital of Strasbourg, Strasbourg, France.

**OBJECTIVES:** Dibotermine alpha is a recombinant human Bone Morphogenetic Protein (rh-BMP-2) that is able to induce a local bone formation by stimulating the differentiation of mesenchymal cells into osteoblasts. It's an alternative to autogenous bone at the anterior lumbar interbody fusion. The purpose of our study is to assess the radiological and clinical effectiveness of dibotermine alpha and the correlation between clinical indications and approved indications.

**METHODS:** We reviewed the clinical and radiographic records of patients who had a spine surgery with laying dibotermine alpha between 2006 and 2008. The patients are included depending on the date of surgery to have enough time to evaluate clinical effect. We used a specific questionnaire validated by surgeon and pharmacist with data from patients, surgery, risk factor, clinical issue.

**RESULTS:** Thirteen patients (9 women and 4 men) received dibotermine alpha. All of these patients had degenerative disc disease. All surgical procedures were performed using an anterior lumbar interbody fusion approach. One patient treated at the L4 S1 and two patients treated at the L5 S1. After 12 months, had bone formation. Radiographics showed that the rate of bone formation was 54%. The fusion success rate was 54%. The evaluation of fusion for 4 patients was difficult because of the interbody fusion cages made of titanium; 12 months later, 31% of patients had improved their pain.

**CONCLUSIONS:** Dibotermine alpha has been used in the approved indications in 52.4% of cases. The off-labelled uses were predominantly cases of pseudoarthrosis. There was no consensus for the treatment of pseudoarthrosis. However the use of dibotermine alpha improves the surgical results and avoids taking bone graft from the iliac crest.

## Pharmacy Practice (adherence to medications)

**291. Barriers to adherence to medications among Kuwaiti patients**

**with type 2 diabetes mellitus.** Fatima B. Jeragh-Alhaddad, B.A., M.Sc., Tina P. Brock, B.A., B.Pharm., M.S., Ed.D., Nick D. Barber, B.Pharm., Ph.D., M.R.Pharm.S., FRSM; School of Pharmacy, London, United Kingdom.

**BACKGROUND:** Type 2 diabetes mellitus (T2DM) is emerging as major public health concern among the Kuwaiti population and nonadherence to medicines is believed to be the most serious barrier to management of the disease. Previous published literature in this area suggests a Western bias which may not adequately describe the Kuwait experience. **OBJECTIVES:** To identify barriers to medication adherence among Kuwaiti patients with T2DM.

**METHODS:** A theoretical sample of Kuwaitis with T2DM was recruited from different general practices and hospitals in Kuwait. Patients were approached by the main investigator while presenting to outpatient appointments where they receive their usual diabetes care. Unstructured, in-depth interviews were performed. The interviews were conducted, recorded digitally and transcribed in Arabic by the main investigator. Field notes augmented the transcriptions. Sampling continued until no new themes appeared (i.e., when saturation of data was achieved) for a total of 20 subjects. Grounded theory was applied and the qualitative data indexing software package MAXQDA 2007 was used to facilitate the analysis.

**RESULTS:** Preliminary data analysis has identified several themes which may constitute barriers to adherence to medications among Kuwaiti patients with T2DM: (1) travelling or being away from home; (2) forgetfulness; (3) skipping doses in relation to meals and/or exercise patterns; (4) adverse effects or fear of their occurrence; and (4) lack of patient education and awareness due to deficiency in role of pharmacists and/or physicians. In addition, preference for Western brands of medications (i.e., patients' lack of confidence in locally-manufactured brands) was a novel issue not previously described in the literature. More detailed analysis is ongoing and will be completed in time for the conference.

**CONCLUSIONS:** Clinicians should focus on devising interventions to improve patients' adherence to their medications by eliminating/minimizing these barriers so that patients can receive the maximum therapeutic benefit of their medications.

## Public Health and Education

**292. My first patient: teen style.** Kimberly Barker, Pharm.D. Candidate,<sup>1</sup> Carrie Kessler, Pharm.D. Candidate,<sup>1</sup> Tynesha Dodd, High School Student,<sup>2</sup> Victoria Mathis, High School Student,<sup>2</sup> Robert Hawthorne Jr, High School Student,<sup>2</sup> Kristal L. Williams, Pharm.D., CDE<sup>3</sup>; (1)Butler University College of Pharmacy and Health Sciences, Indianapolis, Indiana, USA; (2)Crispus Attucks Medical Magnet High School, Indianapolis, Indiana, USA; (3)Butler University College of Pharmacy and Health Sciences/IU Methodist Family Practice Center, Indianapolis, Indiana, USA

**OBJECTIVES:** The purpose of this study is to decrease the presence of unhealthy dietary and physical activity habits, to promote healthy lifestyle changes and to increase awareness of chronic medical conditions among high-students enrolled in a pre-health sciences program. Additionally, this project will provide introductory, patient-care opportunities for the students who, themselves, are their first patient.

Healthy People 2010 set a goal to "Increase the proportion of... health professional training schools whose basic curriculum for health care providers includes core competencies in health promotion and disease prevention." With the advent of medical magnet programs and the increased incidence of common adult medical conditions presenting in childhood, it would be advantageous to incorporate healthy habits and behaviors into pre-health sciences curricula.

**METHODS:** Crispus Attucks Medical Magnet Program's sophomores and juniors are eligible to participate in this educational and interventional study, which is modeled after Butler University College of Pharmacy and Health Sciences' "My First Patient" Program and guided by selected CAPE outcomes. This study consists of investigator-designed, interactive, health-education presentations on obesity, healthy eating, and diabetes prevention and two health knowledge quizzes. Additionally, the students will perform a self-assessment of their nutritional and exercise habits utilizing the investigator-designed form

and will undergo health screenings for Cholestech-LDX obtained blood glucose and cholesterol measurements, blood pressure readings and body composition analysis. Using the information from their health assessments and the presentations, the students will assess their detrimental behaviors and disease risk. Acting as their first patient, the students will design and implement a patient-specific therapeutic-lifestyle plan (TLP) with assistance from the investigators. This project will begin January 2009. The students' health knowledge as well as their ability to implement healthy lifestyle changes and improve their health outcomes will be assessed 3 months after the TLP implementation date.

**RESULTS:** To be presented.

**CONCLUSIONS:** To be presented.

## Pulmonary

**293. Design and preliminary evaluation of a pharmacist collaborative care program in pulmonary arterial hypertension.** *Mathieu Roustit, Pharm.D., (resident), Benoit Allenet, Pharm.D., Ph.D., Audrey Lehmann, Pharm.D., Magalie Baudrant, Pharm.D., Jean Calop, Pharm.D., Ph.D., Christophe Pison, M.D., Ph.D., Pierrick Bedouch, Pharm.D., Ph.D.;* CHU Grenoble, Grenoble, France.

**OBJECTIVES:** Pulmonary arterial hypertension (PAH) is a rare disease characterized by vascular proliferation and remodelling of pulmonary arteries. Despite the increasing number of medications for PAH, poor compliance, pharmacotherapy misuse and insufficient drug monitoring may limit their benefits. As in other chronic diseases, alternative models of care based on a multidisciplinary strategy involving a pharmacist could improve outcomes in PAH. We thus aimed to implement a pharmaceutical care program for PAH patients. Our objective in the present work is to describe this model and to give preliminary results of its evaluation.

**METHODS:** We have recruited inpatients from the pneumology unit of our institution since January 2008. Inclusion criteria were specific treatment for PAH and New-York Heart Association functional class from II to IV. Individual interviews with the clinical pharmacist were planned before the medical round. After compliance assessment, education focused on PAH and PAH medications, their management and self-monitoring, in order to improve compliance. Medication organizer and written information were given at the end of the interview. Other pharmacist interventions included advice to the prescriber and biological monitoring. This program has been performed in close collaboration with chest physicians and specialized nurses. Quality of life, compliance, satisfaction with treatment as well as clinical parameters were recorded.

**RESULTS:** Thirty-two patients have been included since the program implementation. Overall feasibility was good. Preliminary data about the evaluation of this pharmaceutical care program will be shown for the first time at the ACCP/ESCP International Congress on Clinical Pharmacy.

**CONCLUSIONS:** For about one year, we have implemented a pharmaceutical care program for PAH inpatients. We now aim to extend it to outpatients. Moreover, this program is being implemented in other centers. A multi-center, randomized, controlled study is being designed to further assess its efficacy and cost-effectiveness on a wider scale.

## Quality improvement

**294. Evaluation of cardiovascular medication use: development and validation of an assessment tool for use in Germany.** *Tobias Dreischulte, M.Sc.,<sup>1</sup> Susanne Frisse, Dipl.-Pharmazeutin,<sup>2</sup> Andrea Liekweg, Dr.Rer.Nat.,<sup>3</sup> Thomas Twisselmann, Dr.Med.,<sup>3</sup> Gerian Groenefeld, Dr.Med., P.D.,<sup>3</sup> Ulrich Jaehde, Professor, Dr.Rer.Nat.,<sup>2</sup> Stephen A. Hudson, Professor, M.Pharm.;* (1)Pharmaceutical Sciences, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, Scotland, United Kingdom; (2)Rheinische Friedrich-Wilhelms-University, Bonn, Germany; (3)Asklepios Kliniken Hamburg GmbH, Germany, Hamburg, Germany.

**OBJECTIVES:** Hospitalisations provide the opportunity to review and optimise medication use based on current clinical records. This study aimed to test a method to identify gaps in the implementation of evidence-based guidelines regarding medication use in coronary heart disease (CHD), chronic heart failure (CHF) and atrial fibrillation (AF) at the point of hospital discharge.

**METHODS:** European Society of Cardiology (ESC) guideline recommendations relevant to long term medication use in CHD, CHF and AF were used to generate draft assessment criteria (Medication Assessment Tool for chronic cardiovascular conditions-MAT<sub>CVC</sub>). MAT<sub>CVC</sub> was validated by a panel of three cardiology specialists and field-tested in a retrospective survey of patients with a history of either CHD, CHF or AF. Relevant patient data were abstracted from patient discharge letters and electronic laboratory files from three cardiology wards in a German teaching hospital.

**RESULTS:** MAT<sub>CVC</sub> comprised 40 assessment criteria. Inter-rater reliability of data abstraction was assessed by two independent raters conducting CVC assessments in 44 patients in which 34/40 criteria could be tested. 'Good' (K= 0.6–0.8) and 'very good' (K>0.8) inter-rater reliability were demonstrated in 11 and 23 criteria, respectively. In 204 patients assessed at patient discharge, a total of 1940 MAT<sub>CVC</sub> criteria (24%) were applicable (relevant). Of those, there were 719 (37% of applicable) cases of apparently unmet drug therapy needs (discharge 'care issues'). A total of 177 (87%) patients had at least one and 69 (34%) patients had at least five care issues - the latter accounting for 423 (59%) of all discharge care issues.

**CONCLUSIONS:** MAT<sub>CVC</sub> assessment was found to be feasible and reliable. The tool has potential use as an audit instrument; and one means of systematically addressing patients' pharmaceutical care needs. It is envisaged that MAT<sub>CVC</sub> assessment at hospital discharge would inform a plan for patient follow-up in primary care.

**295. Evaluation of cardiovascular medication use: A novel multidisciplinary approach to guideline implementation in Dutch primary care.** *Tobias Dreischulte, M.Sc.,<sup>1</sup> Michiel E. Verhulst, B.Sc.,<sup>2</sup> Leendert H. Heeres, M.Sc., Pharm.D.,<sup>3</sup> Erik E. Gerbrands, M.Sc., Pharm.D.,<sup>3</sup> Jan de Waard, M.D.,<sup>4</sup> Hugh R. Kruyt, M.D.,<sup>5</sup> Johan J. de Gier, Professor, M.Sc., Pharm.D.,<sup>6</sup> Stephen A. Hudson, Professor, M.Pharm.;* (1)Pharmaceutical Sciences, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, Scotland, United Kingdom; (2)Rijksuniversiteit Groningen, Department of Pharmacy, Groningen, The Netherlands; (3)Apotheek 'it Krúswald', Buitenpost/Kollum, The Netherlands; (4)General practice 'J. de Waard', Kollum, The Netherlands; (5)General practice 'Groenkamp', Buitenpost, The Netherlands; (6)Rijksuniversiteit Groningen, Groningen, The Netherlands.

**OBJECTIVES:** In Dutch primary care, electronic patient records are widespread and there is increasing capacity for sharing information between general medical practitioners and community pharmacists. This study explores the feasibility and utility of a previously studied medication assessment tool (MAT<sub>CVC</sub>) as an instrument to facilitate co-operation in guideline implementation.

**METHODS:** Cross-sectional survey of cardiovascular medication use based on a set of UK audit criteria modified after consultation with local physicians to ensure relevance to Dutch guideline recommendations. All patients with cardiovascular risk factors (hypertension- HTN, diabetes-DM) and/or manifest chronic diseases of the circulatory system (coronary heart disease-CHD, transient ischaemic attack-TIA, stroke, peripheral arterial disease-PAD, chronic heart failure-CHF, atrial fibrillation-AF) were identified from electronic records. Relevant patient data were abstracted from records of two pharmacies and five general practitioners in a rural Dutch setting. For individual patients under their care, each general practitioner will examine apparent guideline non-adherences and validate the care issues arising from the audit.

**RESULTS:** (Research in progress): In a total of 12,844 patients we have identified 1,879 (14.6%) patients with risk factors (HTN 1317 (10.3%), DM 569 (4.4%) and/or manifest diseases of the circulatory system (CHD 233 (1.8%), TIA/stroke 165 (1.3%), PAD 62 (0.5%), CHF 43 (0.3%), AF 132 (1.0%). The study will be completed by March 2009. Data on the following outcome measures will be presented: Inter-rater reliability (Cohen's  $\kappa$ ) and prevalence of insufficient data as measures of feasibility; population measures of adherence (%) to MAT<sub>CVC</sub>; frequency distribution of apparently unmet drug therapy needs (care issues) per patient; proportion of care issues judged to require clinical action (checks or changes) and the nature of checks/changes required; prevalence and nature of justified deviations from guideline recommended treatments.

**CONCLUSIONS:** The results of this study will inform the development

of a multidisciplinary quality assurance system for chronic medication use in primary care.

## Rheumatology

**296. How the community pharmacist contributes to the multidisciplinary management of rheumatoid arthritis.** Guillaume Landry, Student,<sup>1</sup> *Virginie Nerich, D.r.*,<sup>1</sup> Anne Sophie Woronoff, Dr.,<sup>2</sup> Daniel Wendling, Pr.,<sup>3</sup> Marie-Christine Woronoff-Lemsi, Pr.<sup>1</sup>; (1)CHU Jean Minjoz, Pharmacy, Besancon, France; (2)Association Nationale de Défense contre l'Arthrite Rhumatoïde (ANDAR), 25000, France; (3)CHU Jean MINJOZ, Department of Rheumatology, Besancon, France.

**OBJECTIVES:** A multidisciplinary approach to managing patients suffering from rheumatoid arthritis is now recommended. The aim of this study is to define how the pharmacist contributes to the management of this disease by exploring the type of service he provides to patients and by assessing what patients expect from him.

**METHODS:** Two questionnaires were sent to pharmacists of the Franche-Comté region and to patients 1/of ANDAR and 2/attending multidisciplinary consultations of Besançon university hospital.

**RESULTS:** The 72 pharmacists participating in this survey (33.8%) felt that they had a role to play in dispensing drugs (98.6%), providing medical equipment (91.7%), educating patients about their treatment (87.5%) and providing moral support (79.2%). On the other hand, only 44.4% of them considered that they should inform patients about their illness and 36.1% about support associations. University training in this area during formal pharmacy studies is considered either "insufficient" or "very insufficient" in 70% of cases. Although 90.3% of the pharmacists think that additional training is necessary, only 37.5% had actually benefited from such training. Of the 135 patients (55.8%) who completed the questionnaire, 95.7% are on the whole "satisfied" with their pharmacist. They contact their pharmacist mainly for information about treatment not requiring drugs, medical equipment, dietetics, herbal medicine and homeopathy. However, the pharmacist comes in only third position, behind specialists and general practitioners, for any request of information related to treatments requiring drugs. Patients' three primary expectations regarding the pharmaceutical management of their disease are as follows: availability of brochures about rheumatoid arthritis, home delivery of drugs whenever necessary, and advice regarding specific medical equipment.

**CONCLUSIONS:** In spite of biases, this study allowed us to assess the expectations of rheumatoid arthritis patients with regard to the pharmaceutical management of their disease, thus clarifying the indispensable contribution that pharmacists make in the management of this disease.

## LATE BREAKERS

### ADR/Drug Interactions

**297. Impact of acid suppression therapy on response to iron replacement for iron deficiency anemia.** *Liza Barbarello-Andrews, Pharm.D.*, Cynthia DePiano, Pharm.D.; Rutgers, The State University of New Jersey, and the University Medical Center at Princeton, Princeton, New Jersey, USA.

**OBJECTIVES:** Theoretically, oral iron absorption should be decreased by administration of chronic acid suppressant therapy (AST) as iron requires an acidic environment for optimal absorption. Since only two case reports describe this interaction with omeprazole, enough data do not exist to determine its clinical significance and if it should be taken into account when prescribing.

**METHODS:** Retrospective chart review including patients from a private, outpatient office setting was conducted in adult patients screened by ICD-9 code after acquiring expedited IRB approval. Those receiving both iron and AST with baseline and serial iron studies and hemoglobin/hematocrit values were selected. Primary outcomes compared percent change in iron studies (iron, TIBC) and Hg/Hct at approximately three and six months as indicators of clinical response.

**RESULTS:** Of the 372 patients screened, 19 patients met inclusion criteria. Ninety percent were female, ranging in age from 46 to 87 years. AST regimens included both histamine antagonists and proton pump inhibitors. Iron formulations included iron sulfate, iron gluconate and

polysaccharide iron complex. Compliance was not documented. Increase in hemoglobin from baseline varied from 2.5% to 36% (average 17%). Iron levels increased an average of 54% (ranging from 0 to 89%).

**CONCLUSIONS:** This initial pilot evaluation did not demonstrate a reproducible, clinically significant decrease in response to iron therapy when AST was concomitantly administered. However, limitations related to the retrospective nature of the study, lack of standardization in agents and regimens, and lack for compliance evaluation must be considered. While poor clinical response to iron therapy may be suspected in some cases based upon previous case reports, this study provides no data to suggest that routine alterations in current prescribing patterns should be implemented in anticipation of this reaction.

**298. Adverse drug reactions from psychotropic medicines reported for children: a retrospective analysis of Danish reports 1998–2007.** *Ebba H. Hansen, Professor, M.Sc., Pharm.*, Lise Aagaard, Ph.D. (Pharm); Department of Pharmacology and Pharmacotherapy, Section for Social Pharmacy, Faculty of Pharmaceutical Sciences, University of Copenhagen, Copenhagen, Denmark.

**OBJECTIVES:** To characterize reports on adverse drug reactions (ADRs) from psychotropic medicines in relation to the child's age and sex, medications, adverse reactions and seriousness; to explore if serious ADRs were mentioned in the product information.

**METHODS:** All ADRs for psychotropic medicines in children 0 to 17 years old reported to the Danish Medicines Agency 1998–2007 were analyzed.

**RESULTS:** Totally 429 ADRs were reported on psychotropic medicines; 60% serious. The largest shares were for infants and 13- to 17-year-olds. The most commonly reported reactions were psychiatric (20%), nervous (19%) and general disorders (12%). Serious ADRs were primarily reported for psychiatric and nervous system disorders. Serious ADRs reported for infants seemed to be related to the mother's use of medicines during pregnancy; two children died from SSRIs. Many medicines did not have an indication for children and were prescribed off-label. 33% of reported serious ADRs were not added to the product information.

**CONCLUSIONS:** Serious ADRs were reported for children on psychotropic medicines used off-label and in infants due to the mothers' use. Information reported on serious ADRs in children should be added to the product information.

## Adult Medicine

**299. Assessment of subcutaneous absorption of enoxaparin for deep vein thrombosis prophylaxis using anti-factor Xa level measurements in non-critically-ill mechanically-ventilated patients.** *Angela O. Shogbon, Pharm.D.*,<sup>1</sup> Steven B. Levy, Pharm.D., BCPS, CGP,<sup>2</sup> Wilfrid Herard, M.D.,<sup>2</sup> Maria Arias, R.N.C., B.S.N.,<sup>2</sup> Henry Cohen, M.S., Pharm.D., FCCM, BCPP, CGP<sup>3</sup>; (1)Mercer University College of Pharmacy and Health Sciences, Decatur, Georgia, USA; (2)Kingsbrook Jewish Medical Center, Brooklyn, New York, USA; (3)Arnold & Marie Schwartz College of Pharmacy and Health Sciences of Long Island University and Kingsbrook Jewish Medical Center, Brooklyn, New York, USA

**OBJECTIVES:** It is uncertain whether mechanical ventilation-induced physiologic changes in organ perfusion alter the pharmacokinetics of subcutaneous medications, particularly low-molecular-weight-heparins (LMWHs). This study compared anti-Xa levels in non-critically-ill patients who were mechanically-ventilated (MV) to those non-mechanically-ventilated (NMV) after subcutaneous administration of enoxaparin for deep vein thrombosis (DVT) prophylaxis.

**METHODS:** Single-center, non-randomized, prospective, open-label, pilot study performed in the ventilator care and medical units of a teaching hospital. Fifteen MV patients (study group) and fifteen NMV patients (control group) were evaluated. Patients were administered enoxaparin 30-mg or 40-mg subcutaneously once daily for DVT prophylaxis based on estimated creatinine clearance. Anti-Xa levels were obtained prior to initial dose and after at least 3 days of enoxaparin therapy, 4 to 6 hours after administration (steady-state peak anti-Xa level). The primary endpoint was difference in mean peak steady-state anti-Xa levels between both groups. Secondary endpoints were percentage of patients with therapeutic anti-Xa levels (0.3–0.7 IU/mL), correlation between various study parameters and peak anti-Xa levels,

and adverse outcomes.

**RESULTS:** There was no statistically significant difference in mean peak steady-state anti-Xa levels between control and study groups ( $0.33 \text{ IU/mL} \pm 0.16$  vs.  $0.30 \text{ IU/mL} \pm 0.12$ , respectively;  $p=0.529$ ). However, a greater number of patients in the control group were within therapeutic anti-Xa range compared to the study group (73.3% vs. 53.3%, respectively;  $p=0.256$ ). No significant correlation was found between any of the study parameters and mean peak steady-state anti-Xa levels in either group.

**CONCLUSIONS:** In this non-critically-ill population receiving enoxaparin for DVT prophylaxis, despite similar mean peak steady-state anti-Xa levels, there was a trend toward a greater number of MV patients with subtherapeutic anti-Xa levels compared to NMV patients. Therefore, larger scale randomized controlled trials are needed to confirm whether mechanical ventilation limits subcutaneous LMWH absorption, and the impact on thromboembolic event rates and adverse outcomes.

**300. Characterization of thromboprophylaxis failures in bariatric surgery patients.** Pamela M. Moye, Pharm.D., BCPS,<sup>1</sup> Celio Burrowes, M.D., FACS,<sup>2</sup> Teresa Pounds, Pharm.D., BCNSP<sup>2</sup>; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, Georgia, USA; (2)Atlanta Medical Center, Atlanta, Georgia, USA.

**OBJECTIVES:** The objective of this study was to characterize clinical and demographic factors associated with thromboprophylaxis failure in bariatric surgery patients.

**METHODS:** This retrospective case-control study identified all patients who underwent bariatric surgery between May 22, 2005, and May 21, 2008 ( $n=1,343$ ). Patients ( $n=11$ ), who were objectively diagnosed with a venous thromboembolism (VTE), were matched 1:10 to controls ( $n=110$ ) by age ( $\pm 5$  years), gender, and body mass index (BMI;  $\pm 5$  years). Baseline demographics, medication use and bleeding events were recorded. Patients either received enoxaparin preoperatively 30 mg, then 40 mg daily or unfractionated heparin (UFH) 5000 units preoperatively, then 5000 units q8h until discharge. No patient received thromboprophylaxis post discharge. Data were compared between cases and controls using *t* test, logistic regression, and  $\chi^2$  as appropriate. A subgroup analysis was also performed based on medication received for thromboprophylaxis.

**RESULTS:** Eighty-nine percent were female, 52% African-American, with BMI of  $48.6 \pm 8.7 \text{ kg/m}^2$  and 54% received enoxaparin for thromboprophylaxis. The mean time from discharge until the diagnosis of VTE was  $11 \pm 5.8$  days, with a mean scheduled follow-up appointment of 14 days post discharge. Overall, there were no statistically significant differences between cases and controls. Among cases who received UFH ( $n=7$ ), those with  $\geq 2$  additional risk factors (all patients had at least 5 RF) were at increased risk of developing a VTE compared to controls ( $n=50$ ) (OR=9.79; 95% CI:1.09-87.7). No demographic or clinical factors differed between cases and controls receiving enoxaparin thromboprophylaxis. No bleeding complications were documented.

**CONCLUSIONS:** No demographic or clinical factors were associated with increased risk of VTE in our bariatric surgery population. However, our data suggest that, fixed dose UFH use in bariatric surgery patients with two or more additional RF may be associated with increased risk of VTE. Additionally, the standard two-week follow-up after bariatric surgery may be insufficient.

## Cardiovascular

**301E. Carvedilol to bisoprolol therapeutic interchange in heart failure patients.** Doreen S. Tan, B.Sc.(Pharm), Ying Ru Ng, B.Sc.(Pharm) Hons; Alexandra Hospital, Singapore, Singapore.

**OBJECTIVES:** Both carvedilol and bisoprolol have been proven to significantly improve survival rates in NYHA classes I-III chronic systolic heart failure patients. Generic bisoprolol, at a cost of 82% less than Carvedilol, was added to our formulary. Moreover, bisoprolol is dosed once daily, which can lead to improved compliance as carvedilol is taken twice-daily. We aim to reduce drug costs for our heart failure patients through a carvedilol-bisoprolol therapeutic interchange programme, while ensuring that outcomes are not adversely affected.

**METHODS:** We recruited 161 subsidized patients on carvedilol from

June 2006 to January 2007. The interchange was made at a ratio of 5:1. Primary physicians were reminded via text messaging on the day of appointment, and were given the choice to switch to Bisoprolol or not. Patient Information Leaflets were given out to patients to explain the switch. We used the Minnesota Living with Heart Failure® Quality of Life (QoL) Questionnaire to gauge how patients were doing, at baseline (T0) and at an interval of approximately 2 months (T1). The QoL survey was carried out either by telephone or face-to-face interviews. Further, readmission rates were also tracked longitudinally 6 months before and after interchange.

**RESULTS:** After excluding 26 patients, eighty-five have been successfully converted, netting annual cost-savings of \$12,321. A t-test comparison of the QoL scores at T0 and T1 revealed non-statistically significant *p* value of 0.826. Readmission rates 6 months post-conversion were lower (10% vs. 18%). Fifty patients remained on Carvedilol.

**CONCLUSIONS:** The interchange programme saved money for our heart failure patients. QoL and readmission rates were not adversely affected by the switch to Bisoprolol. Moreover, branded Bisoprolol is now procured at a price comparable to generics. We advocate the use of cheaper Bisoprolol for NYHA I-III heart failure patients.

Presented at the Federation of Asian Pharmaceutical Associations Conference 2008, but I have updated information.

## Clinical Administration

**302. Anticoagulation Process Improvement utilizing FMEA.** Shah Nawaz Khan, B.S., Haider Syed, M.S., Saleem Ahmad, Ph.D.; Harlem Hospital Center, New York, New York, USA.

**OBJECTIVES:** FMEA (failure mode effects analysis) has become an important tool for patient safety related risk reduction at health care institutions. Anticoagulation therapy is high-risk drug treatment often associated with adverse drug events (ADEs) such as bleeding or thrombosis. Warfarin, an oral anticoagulant, had been routinely used at Harlem Hospital Medical Center (HHMC). In contrast to national average (5%), much higher warfarin related ADEs (12.5%) had been reported at HHMC. Under the supervision of department of pharmacy and in compliance with the Joint Commission NPSG 3E, a medication safety team at HHMC, conducted FMEA. The results of FMEA were utilized to implement strategies in improving anticoagulation process.

**METHODS:** A team of professionals (doctors, nurses and pharmacists) was assembled. In order to assess process and possible system failures, a work sheet (similar to GNYHA or ISMP work sheet) was developed. Following brainstorm meeting, a practice session was arranged to educate team members with FMEA. During initial analysis, team members identified associated steps or system components that could fail ("failure modes") in anticoagulation process. Following discussion, team members agreed upon scoring criteria for the probability of failures and associated severity. FMEA test was successfully conducted. The results were analyzed which identified potential failure modes that could be improved or controlled by an intervention. Subsequently, strategies for improvement of anticoagulation process were developed and implemented.

**RESULTS:** Analysis of FMEA results revealed several failure modes that included prescribing knowledge deficit, laboratory test ordering and monitoring error, failure in recognizing drug-drug interactions and insufficient patient counseling. Following implementation of corrective measures, effectiveness of actions taken was evaluated. As compared to baseline, follow up data demonstrated significant reduction in warfarin related ADEs.

**CONCLUSIONS:** A post-FMEA system modification and refinement in anticoagulation process produced significant reduction in warfarin related ADEs at HHMC.

**303. Compliance with SCIP antibiotic standards among hospitals in a group purchasing organization.** Scot E. Walker, Pharm.D., M.S.; Amerinet, Inc., St. Louis, Missouri, USA.

**OBJECTIVES:** Beginning in 2010, Medicare reimbursement for hospitals will be decreased for facilities whose core quality measure scores are too low. To help facilities belonging to a group purchasing organization improve their scores related to the Surgical Care Improvement Project (SCIP) antibiotic standards we analyzed current SCIP scores to identify

areas for an educational program.

**METHODS:** Using a database of SCIP scores for U.S. hospitals we used facility identifiers to select a sample of hospitals. The average SCIP scores of these facilities were compared to national averages. A weighted average score was also calculated by multiplying each hospital's score by its procedure volume. It was not possible to test the significance of the differences in the scores, because the method of calculating the national averages was not described.

**RESULTS:** We identified 850 hospitals for the analysis. The average hospital in the group reported the percentage of surgery patients who received preventative antibiotic(s) one hour before incision of 82% with a weighted average of 88%, compared to the national average of 84%. The average hospital in the group reported a percentage of surgery patients who received the appropriate preventative antibiotic(s) for their surgery of 91% with a weighted average of 94%, compared to the national average of 91%. The average hospital in the group reported the percentage of surgery patients whose preventative antibiotic(s) was stopped within 24 hours after surgery of 80% with a weighted average of 83%, compared to the national average of 82%.

**CONCLUSIONS:** The performance for SCIP quality measures involving antibiotics was similar to national performance by this group of hospitals. While hospitals appear to have appropriate measures in place to select a recommended antibiotic, additional measure are needed to make sure the antibiotic is given on time and discontinued within 24 hours.

## Critical Care

**304. Frequency of carbapenem usage with medications that undergo glucuronidation in the critically ill.** *Troy D. Kish, Pharm.D.,<sup>1</sup> Henry Cohen, MS, Pharm.D., FCCM, BCPP, CGP,<sup>2</sup> Bishoy Luka, Pharm.D.,<sup>1</sup> Rajat Mukherji, M.D.;* (1)Kingsbrook Jewish Medical Center, Brooklyn, New York SA; (2)Arnold & Marie Schwartz College of Pharmacy, Health Sciences of Long Island University, and Kingsbrook Jewish Medical Center, Brooklyn, New York, USA.

**OBJECTIVES:** Sixty percent of valproic acid (VPA) metabolism constitutes a Phase I reaction via microsomal and mitochondrial oxidation; 40% undergoes glucuronidation to VPA-glucuronide (VPA-G), an inactive metabolite which can be hydrolyzed back to active VPA; and <3% is unchanged in the urine. Carbapenems cause a decline in plasma VPA levels and increase urinary concentrations of VPA-G. Mammalian studies report three possible mechanisms for this interaction: induction of UDP-glucuronosyltransferase (UGT), a glucuronidation enzyme; increase of uridine-5'-diphosphate-D-glucuronic acid (UDGPA), a catalyst used in hepatic glucuronidation; and inhibition of  $\beta$ -hydrolase which converts VPA-G back to VPA. Since 1997, 15 publications expounding on over thirty cases have been reported worldwide. The FDA placed a precaution for all carbapenems stating, "...alternative antimicrobial or antiepileptic therapy should be chosen in these select patients." The Ministry of Health and Welfare in has banned the concomitant use of these medications. We hypothesize that the concurrent use of carbapenems with medications that undergo glucuronidation occurs frequently in the ICU, and may potentially render these medications inactive.

**METHODS:** A report was generated to identify ICU patients receiving a carbapenem  $\geq$  7 days between 05/01/08 and 11/20/08. A MEDLINE search from 1995 to December 2008 was conducted to identify substrates of glucuronidation. We assessed the frequency of concomitantly prescribing carbapenems and agents that undergo glucuronidation in the ICU.

**RESULTS:** Out of 50 patients, 48 (96%) were concomitantly prescribed a carbapenem and at least one substrate of glucuronidation. Most common substrates included acetaminophen (32; 67%); metronidazole and furosemide (22; 46%); lorazepam (11; 23%); morphine (8; 17%); and hydromorphone (7; 15%).

**CONCLUSIONS:** In the ICU, carbapenems are frequently prescribed with agents undergoing glucuronidation. Clinicians should be cognizant of the high prevalence of carbapenems being co-administered with medications undergoing glucuronidation and may consider using alternative agents to prevent possible interactions.

## Drug Information

**305. Selective digestive decontamination suspension: galenic, physico-chemical and microbiological stability.** *Aur lie Le Ridou, Pharm.D., Ronan Barbotin, Pharm.D., Olivier Tribut, Pharm.D., Loic Javaudin, Pharm.D., Gilles Dollo, Pharm.D, Ph.D.;* Rennes University Hospital, Rennes, France.

**OBJECTIVES:** Selective digestive decontamination (SDD) is a prophylactic strategy used to reduce the incidence of respiratory tract infections in critically ill patients intubated and mechanically ventilated. In our hospital, from June 2007 to June 2008, about 10 patients have received daily a prophylactic SDD as a suspension (15 ml qid). Our Pharmacy Department prepares batches of 60 ml vials filled with an antibiotic containing solution (colimycin and tobramycin) and an antifungal suspension (amphotericin B). The objective was to study the physico-chemical, galenic and microbiological stability of the SDD suspension stored between +2 and +8°C in order to validate or modify the shelf-life initially fixed to 7 days.

**METHODS:** The stability study consisted in visual examination, pH determination, granulometric analyse (Mastersizer, Malvern Instruments®), zeta potential measurement (NanoZS, Malvern Instruments®), microbiological contamination (Bactec® aerobic and anaerobic) and drug concentration assay (using Fluorescence Polarisation Immuno Assay for tobramycin and specific and sensitive LC-MS/MS technique for colimycin and amphotericin B). Each analyse was carried out on 3 different batches, from resistant-light vials taken off at day 0, 7, 14, and 21.

**RESULTS:** The orange aspect of the suspension did not change from day 0 to day 21. The pH remained statistically unchanged (student *t*-test) from day 0 (pH = 8.31  $\pm$  0.02) to day 14 (pH = 8.27  $\pm$  0.03) but a significant decrease was seen at day 21 (pH = 8.25  $\pm$  0.02; p<0.05) despite the lack of microbiological contamination from day 0 to day 21. During the study period, no significant modification was observed for particles mean volumetric diameters (around 4.8  $\mu$ m) neither for zeta potential measurements (around -17 mV). For each drug tested, drug concentrations remained statistically unchanged during the study period.

**CONCLUSIONS:** Under our storage conditions, the oral suspension was seen to be stable for at least 14 days that allowed us to extent the expiry date from 7 to 14 days.

## Education/Training

**306. Preparation of pharmacy clerkship students for advanced pharmacy practice experiences.** *Kellie L. Bennett, Pharm.D., BCPS,<sup>1</sup> Amy Lullo, R.Ph.,<sup>2</sup> Susan Cornell, Pharm.D., CDE<sup>2</sup>;* (1)Sullivan University College of Pharmacy, Louisville, Kentucky, USA; (2)Midwestern University, Chicago College of Pharmacy, Downers Grove, Illinois, USA.

**OBJECTIVES:** Colleges of pharmacy are continually monitoring and trying to improve their standards to better prepare their students. Very few studies have been published evaluating the methods to preparing pharmacy students for their clinical rotations. The primary objective of this research was to observe the methods colleges of pharmacy use to assess preparedness for experiential rotations, and especially, whether or not different schools have an exam that students are required to pass prior to starting these rotations.

**METHODS:** Using a list serve for pharmacy schools in the United States, a survey was sent to the director or associate director for the Office of Experiential Education at each school. The survey included questions regarding final experiential experiences and any efforts made prior to rotations to help prepare students for these experiences.

**RESULTS:** The overall response rate for the entire survey was 27.2%. Forty-seven respondents (52.8%) felt their students were well prepared to begin their final experiential rotations. Of the various methods reported, the most common requirement for students was a minimum GPA requirement (61.5% of respondents). The required GPA ranged from 2.0 to 3.2 on a 4.0 scale. Other common assessments that were reported included a final cumulative exam (24%), a top 200 test (27.4%), a calculations test (26.4%), and a laboratory competency (36.2%). If the specific requirement was not met, remediation was the most common action taken; however, many other alternatives were reported. 98.4% of the responders reported that only 0-5% of their students fail a rotation due to knowledge deficits.

**CONCLUSIONS:** Many different methods are used to assess the preparedness of students prior to starting their final experiential experiences. Regardless of what the requirement is, there is really no clear cut answer as to what should be done if the student fails to meet the requirement.

**307. Comparison of students' perceptions of preparedness for an oral examination versus a written examination.** *Justine Gortney, Pharm.D., BCPS, Lisa M. Lundquist, Pharm.D., BCPS, Phillip S. Owen, Pharm.D., BCPS; Mercer University, Atlanta, Georgia, USA.*

**OBJECTIVES:** To determine the relationship between students' preparedness for oral versus written examinations in a therapeutics course.

**METHODS:** During a second year therapeutics course, instructors incorporated an oral examination along with traditional written examinations. IRB approval was obtained, participation was voluntary and students signed informed consent. The oral examination incorporated a patient case with corresponding disease states and therapies previously tested in a written format. Prior to taking each examination, a perceptions questionnaire was distributed to the students. This one-page questionnaire consisted of questions related to therapeutics topics on the examination. 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. Primary endpoints were evaluated by the Wilcoxon Rank Sum test and included the students' overall perception of preparedness on both the oral and written examinations. Secondary endpoints included a correlation of perceived preparedness and actual performance (score of survey versus score on test question) and comparison of examination scores. These secondary endpoints were evaluated using Pearson correlation and paired *t*-tests.

**RESULTS:** Of the 143 students, eighty five students completed both questionnaires. There was no difference in students' perception of preparedness for the oral versus written examination ( $p=0.13$ ). Overall, students' perception of preparedness was  $3.11 \pm 0.38$  and  $2.99 \pm 0.14$  for the oral and written examinations, respectively. Correlation of perceived preparedness and actual performance varied by type of test taken with less on the oral ( $r=0.13$ ) than the written ( $r=0.42$ ). A significant difference was found in examination averages ( $P<0.01$ ) with higher scores on oral ( $94.15 \pm 6.10$ ) versus the written ( $84.87 \pm 6.35$ ).

**CONCLUSIONS:** There was no difference in students' perception of preparedness for oral and written examinations, but their perception of preparedness did not always correlate with examination grade.

**308. Therapeutic education for stroke hypertensive patients: preliminary results of a pilot study.** *Beaussier Hélène,<sup>1</sup> Rouault Anne,<sup>1</sup> Houot Mélanie,<sup>1</sup> Bézie Yvonnick,<sup>1</sup> Zuber Mathieu<sup>2</sup>;* (1)Department of Pharmacy Groupe Hospitalier Paris Saint Joseph, Paris, France; (2)Department of Neurology Groupe Hospitalier Paris Saint Joseph, Paris, France.

**BACKGROUND:** Hypertension (HT) increases arterial stiffness that contributes to generate ischemic events. Medication adherence and lifestyle factors are the main identified contributors of uncontrolled blood pressure under antihypertensive medication. Therapeutic education (TE) focused on antihypertensive medication may be of primary importance in stroke patients considering the major causal role of HT in cerebrovascular events.

**OBJECTIVES:** To assess stroke patients' experience of HT and their motivation to undergo TE sessions, in order to consequently develop a standardized TE program adapted to such patients.

**METHODS:** A three months preliminary survey was conducted in hypertensive patients prospectively hospitalized in a stroke unit for an acute cerebral ischemic event and treated for HT before or following stroke. The support was an "open and short questions" questionnaire divided into three parts: the medical patient abilities to participate, the patient knowledge about HT and the TE patient approach.

**RESULTS:** 28 patients participated in the survey (14 women, 14 men; age: 50 to 85 years). 17 patients were treated for HT before hospitalization. Two patients were excluded because of medical inability and 9 patients had minor attention troubles. 35% of patients had a good knowledge about HT, 30% and 35% had few or no notion, respectively.

One third of the patients ignored their HT. Half of patients was motivated to undergo TE sessions, 23% were undecided and 27% were not interested. Most motivated patients asked for more information about the disease, its complications and treatment management. Among them, 54% had a good knowledge about HT whereas 85% of undecided and uninterested patients had few or no notion about HT.

**CONCLUSIONS:** To prevent cardio- and cerebrovascular risks in stroke patients, it may be firstly important to motivate patients, in order to secondly improve their knowledge and cooperation using TE programs.

**309. Impact of a student-supported pharmacy assessment program on venous thromboembolism assessment and prophylaxis rates in hospitalized patients.** *Laura E. Butkivich, Pharm.D.,<sup>1</sup> Zachary A. Stacy, Pharm.D., BCPS,<sup>2</sup> Michael W. Daly, Pharm.D., BCPS,<sup>2</sup> Way Y. Huey, Pharm.D., FCCM, BCPS,<sup>3</sup> Charles T. Taylor, Pharm.D., BCPS<sup>4</sup>;* (1)University of Missouri Hospital and Clinics, Columbia, Missouri, USA; (2)St. Louis College of Pharmacy, St. Louis, Missouri, USA; (3)St. Luke's Hospital, Chesterfield, Missouri, USA; (4)University of Minnesota College of Pharmacy, Minneapolis, Minnesota, USA.

**OBJECTIVES:** Model experiences are needed to demonstrate appropriate integration of pharmacy students into health-systems to enhance existing clinical services and meet the Accreditation Council for Pharmacy Education (ACPE) requirement that pharmacy students be able to provide population-based care upon graduation. One potential clinical service is venous thromboembolism (VTE) prophylaxis, which remains underused in many institutions despite the existence of evidence-based consensus guidelines. The objective of this study was to determine if the addition of a pharmacy student-supported VTE risk assessment strategy could improve rates of VTE prophylaxis.

**METHODS:** After receiving education and training on how to use a pre-existing institutional VTE risk assessment form, pharmacy students assessed newly admitted patients throughout a 493-bed community teaching hospital for a total of 5 weeks. Students made recommendations to initiate VTE prophylaxis under the supervision of a pharmacy resident or preceptor. The primary clinical endpoints included the total number of patients assessed for VTE risk, number in need of VTE prophylaxis, and number who received "any", "suitable", and "optimal" VTE prophylaxis. VTE prophylaxis rates were compared to previously collected rates at the hospital.

**RESULTS:** A total of 554 patients were assessed for VTE risk with 295 patients meeting the inclusion criteria. One hundred and three recommendations were made to physicians with 41% of these recommendations being accepted. Compared to previous rates, the percentages of patients receiving "any", "suitable", and "optimal" VTE prophylaxis increased from 70.5% to 82.7% ( $p=0.0005$ ), 64.4% to 75.9% ( $p=0.0022$ ), and 56.3% to 68.5% ( $p=0.0022$ ), respectively.

**CONCLUSIONS:** A student-supported VTE risk assessment strategy resulted in a significant increase in VTE prophylaxis rates at a community teaching hospital, and could be used as a model for other institutions to help meet the ACPE requirement that pharmacy students be able to provide population-based care upon graduation.

## Gastroenterology

**310. Protective effects of Nigella sativa oil on antituberculous drug combination-induced hepatotoxicity in rats.** *Nur Sener, M.Sc.,<sup>1</sup> Fikret V. Izzettin, Prof.,<sup>2</sup> Ozlem Ozakpinar, M.Sc.,<sup>1</sup> Murat B. Rabus, M.D.,<sup>3</sup> Betül Okuyan, M.Sc.,<sup>2</sup> Mesut Sancar, Ph.D.,<sup>2</sup> Elcin Yorukoglu, Pharm.,<sup>2</sup> Fikriye Uras, Prof<sup>1</sup>;* (1)Marmara University Faculty of Pharmacy, Biochemistry Department, Istanbul, Turkey; (2)Marmara University Faculty of Pharmacy, Clinical Pharmacy Department, Istanbul, Turkey; (3)Kosuyolu Heart and Research Hospital, Cardiovascular Surgery Department, Istanbul, Turkey.

**OBJECTIVES:** This study aims to investigate the protective effect of *Nigella sativa* oil on antituberculous drug combination (isoniazid and rifampicin)-induced hepatotoxicity in rats.

**METHODS:** Male Wistar albino rats weighing 200–300g were divided into four groups, each consisting of 5 rats: control group 1 (normal saline 0.2 mL/kg; intraperitoneal injection [i.p.]); control group 2 (*Nigella sativa* oil 0.4 mL/kg; i.p.); hepatotoxicity model (isoniazid 50 mg/kg; i.p. and rifampicin 100 mg/kg; i.p.); and treatment group (isoniazid 50 mg/kg; i.p. and rifampicin 100 mg/kg; i.p. and *Nigella*

*sativa* oil 0.4 mL/kg; i.p.). The animals were treated for 10 days. Serum liver functions tests and histopathological examination of liver tissues were carried out to investigate the protective effect of *Nigella sativa* oil on antituberculous drug combination-induced hepatotoxicity in rats.

**RESULTS:** Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin levels were significantly lower for the treatment group when compared with hepatotoxicity model ( $p < 0.05$ ). Histopathological examination of liver tissues revealed no significant difference between groups; however degeneration observed in liver tissues of the treatment group was lower than that observed in the tissues of hepatotoxicity model ( $p > 0.05$ ).

**CONCLUSIONS:** *Nigella sativa* oil was found to have protective effect on antituberculous drug combination- induced hepatotoxicity in rats.

## Hematology/Anticoagulation

**311. Pharmacist-managed direct thrombin inhibitor therapy improves safety in patients with heparin-induced thrombocytopenia.** Bob Lobo, Pharm.D.,<sup>1</sup> Amanda M. Howard-Thompson, Pharm., D.,<sup>2</sup> Mandy Gillion, Pharm.D.,<sup>3</sup> Christopher Finch, Pharm.D.<sup>2</sup>; (1)Vanderbilt University, Nashville, Tennessee, USA; (2)University of Tennessee College of Pharmacy, Memphis, Tennessee, USA; (3)Methodist University Hospital, Memphis, Tennessee, USA.

**OBJECTIVES:** Heparin-induced thrombocytopenia is generally treated with direct-thrombin inhibitors. However, use of direct-thrombin inhibitors requires careful dosing and monitoring in order to reduce the risk for bleeding and other complications. The objective of this study was to determine whether pharmacist managed direct-thrombin inhibitor therapy was safer than standard care.

**METHODS:** Use of direct-thrombin inhibitors was initially assessed during a two-year period (January 2005–February 2007). Despite use of a protocol to manage the direct-thrombin inhibitor anticoagulation, the initial assessment concluded that there were significant safety concerns with direct-thrombin inhibitor use. Since pharmacists were already assisting with anticoagulation in other populations, it became hospital policy that pharmacists would be responsible for managing direct-thrombin inhibitors in all patients with heparin-induced thrombocytopenia. This study compared the safety of direct-thrombin inhibitor use in patients with heparin-induced thrombocytopenia before and after the policy for pharmacist managed therapy. A similar dosing and monitoring protocol was used in all patients during the initial assessment phase and the follow-up phase.

**RESULTS:** There were 18 patients treated with direct-thrombin inhibitors during the initial assessment and ten during the follow-up assessment. Improved safety with pharmacist managed direct thrombin inhibitor therapy compared to the initial period was noted as evidenced by the following: inappropriate lepirudin bolus reduced (50% versus 0%), incorrect direct-thrombin inhibitor rate reduced (33% versus 0%), initial aPTT drawn at appropriate time (39% versus 70%), major bleeding reduced (17% versus 0%), inappropriate re-exposure to heparin reduced (39% versus 0%).

**CONCLUSIONS:** Pharmacist managed direct-thrombin inhibitor therapy improved the safety of anticoagulation in patients with heparin-induced thrombocytopenia.

## Infectious Diseases

**312. Role of ward pharmacist in management of systemic antifungal drugs in hematology department of San Giovanni Battista Hospital, Turin, Italy.** Francesco Cattel, Structured Pharmacy, Manager, Massimo Massaia, Professor of Hematology, Annalisa Gasco, Structured Pharmacy Manager, Matilde Scaldaferrri, Specializing Pharmacist, Angelo Potenzieri, Specializing Pharmacist, Candida Vitale, Physician, Eleonora Cerutti, Specialized Pharmacist, Sara Boffa, Specialized Pharmacist, Evelyn J. Pennone, Specializing Pharmacist, Lara Tomatis, Specializing Pharmacist, Silvana Stecca, Director, Pharmacy Manager; San Giovanni Battista Hospital, Turin, Italy.

**OBJECTIVES:** This study evaluated Invasive Fungine Infections (IFI) epidemiology and treatment approach, in terms of prophylaxis, empirical, pre-emptive or target therapy, in Hematology Dept. of San Giovanni Battista Hospital and compared prescribed antifungal therapy to ECIL2007 Guidelines.

**METHODS:** Medical records of 145 patients admitted between May 1

and October 31, 2008 were reviewed. Patient's medical history and in-hospital course were documented.

**RESULTS:** Systemic antifungal drugs were prescribed in 61.0% of patients; of these, 56.2% and 19.1% were, respectively, multiple myeloma and Non-Hodgkin Lymphoma patients. We found 12 possible IFI, 1 probable IFI and 1 proven IFI cases; thus incidence of proven and probable IFI in the overall population was 1.37%. In antifungal treated population, treatment was conducted as primary prophylaxis in 78.7%, secondary prophylaxis in 2.2%, empirical therapy in 5.6% and pre-emptive therapy in 2.2% of patients, while 7.9% of them had primary prophylaxis followed by empirical (1.1%) or pre-emptive therapy (6.7%), or pre-emptive subsequent to empirical therapy (2.2%). Shift to pre-emptive therapy was due to evidence of suggestive signs in TC results. ABMT (autologous bone marrow transplant) was performed in 35.1% of patients who underwent prophylaxis. Primary prophylaxis patients received fluconazole (80.2%), posaconazole or itraconazole (5.2%, respectively); 5.8% of patients had sequence prophylaxis. Empirical therapy was conducted mainly with itraconazole or lipid-complex amphotericin B. In pre-emptive therapy, mostly used drugs were voriconazole and fluconazole, sequences liposomal amphotericin-B–voriconazole and liposomal amphotericin-B–caspofungin–voriconazole were also used. Voriconazole was the drug of choice in target therapy.

**CONCLUSIONS:** We found a good degree of adherence to international Guidelines recommendations, such as ECIL2007 Guidelines. The results of this study highlight the shift of possible/probable IFI and pre-emptive approach concepts from literature to clinical practice but define the need for precise definition of pre-emptive therapy in terms of drug choice.

**313E. Comparison of linezolid (LZD) and daptomycin (DAP) for vancomycin-resistant enterococcus bacteremia (VREB).** Laura LoCastro, Pharm.D.,<sup>1</sup> Jason C. Gallagher, Pharm.D., BCPS<sup>2</sup>; (1)University of the Sciences in Philadelphia, Philadelphia, Pennsylvania, USA; (2)Temple University Hospital, Philadelphia, Pennsylvania, USA.

**OBJECTIVES:** To compare the microbiological cure rate of LZD and DAP for the treatment of VREB. Due to the lack of clinical data supporting the use of any particular antibiotic for VREB, and high mortality rate, the objective was to support the use of a particular antibiotic for VREB.

**METHODS:** Retrospective cohort study of patients who received either LZD or DAP for the treatment of VREB from January 2004 to March 2008. Patients were included if they received LZD or DAP and had a positive blood culture for VRE. Patients were excluded if they had a negative culture prior to the initiation of LZD or DAP, or received less than 3 days of therapy. Primary endpoint was microbiological cure, defined as negative blood cultures for VRE at the end of therapy (EOT). Clinical outcomes at the EOT and adverse events were evaluated. Clinical outcomes were defined as positive (clinical cure or improvement), negative (clinical worsening or death within 7 days of the EOT), or indeterminate. Between group comparisons were made using the student's t-test or chi-square test as appropriate.

**RESULTS:** 76 patients were included; 45 patients received LZD and 31 patients received DAP. Median duration of therapy was similar between groups (LZD 11 days [4–62], DAP 13 days [1–91],  $p = \text{NS}$ ), as was the median duration of VREB after the drug was started (LZD 2 days [1–11], DAP 2 days [0–24],  $p = \text{NS}$ ). Characteristics were similar between groups, except thrombocytopenia was more common at baseline in DAP group (48.4% vs. 17.8%,  $p < 0.05$ ). No difference in VREB microbiological cure in patients who received LZD compared to DAP (88.9% vs. 80.6%,  $p = \text{NS}$ ). Clinical success occurred in 46.6% of patients receiving LZD compared to 58.1% in the DAP group ( $p = \text{NS}$ ).

**CONCLUSIONS:** DAP and LZD therapy for VREB results in similar outcomes. Our report suggests that either agent may be used to treat VREB.

Presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy/Infectious Diseases Society of America 46th Annual Meeting, Washington, District of Columbia, USA, October 25–28, 2008.

**314. Antibiotic failure rates in outpatient community acquired pneumonia.** *Brooke Pugmire, Pharm.D., Peet de Villiers, Pharm.D., Rex Force, Pharm.D.; Departments of Family Medicine and Pharmacy Practice, Idaho State University, Pocatello, Idaho, USA.*

**OBJECTIVES:** North American guidelines recommend macrolides first-line for outpatient treatment of community acquired pneumonia (CAP), but European guidelines favor  $\beta$ -lactams due to increasing *Strep. pneumoniae* resistance to macrolides. We compared macrolide,  $\beta$ -lactam, and fluoroquinolone failure rates among CAP outpatients.

**METHODS:** Paid medical and pharmacy claims were analyzed from January 2006 through November 2008 among adults aged 18–64 years to identify cases of pneumonia. Cases with risk factors for drug-resistant pathogens (hospitalization or antibiotic exposure in the previous 90 days) were excluded. Office visits for CAP were identified and linked to an oral antibiotic claim within five days. Cases were grouped by initial antibiotic class prescribed. Apparent treatment failures were defined as a subsequent hospitalization for pneumonia or a claim for a different antibiotic within 14 days. Failure rates were compared between antibiotic groups.

**RESULTS:** A total of 2,504 cases of outpatient CAP were analyzed over the study period. The percent of office visits without a linked oral antibiotic was 75.3%. Among the 550 cases initially treated with a single antibiotic, 259 (47.1%), 146 (26.5%), and 107 (19.5%) were with a macrolide, fluoroquinolone, and  $\beta$ -lactam, respectively. Among cases treated initially with a macrolide, 12.7% had an apparent treatment failure. In comparison, apparent failure rates for initial fluoroquinolone and beta-lactam users were 11.6% ( $p=0.747$ ) and 4.7% ( $p=0.021$ ), respectively. Rates of failure were not different between the fluoroquinolone and beta-lactam groups ( $p=0.052$ ).

**CONCLUSIONS:** Among cases of outpatient CAP, apparent treatment failure rates were significantly higher for macrolides compared with  $\beta$ -lactams. High-dose  $\beta$ -lactam monotherapy likely remains effective for outpatient treatment of CAP.

## Medication Safety

**315. Audit of errors and quality of patient medication hospital discharge information.** *Tommy Eriksson, Assy.Prof., Ph.D., M.Sc.Pharm., Emma Hamrin, M.Sc.Pharm., Åsa Bondesson, Ph.D., M.Sc.Pharm.; Hospital Pharmacy, University Hospital, Lund, Sweden.*

**OBJECTIVES:** As part of a Medication Reconciliation programme (within the Lund-model) we have developed a tool, Discharge Information (DI). It is written for and given to the patient, and sent to primary and nursing/community care on the day of discharge. The DI includes a Medication Report, explaining medication changes and the reason for changes, and an updated Medication List. We have published evidences that the Medication Report decreases medication errors and health-care contacts. The DI is mandatory at Lund University Hospital and instructions are available. We performed an audit on implementation and quality aspects.

**METHODS:** A checklist for error and quality follow-up was developed based on qualitative methods and patient interviews. During 3 weeks in 2008 an audit of included discharged patients and wards (>5 drugs and >65years) were performed.

**RESULTS:** 16 of 37 (44%) wards had routines and produced at least one DI. In total 174 of 602 (29%) patients received a DI. Medication changes (what) and reasons for it (why) was without errors in 33 and 20% of the Medication Reports. The Medication List was correct in 53%. The general quality/readability for the patient was low with a mean of 2.3 errors. There were large differences between the different wards.

**CONCLUSIONS:** The audit checklist was easy to use and we found high error rates and low quality. The results have been presented and compared for each ward for improvement and a new audit will be performed. It is very important for our hospital to continue to lead the development since Medication Reconciliation now is highlighted nationally as one of the most important strategies for improving patient safety. Also the EUNetPas as approved the tool to be tested in hospitals within the EU.

**316E. Improving accessibility, effectiveness, safety and work life with pharmacy technician on the patient care units.** *T.H. Diem Vo, B.Pharm., M.Sc., MBA, Alain Biron, N. Ph.D.(C), Patricia Lefebvre, B. Pharm., M.*

*Sc., FCSHP, Linda Ward, M. Sc.(A); McGill University Health Centre, Montreal, Quebec Canada.*

**OBJECTIVES:** The objectives were: (1) document impacts of pharmacy technicians introduced on six patient care units for medication system's accessibility, effectiveness, safety and work life; (2) identify patient care unit characteristics where their contributions were most beneficial.

**METHODS:** A pre- and post- (6 months) design was used to evaluate potential impacts. Data was collected through direct observation (number of missing doses, medication preparation and missing doses resolution time), work sampling, self-report measure (Medication Administration System—Nurses Assessment of Satisfaction Scale (MAS-NAS) (Hurley et al., 2008), Work Climate survey (Gagnon et al., 2008), and structured interviews. Indicators of patient care units' characteristics (volume of prescriptions, patient-days, admissions, average length of stay) were collected from the organization's administrative databases.

**RESULTS:** Following introduction of pharmacy technicians, the proportion of missing doses decreased (pre=9.3%, post=6.9%;  $p=0.045$ ), nurses spent less time solving medication availability problems (pre=2:39 min, post=0:32 min;  $p=0.02$ ), and nurses medication preparation time decreased (pre=20:57 min post=12:39 min;  $p=0.01$ ). Proportion of time spent by clinical pharmacist on technical tasks decreased (pre=4.5%, post=2.5%;  $p>0.05$ ). As for medication safety, proportion of missing doses compensated by nurses in taking from another patients stock or stockpile medication decreased (pre=65.8%, post=30.8%,  $p<0.001$ ). Work life of pharmacy technicians' improved as they reported feeling more valued although challenges were present. Clinical pharmacists expressed more satisfaction with increased time for clinical activities. Nurses' satisfaction with the medication system improved ( $p<.001$ ). The magnitude of benefits depended on the following characteristics: presence of clinical pharmacist, prescriptions volume, and quantity and variety of floor stock medication.

**CONCLUSIONS:** Introducing pharmacy technicians on patient care units improved medication system's performance, and work life of nurses and Pharmacy employees. Medication system's improvements are possible with optimization of existing resources.

Some of the results will be presented at the International Forum on Quality and Safety in Health Care 2009, Berlin, Germany, March 18–20, 2009.

## Oncology

**317E. Prespective experience in the Italian Piedmont network for oncology of complex cooperation among oncologists, pharmacists and nurses in a modern oncology unit.** *Elena Giubellino, Ph.D., Cristiano Oliva, M.D., Alessandro Comandone, M.D.; Gradenigo Hospital, Turin, Italy.*

**OBJECTIVES:** To individualize collaboration areas of Clinical Pharmacist in the Oncology Team in Italian experience.

**METHODS:** From March 2007, we implemented the direct collaboration among Oncologists, Nurses and Pharmacists. The constant presence of one Pharmacist in the Division of Oncology and in the Centralized Area for cytotoxic drugs handling is the new aspect of this cooperation

**RESULTS:** In 20 months of collaboration 7020 outpatient endovenous cycles of therapy, 1993 ambulatory distribution of oral drugs and 1551 inpatients chemotherapy courses were administered. We assessed 7 main areas of collaboration: (1) Pharmaceutical: in-use and beyond-use stability, conservation of the solutions after reconstitution or dilution, sterility evaluation, drugs-drugs and device-drugs compatibility, preservation temperature. (2) Clinical Governance: centralised and computer assisted preparation of cytotoxics, adoption of closed systems for handling cytotoxics. Environmental management of medical wastes and residual drugs to be discarded. (3) Legal: evaluation of legal aspects about hazardous drugs, application of the rules for off label therapies, distribution of oral drugs, collaboration in investigative studies, adjournment of EMEA and AIFA decisions, GCP studies monitoring. (4) Galenical preparation of supportive care agents (eg., mouthwashes for mucositis). (5) Patient education: administration of educational materials and counselling to improve adherence to treatment protocols. (6) Economical process analysis: cost effectiveness of different treatment, File-F procedures accomplishment. (7) Educational Program: weekly check-up of the system; monitoring and changing of the critical moments of the procedure.

**CONCLUSIONS:** In our experience a strict and daily cooperation among Oncologists, Pharmacist and Nurses is mandatory for a safe and cost-effective preparation and administration of cytotoxics.

Presented at the 37th European Symposium on Clinical Pharmacy 22–24 October 2008 in Dubrovnik, Croatia.

**318. Compounding project: calcium levofolinate.** Anna Bianca Calzona, Pharmacy, Daniela Checquolo, Pharmacy Simona Ferraiuolo, Pharmacy, Giovanni Guarany, Pharmacy, Gerardo Miceli Sopo, Pharmacy, *Grazia Mingolla, Pharmacy*, Roberto Tazza, Pharmacy; Sandro Pertini Hospital, Rome, Italy.

**OBJECTIVES:** Calcium 10 mg/ml multi-dose packs (bags) are prepared at Clinical Laboratory of S. Pertini Hospital. Calcium Levofolinate is used in personalized therapies for some oncology regimes as FOLFOX, ROSWELL-PARK and DE GRAMONT. It is used to increase 5FU therapeutic effect administered as bolus or as continuative infusion. This study wants to validate the operating procedure of the multi-dose packs preparation; specifically it wants to control microbiological stability.

**METHODS:** The health provider prepares Calcium Levofolinate 10 mg/ml packs starting by 17 mg of freeze-dried powder. Overall he prepares 490 mg of Calcium Levofolinate on a horizontal laminar flow hood in a controlled contamination room. Their physical and microbiological standards controlled every six months. Microbiological control is realized on samples collected from a pack used three days at least. Controls dictated by FU, sterility and apyrogenic tests (LAL test), bacteriological tests to search and to count mesophilic bacteria, coliform bacteria, *E. coli*, *P. aeruginosa*, *S. enterica*, *S. aureus*, Bacillus Cereus, fungus are made. All tests are effectuated with a random sampling on 7% realized preparations. These one are negative for every pack and any bacterial e/o fungal e/o mycotic contamination is found.

**RESULTS:** From January to December 2006, 2228 Calcium personalized preparations are realized, 379 for FOLFIRI regime, 1259 for FOLFOX regime, 184 for Roswell-Park, 255 for De Gramont regime and 151 for other regimes.

The total consumption is 100 Calcium Levofolinate 10 mg/ml multidose packs, altogether using 2800 phials, with a cost of 2100 €. Instead 3285 phials would be used without multidose packs, with a cost of 24683 €.

**CONCLUSIONS:** The preparation of multidose pack permits to optimize production times and consumption of the drug. Costs are very reduced, with an annual savings of about 15%.

**319. Health technology assessment: trastuzumab.** Anna Bianca Calzona, Pharmacy, Daniela Checquolo, Pharmacy, Rossella Distillo, Pharmacy, Simona Ferriuolo, Pharmacy, Giovanni Guarany, Pharmacy, Gerardo Miceli Sopo, Pharmacy, *Grazia Mingolla, Pharmacy*, Daniela Scolaro, Pharmacy, Roberto Tazza, Pharmacy; Sandro Pertini Hospital, Rome, Italy.

**OBJECTIVES:** Cost-effectiveness analysis of adjuvant in patients with high-risk HER2-positive breast cancer.

**METHODS:** In evaluation of "Cost Effectiveness of Adjuvant: Trastuzumab in Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer" published in *Journal of Clinical Oncology*, February 2007 we estimated data in Sandro Pertini Hospital about women with early-stage HER2-positive breast cancer from August 2006 to May 2008.

**RESULTS:** A Markov model was used to data for the study "Cost Effectiveness of Adjuvant: Trastuzumab in Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer." The Markov model is able to value the consequences of the therapy about healthy and in the future. The Markov model calculated that adjuvant trastuzumab cause an incremental cost-utility ratio of 17,536€ for patient (14,861€ per QALY), which is lower than the common threshold values (in Italy 12,000–60,000€ for Messori et al.). From August 2006, at Sandro Pertini Hospital, about 41 women were to undergo treatment with adjuvant Trastuzumab. The incremental cost-utility ratio for patient compared to standard chemotherapy, for a year, was of 8060€ (6830 € per QALY).

**CONCLUSIONS:** Trastuzumab extends the clinical advantage of chemotherapy to an appropriate cost for the value added: the authors concluded that, in the longer term, adjuvant trastuzumab is a cost-effective therapy for women with early breast cancer, better than expected.

## Patient care

**320. Diabetic patients' knowledge of therapeutic goals, adherence to medications and life style modifications in Kuwait.** *Abdelmoneim Awad Hussein, B.Pharm., M.Pharm., Ph.D.*, Hala Dalle, B.Pharm; Faculty of Pharmacy, Kuwait University, Kuwait City, Kuwait.

**OBJECTIVES:** This study was conducted to describe: (1) the patients' knowledge of diabetes therapeutic goals (2) their self-reported adherence to medications and life style modifications.

**METHODS:** A total of 266 diabetic patients were randomly selected from six diabetic clinics to be included in the survey. Data were collected via face-to-face structured interview of the respondents using a pre-tested questionnaire. Data were entered into SPSS version 16 for analysis.

**RESULTS:** The response rate was 92.8%. The frequency (%) of patients who reported to know their recent levels of LDL-C, blood pressure, HbA1c were 11 (4.5%), 134 (54.3%), and 19 (7.7%), respectively. The frequency (%) of patients who admitted to know the target goals for LDL-C, blood pressure, HbA1c, fasting, and postprandial blood glucose levels were 6 (2.4%), 122 (49.4%), 14 (5.7%), 153 (61.9%), and 135 (54.7%), respectively. Those who reported the correct target goals for LDL-C, blood pressure, HbA1c, fasting, and postprandial blood glucose levels were 4 (1.6%), 1 (0.4%), 3 (1.2%), 139 (56.3%), and 115 (46.6%) patients, respectively. A total of 119 (48.2%) patients reported to be non-adherent to their medications, the most common cause was forgetfulness (40.5%). Only 19 (7.7%) patients reported that they had seen a dietician, and 22 (8.9%) claimed that they always follow a diabetic diet. Thirty one (12.6%) patients reported that they were always engaged in a regular exercise program.

**CONCLUSIONS:** The respondents' knowledge about diabetes therapeutic goals was generally poor. Lifestyle modifications that are essential in the management of diabetes were not followed by most of the study participants. The current findings highlighted the need for the implementation of a multi-disciplinary team approach to encourage patient education and self-care, and share responsibility for patients achieving diabetes therapeutic goals.

## Pediatrics

**321. Efficacy and safety of omalizumab added to optimized asthma care in children with inadequately controlled allergic asthma.** B. Lanier Jr., M.D.,<sup>1</sup> T. Bridges, M.D.,<sup>2</sup> M. Kulus, M.D.,<sup>3</sup> A. FowlerTaylor, RPh,<sup>4</sup> M. Blogg, M.D.,<sup>5</sup> R. Maykut, M.D.,<sup>4</sup> M. Massanari, Pharm.D.,<sup>4</sup> P. Jimenez, M.D.<sup>4</sup>; (1)University of North Texas, Fort Worth, Texas, USA; (2)Georgia Pollens Clinical Research Centers Inc, Albany, Georgia, USA; (3)Medical University of Warsaw, Warsaw, Poland; (4)Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA; (5)Novartis Horsham Research Centre, Horsham, United Kingdom.

**OBJECTIVES:** Many children with asthma are inadequately controlled despite available therapies. Omalizumab, the humanized anti-IgE monoclonal antibody approved for use in adults/adolescents with inadequately controlled moderate-to severe allergic asthma, may also improve allergic asthma control in children.

**METHODS:** This double-blind, randomized study enrolled children (6 to <12 y) with moderate or severe allergic asthma inadequately controlled on ICS. ICS doses were optimized and baseline measures established in an 8-wk run-in. Children who remained symptomatic received omalizumab (75–375 mg sc, q2 or q4 wk) or placebo for 52 wk, split into fixed ICS dose (24 wk) and adjustable ICS dose (28 wk) phases. Patients kept daily diaries of symptom scores and rescue B-agonist use. Primary endpoints were safety over 52 wk and rate of clinically significant asthma exacerbations at 24 wk. Secondary endpoints were exacerbation rates at 52 wk, and change from baseline in nocturnal symptom scores, rescue B-agonist use and quality of life (QoL; PAQLQ(S)) at 24 wk.

**RESULTS:** 628 patients (omalizumab, n=421; placebo, n=207) received study medication. Efficacy was analyzed for 576 (omalizumab, n=384; placebo, n=192). Omalizumab reduced the CSAE rate during ICS fixed-dose phase by 31% vs. placebo: respective rates were 0.45 and 0.64, rate ratio 0.693 (p=0.007, Poisson regression). Rates over 52-wk period were 0.78 and 1.36, a 43% reduction vs. placebo (p<0.001). Change from baseline in nocturnal symptom scores, rescue B-agonist use and QoL

scores were not statistically significantly. Adverse events (AEs) were similar between groups; most common were nasopharyngitis, sinusitis and URTI, and most (91%) were mild or moderate. No anaphylaxis to omalizumab occurred, nor were there any malignancies in omalizumab patients. No cases of thrombocytopenia were reported.

**CONCLUSIONS:** In children with inadequately controlled allergic asthma, omalizumab added to optimized treatment improved asthma control, demonstrated by fewer asthma exacerbations.

**322. Population pharmacokinetics of intravenous hydrocortisone in neonates.** Varsha Bhatt-Mehta, M.S. (CRDSA), Pharm.D., FCCP,<sup>1</sup> John D.E. Barks, M.D.,<sup>1</sup> Delia M Vazquez, M.D.,<sup>1</sup> Paul Williams, Pharm.D., FCP, FCCP<sup>2</sup>; (1)University of Michigan, Ann Arbor, Michigan, USA; (2)University of The Pacific, Stockton, California, USA.

**OBJECTIVES:** (1) Develop a Population Pharmacokinetics (PPK) based model for intravenous Hydrocortisone (IVHC) and estimate the clearance (CL) and volume of distribution ( $V_d$ ) for IVHC.

**METHODS:** A non-interventional study of residual plasma from routine laboratory tests. Sample size and the number and timing of HC samples determined using Monte Carlo simulations (NONMEM<sup>1</sup> (Iconus Inc, MD). IVHC administered per a predesigned dosing protocol including a baseline cortisol level. Residual plasma for free cortisol (FC) concentrations at baseline and following IVHC collected from the clinical laboratory and frozen at -80°C until analysis (LC-MS). The data were modeled in NONMEM<sup>1</sup> using ADVAN3, TRANS4. Gestational age (GA), postnatal age (PNA), treatment weight (WT), and postconceptional age (PCA) were variables in the final model. Endogenous FC was also modeled. The random effects were described as proportional error models.

**RESULTS:** 65 patients with a baseline cortisol and two additional HC concentrations during steady state (power =90%) contributed 200 HC concentrations in the final analysis. The Mean ( $\pm$  SD) GA, PNA and WT were 29.9  $\pm$  5.8 weeks, 1.78  $\pm$  3.36 weeks and 1.72  $\pm$  1.15 kg, respectively. In the final irreducible model: CL (L/hr) =GA\*0.0144, inter-compartmental CL=0.347 L/hr, V1 (central compartment) = 0.0074 L and V2 (peripheral compartment) = 1.29 L.  $V_i$  (total  $V_d$ ) = 1.2974 L. The interindividual random effect (%CV) = 48% and the residual variability (%CV) = 83%.

**CONCLUSIONS:** CL of IVHC is GA dependent but not associated with WT or PNA. The peripheral compartment has a larger  $V_d$  suggesting majority of the drug is distributed peripherally.  $V_d$  is not influenced by WT, PNA or GA in this model. Large intraindividual variations may be reflective of the critical illness and fluctuating hemodynamics. The interindividual variations are possibly due to widely variable GA. These results along with the yet to be estimated pharmacodynamic model for IVHC will be employed to propose a population specific dosing strategy.

**323. Opening the white boxes: The licensing documentation of efficacy and safety of psychotropic medicines for children.** Lise Aagaard, Ph.D.(Pharm), B.A.(Econ),<sup>1</sup> Steffen Thirstrup, Ph.D., M.D.,<sup>2</sup> Ebba H. Hansen, Professor, M.S., Pharm<sup>1</sup>; (1)Department of Pharmacology and Pharmacotherapy, Section for Social Pharmacy, Faculty of Pharmaceutical Sciences, University of Copenhagen, Copenhagen, Denmark; (2)The Danish Medicines Agency, Copenhagen, Denmark.

**OBJECTIVES:** To explore the available evidence in a regulatory agency on the safety and efficacy of medicines frequently prescribed for children.

**METHODS:** We analysed the documentation in registration files, renewal registration files, summaries of product characteristics and scientific assessment reports in the Danish Medicines Agency for two psychotropic medications prescribed for children: methylphenidate and citalopram to discover what data pertaining to the pediatric population are available to the regulatory agency.

**RESULTS:** The licensing of methylphenidate for treating Attention-Deficit Hyperactivity Disorders (ADHD) in children from the age of six was based on a single-dose crossover study and, a two-week double blind, parallel group clinical trial in 100 patients from ages 6–12 and published literature. Citalopram is not licensed for pediatric use in Denmark. Citalopram was being investigated in three ongoing clinical trials lasting 8–24 weeks in 423 patients aged 7–18 years. The

registration files contained no data on the long-term efficacy and safety of citalopram in pediatric use. Registration material also contained information on planned clinical trials with methylphenidate and citalopram among children/adolescents.

**CONCLUSIONS:** Evidence on the efficacy and safety of methylphenidate and citalopram for pediatric use in the Danish Medicine Agency is limited, supports the need for further clinical trials. Medicine prescription for the pediatric population should be monitored in order to identify risks that were not identified at the time of licensing. The results of clinical trials already conducted should be made publicly available.

## Pharmacoeconomics/Outcomes

**324E. Quality of life assessment in diabetic patients attending outpatient clinic in a tertiary health care facility.** Ehijie Enato, Ph.D.,<sup>1</sup> Ephraim Ekweanua, Pharm.D.,<sup>2</sup> Azuka C. Oparah, Ph.D.,<sup>1</sup> Michael E. Arigbe-Osula, Pharm.D.,<sup>1</sup> Ochuwa E. Aghomo, M.Pharm.<sup>1</sup>; (1)Department of Clinical Pharmacy & Pharmacy Practice, Faculty of Pharmacy, University of Benin, Benin City, Nigeria; (2)Federal Medical Center, Asaba, Asaba, Nigeria.

**OBJECTIVES:** To evaluate quality of life (QoL) of diabetic patients attending outpatient clinic of a tertiary health care facility in Nigeria.

**METHODS:** The study was carried out on 309 out of 400 consecutive patients presenting for routine check at a diabetic clinic in Nigeria. Demographic data were collected, while QoL was assessed using diabetic-specific instrument - Diabetes 39 (D-39) developed and previously validated elsewhere. Descriptive statistics on sample characteristics was computed. Differences between means were explored using Student's *t* test or ANOVA. Cronbach's  $\alpha$  test was used to determine reliability of the instrument, while QoL was assessed using a transformed score on a scale of "0" to "100" (highest to lowest) QoL.

**RESULTS:** Demographic and clinical profiles indicated: mean age of 60  $\pm$  12.2 years, 45% males, a majority were business men/women (36%) and retired (34%), had at least secondary educational level (57%). 98% of them had type I diabetes, and 57% of the patients were previously diagnosed 5 years prior to their enrolments into the study. Hypertension (37%) was the most prevalent co-morbid disease. 74% of the patients were on oral hypoglycemic agents. The mean blood sugar level was 7.65  $\pm$  2.74 mmol/L. The cronbach's alpha of the different sub.Scales ranged from 0.56 to 0.90. The QoL was found to be: Diabetes control, 33; Anxiety and worry, 42; Social burden, 20; Sexual function, 38, and Energy and morbidity, 39. Level of education or duration of illness did not affect the QoL of the respondents ( $p>0.05$ ). However, females had significantly better QoL on sexual function than males ( $p<0.05$ ). Also, on energy and mobility sub.Scale, patients less 60 yrs old had better QoL than those greater than 60 yrs ( $p<0.05$ ).

**CONCLUSIONS:** Though diabetic patients had better than average QoL, there is need to improve QoL of males and senior citizens with the disease in this health care facility.

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## Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**325. Effects of omeprazole on the pharmacokinetic profiles of lisdexamfetamine dimesylate and extended-release mixed amphetamine salts in adults.** Mary Haffey, R.Ph., Mary Buckwalter, M.S., Pinggao Zhang, Ph.D., Robert Homolka, M.S., Patrick Martin, M.D., Ken Lasseter, M.D., James Ermer, M.S.; Shire Development Inc., Wayne, Pennsylvania, USA.

**OBJECTIVES:** To evaluate the pharmacokinetics of lisdexamfetamine dimesylate (LDX), a long-acting prodrug stimulant, and extended-release mixed amphetamine salts (MAS-XR), alone or with omeprazole, a proton pump inhibitor (PPI).

**METHODS:** This open-label, randomized, 4-period crossover study enrolled healthy adults (18-45 years). Subjects alternately received single doses of LDX 50 mg and MAS-XR 20 mg. Following washout, subjects received omeprazole (40 mg/d X 14 days), with alternate single doses of LDX 50 mg or MAS-XR 20 mg added on days 7 and 11. Blood

was collected 0–96 hours postdose for pharmacokinetic analysis by theoretical and actual collection times. Safety assessments included adverse events (AEs).

**RESULTS:** Overall, 24 subjects were randomized; 21 completed the study. For LDX monotherapy, amphetamine mean exposure was 45 ng/mL and 713 ng·h/mL, while along with omeprazole it was 46 ng/mL and 763 ng·h/mL, for  $C_{max}$  and  $AUC_{inf}$ , respectively. The median  $t_{max}$  was 3h with and without omeprazole. For MAS-XR monotherapy, amphetamine mean exposure was 36 ng/mL and 641 ng·h/mL, while along with omeprazole it was 38 ng/mL and 645 ng·h/mL, for  $C_{max}$  and  $AUC_{inf}$ , respectively. The median  $t_{max}$  was 5h and 2.75h with and without omeprazole. Both medications were well tolerated; AEs were consistent with amphetamines.

**CONCLUSIONS:** Total exposure was unaffected by omeprazole for both compounds. However, ~50% of subjects receiving MAS-XR showed an earlier ( $\geq 1h$ )  $C_{max}$  while on omeprazole, indicating unpredictable release of active drug by the second bead of MAS-XR related to reduced stomach acid while on a PPI and compromising the pulsed delivery of MAS-XR. No clear trend was observed for LDX. Thus, the prodrug characteristics of LDX provided a more consistent delivery of amphetamine.

## Psychiatry

326. Systematic review: treatment of mental health disorders in the Arab countries. *Soumana A. Nasser, Pharm.D.*; School of Pharmacy, Lebanese American University, Beirut, Lebanon.

**OBJECTIVES:** To review the adequacy of treatment and service use in mental health disorders in the Arab World.

**METHODS:** The search engines used were PubMed, Psychinfo and IDRAAC web. Total number of abstracts screened was 6321 abstracts, out of which 86 articles were suspected to be relevant. Total number of screened articles was 64, out of which 27 articles were relevant and 37 articles were non relevant.

**RESULTS:** The retrieved and evaluated articles ( $n=21$ ) on the treatment of psychiatric disorders in the Arab world were studies conducted in Arab countries such as Saudi Arabia, Kuwait, Lebanon, Jordan, the United Arab Emirates, Bahrain. The main focus of 12 studies was to evaluate the referral types and/or the rate of treatment which were noted to be inadequate. Findings of 9 studies revealed that Arab patients with mental health problems are likely to seek help from a non-mental health specialty sectors such as a primary care physician, a religious healer, or an emergency room provider. Data in 7 different studies highlights the need to educate people about mental health disorders and its treatment and to facilitate the liaison between psychiatry services and other services such as general medicine. Findings of 6 studies highlight the need of improving treatment of mental health disorders in different type of treatment settings. Results from two studies on the treatment of psychiatric disorders in Lebanon showed that 17% of 1031 respondents met criteria for at least one disorder during one year period and that only one-tenth of them received treatment.

**CONCLUSIONS:** Available literature on the treatment of mental health disorders in the Arab world showed that people with psychiatric illness are not adequately treated and highlighted the need of improving psychiatric treatment in different type of settings as well as public awareness in this field.

327. Attitudes of pharmacy students toward patients with mental illness in Benin City, Nigeria. *Ehijie F.O. Enato, Ph.D.*<sup>1</sup>, Chioma M. Okpalla, Pharm.D.<sup>2</sup>; (1)Department of Clinical Pharmacy & Pharmacy Practice, Faculty of Pharmacy, University of Benin, Benin City, Nigeria; (2)At the time of the study, Dr Okpalla was a Pharm.D. student at the Faculty of Pharmacy, University of Benin, Benin City, Nigeria.

**OBJECTIVES:** To evaluate the attitudes of pharmacy students toward patients with mental illness and providing pharmaceutical care (PC) to them.

**METHODS:** The study was carried out among the 4<sup>th</sup>-year ( $n=74$ ), 5<sup>th</sup>-year ( $n=58$ ), and 6<sup>th</sup>-year ( $n=81$ ) Doctor of Pharmacy students of the Faculty of Pharmacy, University of Benin, Nigeria. Data were collected using a survey instrument which included information on the respondents' demography. The students' social distance, stigmatization, and opinions toward providing PC to mentally ill patients were explored with same questionnaire. The responses were anchored on 5-point

Likert-type scale. At the time of the study, the 4<sup>th</sup>-year students had not received any lecture on mental health, but the 5<sup>th</sup>- and 6<sup>th</sup>-year students had received lecture on pathophysiology and therapeutics of some mental disorders. In addition, the 6<sup>th</sup>-year students had undergone the first half of 6-week clinical rotation at a psychiatric hospital.

**RESULTS:** The study achieved a response rate of 79% (213/271). Slightly over half (51%) of the respondents were males, and a majority (89%) were 29 years and below. Among the 4<sup>th</sup>-, 5<sup>th</sup>-, and 6<sup>th</sup>-year students, 19%, 12%, and 95%, respectively, said they had had previous contact with someone with mental illness. The mean values for social distance for the three levels, were:  $1.85 \pm 0.94$ ,  $1.87 \pm 0.86$ , and  $2.20 \pm 0.94$ ; stigmatization:  $3.12 \pm 0.97$ ,  $3.02 \pm 0.94$ , and  $2.83 \pm 1.01$ , and PC attitude to mentally ill:  $3.57 \pm 1.15$ ,  $3.47 \pm 1.13$ , and  $3.97 \pm 1.00$ , respectively. In all, the 6<sup>th</sup>-year students expressed lower social distance, less stigmatization, and slightly higher positive attitude towards providing PC to mentally ill.

**CONCLUSIONS:** Pharmacy students have positive attitudes toward providing PC for mentally ill patients; however, the students expressed social distance and stigmatizing opinions may limit their efforts. These findings may be relevant to psychiatry pharmacy education in Nigeria.

## Rheumatology

328. French women post-menopausal osteoporosis treatment. *Cedric Collin, Pharm.D.*, Elise Rochais, Pharm.D., Yvonnick Bezie, Pharm.D., Ph.D., Gerald Rajzbaum, M.D.; Groupement Hospitalier Paris Saint-Joseph, Paris, France.

**OBJECTIVES:** Post-menopausal (PM) women have an increased likelihood of osteoporosis resulting from the decline in circulating estrogens levels. Management of PM osteoporosis treatment is predominantly composed with hormonal therapy (HT), bisphosphonates or calcium and vitamin D. Each treatment had demonstrated potential efficacy with increasing bone mineral density (BMD) and/or lowering risk fractures. The aim of this study is to evaluate impact of treatments on osteoporosis in a longitudinal follow-up of a French PM cohort.

**METHODS:** Women with two office visits were included from January 2001. Data collected at baseline were previous fractures, medical therapy (HT, bisphosphonates and calcium-vitamin D), cardiovascular risk factors and time exposure to treatment. Novel fractures were collected during follow-up. Baseline BMD was assessed at the femoral site using dual energy x-ray absorptiometry (Lunar Company, Lambesc, France). Statistical analysis used chi-square test, logistic regression for discrete variables and linear regression for continuous variables.

**RESULTS:** 416 women were included ( $64 \pm 10$  yrs) with  $3.9 \pm 1.0$  years follow-up. 144 had calcium-vitamin D treatment, 86 HT and 47 bisphosphonates. 165 had prevalent fractures and 58 novel fractures were reported during follow-up. In univariate analysis, risk of having novel fracture were significantly increased when bisphosphonates, HT and calcium-vitamin D were not administered (respectively OR=5.0, 95% Confidence Interval: 3.7-6.8,  $P<0.0005$ ; OR=5.5, 4.0-7.6,  $P<0.0005$ ; OR=6.0, 4.1-8.7,  $P<0.0001$ ). After adjustment for age, BMI, smoking, HTA, diabetes, hypercholesterolemia and prevalent fractures, the risk was unchanged only in patients with calcium-vitamin D treatment (OR=1.9, 1.0–3.8,  $P=0.05$ ). BMD was negatively correlated with time exposure to calcium-vitamin D ( $P<0.05$ ) whereas no correlation was found between BMD and time exposure to HT and bisphosphonates.

**CONCLUSIONS:** Despite well-known efficacy of post-menopausal therapies, calcium-vitamin D treatment is related to a significant reduction of the risk of fractures and women bone remodelling is greater whenever long-term calcium-vitamin D is administered.

## PEDIATRIC RESEARCH AND PRACTICE ABSTRACTS

330. Study the efficacy of two different regimens of amikacin in neonatal sepsis. *Manal H. El Hamamsy, Ph.D.*, Angi A., Mohsen A., Heshm A., Abd Elhadi, Hedaia Awad, M.D., Ph.D., M.D.; faculty of pharmacy, Ain Shams University, Cairo Egypt, Cairo.

**OBJECTIVES:** to compare the efficacy and safety (nephrotoxicity) of once daily versus twice daily dosing of amikacin in neonates with suspected or proven sepsis.

**METHODS:** Thirty neonates of gestational age  $\geq 36$  weeks with sepsis admitted between March 2007 to October 2007 in Neonatal Intensive Care Unit of Gynecology hospital Ain-Shams University were divided into two groups: group I (n=15), neonates received amikacin at a dose of 15 mg/kg once per day; and group II (n=15), received amikacin at a dose of 7.5 mg/kg twice per day. All neonates received classical treatment of sepsis including antibiotics, vascular support, inotropic support if needed. Clinical efficacy was compared using both observation of clinical status and normalization of laboratory tests.

**RESULTS:** No significant difference was shown between both groups regarding the use of  $\beta$ -lactam antibiotics with amikacin ( $p=0.605$ ). No significant difference between group I and group II in either baseline or day-7 serum creatinine was demonstrated ( $p>0.05$ ). No oliguric or polyuric problems were encountered in any infant during therapy. Among all patients in the study, 33.3% needed inotropes and/ vascular expanders, distributed as 60% in group II and 40% in group I. The difference did not reach statistical significance ( $p>0.05$ ). No significant difference was found between the two groups in clinical efficacy or renal toxicity.

**CONCLUSIONS:** It was found that amikacin given in once daily dose was as effective as the conventional regimen of twice daily dosing using criteria set by the study which combined observation of clinical status and normalization of laboratory tests (CRP, CBC and platelet count).

**331E. Light protection of infusions in the Neonatal Intensive Care Unit (NICU)—the Martha Stewart way.** Elin H. Bergene, Pharmacy Candidate; Trondheim Hospital Pharmacy, Trondheim, Norway.

**OBJECTIVES:** In NICUs, parenteral nutrition and drug infusions may be exposed to potentially harmful light. Ultra Violet Radiation (UVR) is only partly filtered by windows and may cause photodegradation of parenteral nutrition and drugs as reactive singlet oxygen is produced in glucose infusions exposed to UVR.<sup>1</sup> The use of phototherapy for jaundice treatment may cause peroxidation of parenteral nutrition.<sup>2</sup> To protect infusions from light, we wanted to make reusable light protection sheaths.

**METHODS:** The UVR during phototherapy and inside the window of the NICU was measured using a radiometer's UVA detector. Light penetration through a microfiber textile was compared to aluminium foil using a spectrophotometer. In addition, the UVA detector was covered with the textile and UVA radiation recorded. The textile was cut into strips to fit the infusion line and in-line filter and Velcro was used for attachment.

**RESULTS:** 20–30% of the suns UVA radiation was detected at 50–100 cm from the window were racks of syringe pumps are placed. This number has been reported at 50% and higher<sup>3</sup> indicating structural differences of the windows. The light penetration of the textile was similar to that of aluminium foil when measured by a spectrophotometer. Covering the UVA detector with the textile eliminated the detection of UVA radiation. During phototherapy, the UVA radiation was negligible. The material was solid enough to withstand repeated washings. It took approximately 15 minutes to make one sheath, and the material cost was \$10.

**CONCLUSIONS:** Inexpensive, easy to make, reusable light protection sheaths for the NICU protect i.v. infusions from potential harmful UVR from the sun and during phototherapy.

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- Presented at the 14th annual conference of the Neonatal and Paediatric Pharmacist Group, Birmingham, England, November 14–16, 2008.

**332. Optimizing bactericidal exposure for  $\beta$ -lactams using extended infusions in the pediatric population.** Joshua D. Courter, Pharm.D.,<sup>1</sup> Joseph L. Kutl, Pharm.D.,<sup>2</sup> Jennifer E. Giroto, Pharm.D., BCPS,<sup>1</sup> David P. Nicolau, Pharm.D., FCCP, FIDSA<sup>2</sup>; (1)Connecticut Children's Medical Center, Hartford, Connecticut, USA; (2)Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, Connecticut, USA.

**OBJECTIVES:** Administration of  $\beta$ -lactams via extended infusion has been utilized in adults to optimize drug exposure and clinical outcomes. As children exhibit increased drug clearance compared with adults, this dosing strategy may be of further benefit to pharmacodynamic optimization.

**METHODS:** Standard cefepime, ceftazidime, imipenem/cilastatin, meropenem, and piperacillin/tazobactam dosing regimens using administration times of 0.5-, 3-, or 24-hour infusions were simulated in a population of 2 year old children using Monte Carlo techniques. The probability of target attainment (PTA) was calculated for each dosing regimen. Free drug concentrations above the minimum inhibitory concentration (MIC) for 40% and 50% of the dosing interval were used as pharmacodynamic targets for the carbapenems, and the penicillins/cephalosporins, respectively. MIC frequencies for *Pseudomonas aeruginosa* were obtained for two pediatric acute care institutions in order to calculate cumulative fractions of response (CFR).

**RESULTS:** Standard 0.5-hour infusions resulted in poor PTA for most  $\beta$ -lactams at their susceptibility breakpoints, whereas 3-hour infusions markedly improved PTA for ceftazidime (80% to 100% at 8  $\mu$ g/mL), imipenem (41% to 91% at 4  $\mu$ g/mL), and meropenem (33% to 97% at 4  $\mu$ g/mL). Cefepime 150 mg/kg/day PTA showed little improvement for organisms at its susceptibility breakpoint with a 3-hour infusion (97% to 100% at 8  $\mu$ g/mL), while piperacillin/tazobactam could not achieve a PTA  $>21\%$  for any dosing regimen at its breakpoint (64  $\mu$ g/mL), though large improvements were observed at lower MICs with the 3-hour infusions. Further improvements over 3-hour infusions were not observed when 24-hour infusions of cefepime or piperacillin/tazobactam were simulated. CFR values for all drugs at both institutions improved when extended infusions were employed.

**CONCLUSIONS:** Extended infusion dosing strategies improved the likelihood of obtaining bactericidal targets for these  $\beta$ -lactams in a simulated pediatric population. Based on these data, pediatric studies employing these strategies are warranted.

**333. Experience with topical pimecrolimus in the treatment of atopic dermatitis in African American children.** Paul J. Munzenberger, M.S., Pharm.D.,<sup>1</sup> Farah Malick, M.D.,<sup>2</sup> Rosemary Shy, M.D.,<sup>3</sup> Fasahat Hamzavi, M.D.,<sup>2</sup> Elizabeth Secord, M.D.,<sup>3</sup> Ronald Thomas, Ph.D.<sup>4</sup>; (1)Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan, USA; (2)Department of Dermatology, Wayne State University, Detroit, Michigan, USA; (3)School of Medicine, Wayne State University, Detroit, Michigan, USA; (4)Department of Pediatrics, Children's Hospital of Michigan, Detroit, Michigan, USA.

**OBJECTIVES:** To evaluate the efficacy of pimecrolimus cream (PCr) 1% in African American (AA) children with atopic dermatitis (AD).

**METHODS:** This was a 3-week, single-blind, placebo-controlled, within-patient, randomized trial in AA children with mild to moderate AD. Patients applied bid PCr 1% or placebo (Plc) and emollient to similarly affected areas for 3 weeks. At baseline, 1 and 3 weeks following treatment initiation, the AD areas were evaluated for severity with an m-EASI which rates erythema, infiltration /population, excoriations and lichenification 0 (none) to 3 (severe). Secondary outcomes were the modified IGA score which rates AD from 0 (clear) to 5 (very severe), a hypopigmentation scale and use of rescue medication. Pair wise comparisons were done to determine significant ( $p<0.05$ ) within and between treatment changes.

**RESULTS:** Sixteen patients were enrolled. Thirteen & 9 patients were available for evaluation at the 1 & 3 week visits, respectively. Changes in the m-EASI within treatment mean scores from baseline to weeks 1 and 3 were significant for both the PCr (wk1: 6.3 to 4.5,  $p=0.03$ ; wk3: 6.3 to 4.3,  $p=0.03$ ) and Plc (wk1: 6 to 4,  $p=0.01$ ; wk3: 6 to 3.6,  $p=0.006$ ). No significant changes occurred from weeks 2 to 3 at either treatment areas. There were no between treatment significant differences at any visit. Analysis of IGA scores for within and between treatments yielded similar results. One patient developed mild hypopigmentation at both treatment areas. Rescue medication was reported used by 4 and 1 patient at weeks 1 and 3, respectively.

**CONCLUSIONS:** While the Plc and PCr treatment areas both improved, there was no significant difference between treatments. The small number of patients, mild to moderate severity and use of emollient may have contributed to these results. PCr was well tolerated in this AA sample.

**334. Neonatal and pediatric peripheral parenteral nutrition—what is a safe osmolarity?** Jeffrey J. Cies, Pharm.D., BCPS,<sup>1</sup> Wayne S. Moore II, Pharm.D.<sup>2</sup>; (1)St. Christopher's Hospital for Children, Philadelphia, Pennsylvania, USA; (2)Alfred I. duPont Hospital for Children, Wilmington, Delaware, USA.

**OBJECTIVES:** To reach nutritional goals, PPNs often exceed an osmolarity of 900 mOsm/L. There is some evidence suggesting PPNs with osmolarities >900 mOsm/L are safe in adults. However, the neonatal and pediatric data suggests the PPN osmolarity limit should be between 500-700 even though the American Society of Parenteral and Enteral Nutrition (ASPEN) recommends a limit of 900 mOsm/L. This is a retrospective cohort study from 1/1/05–12/31/07 to determine if PPN's with an osmolarity >900 mOsm/liter result in an increased rate of thrombophlebitis in neonatal and pediatric patients.

**METHODS:** Patients from birth to 21 years were included. The rate of thrombophlebitis reported in the literature ranges from 5% to 75 %. For the purpose of a sample size calculation, the rate of thrombophlebitis was assumed to be 10%. To detect a 10% difference in the rate of thrombophlebitis with  $\alpha = 0.05$ , power of 80%, a sample of 200 patients in each group is needed.

**RESULTS:** Baseline demographic data was similar between groups. The average osmolarity for neonatal and pediatric PPNs was 928 (range 641–1498) and 963 mOsm/L (range 752–1529), respectively. For neonatal PPNs, the incidence of thrombophlebitis was 24 per 100 patient days and 22 per 100 patient days for PPNs >900 and  $\leq$ 900 mOsm/L, respectively (RR = 1.08, 95% CI 0.4–2.5). For pediatric PPNs, the incidence of thrombophlebitis was 42 per 100 patient days and 49 per 100 patient days for PPNs >900 and  $\leq$ 900 mOsm/L, respectively (RR = 0.87, 95% CI 0.69–1.27).

**CONCLUSIONS:** There was no difference in the rate of thrombophlebitis for PPNs >900 mOsm/L compared with PPNs  $\leq$ 900 mOsm/L for neonatal and pediatric patients. Based on the similar rates of thrombophlebitis, increasing the PPN osmolarity limit to 1000–1100 mOsm/L to meet nutritional goals may be appropriate.

**335. Retrospective review of agents used to prevent contrast induced nephropathy in pediatric patients.** Jonathan M. Kline, Pharm.D.,<sup>1</sup> Davey Legendre, Pharm.D.<sup>2</sup>; (1)West Virginia University School of Pharmacy, Martinsburg, West Virginia, USA; (2)Central Mississippi Medical Center, Jackson, Mississippi, USA.

**OBJECTIVES:** Many agents are utilized for the prevention of contrast induced nephropathy (CIN) in adults even though the evidence for their use is inconclusive. These include sodium bicarbonate infusions, n-acetylcysteine, dopamine, crystalloid fluid boluses, and others. These same agents are often used in pediatric patients, but have even less data associated with their efficacy and safety. The purpose of this retrospective drug utilization review is to describe the use of preventative agents given to pediatric patients who were given contrast and their development of CIN.

**METHODS:** All patients who received a non-barium contrast agent between January 1, 1993 and December 31, 2006 and were not yet 18 years of age were identified from hospital billing records. A retrospective chart analysis was utilized to gather study data. A total of 1495 patients were identified of which, 526 met study criteria. Patients were excluded from analysis if a serum creatinine was not obtained before and after contrast administration. CIN was defined as a rise in the SCr greater than or equal to 25% from baseline and greater than or equal to 1.0 mg/dL.

**RESULTS:** Results will be presented following the completion of data collection and analysis. The incidence of CIN for each preventative agent will be calculated.

**CONCLUSIONS:** This project will be used to access any correlation between CIN and preventative agents used in pediatric patients. The results could be used to guide future research on CIN in pediatric patients.

**336. Main tendencies in the use of antibiotics in the Children Hospital in Latvia (2005–2008).** Inese Sviestina, M.A., M.Sc.; Children Hospital Gailezers, Riga Stradins University, Riga, Latvia.

**OBJECTIVES:** To establish whether there was a relationship between the number of antibacterial agents used and total antibiotic use of

antibiotics in the Children hospital Gailezers. This is the first study, which analyses the usage of antibiotics in the hospital.

**METHODS:** The data of systemic antibiotics in Anatomical Therapeutic Chemical (ATC) class J01 were collected and expressed in defined daily doses (DDD) per 100 occupied bed days (DDD / 100 BD) delivered by pharmacy for the years 2005–2008. For each antibiotic (which does not include antifungals, antibacterials for tuberculosis and topical antibiotics) the total consumption in DDDs were collected per each hospital unit and per hospital in general.

**RESULTS:** Penicilins are most commonly used Beta-lactams (mainly due to high amoxicillin and ampicillin consumption). Aminoglycosides are the second most frequently used antibiotic group. The use of cephalosporins remained fairly constant during the study period, but there were changes in the relative use of different cephalosporin groups. The use of earlier cephalosporins gradually decreased, whereas the use of the more recently developed cephalosporins increased. Carbapenems, glycopeptides, tetracyclines and fluoroquinolones were rarely used in the hospital. Relationship between number of different antibiotics and the total use of antibiotics were found. (There were 45 antibiotics used in 2005 and 27. antibiotics in 2007.)

**CONCLUSIONS:** Antibiotic consumption (DDD per BD) decreases since 2005. (32.752 DDD/100 BD in 2005 to 28.709 DDD/100 BD in 2007). There are seasonal variations with much smaller use in summer than in winter. Intravenous administration route were most common in the hospital. The total consumption is related to number of antibiotics used in the hospital.

**337. Stability of dexamethasone oral liquid formulation.** Céline Saint-Laurent, Pharm.D., Sylvain Rajezakowski, Pharm.D., Stéphanie Silly-Violette, Pharm.D., Antoine Dupuis, Ph.D; Centre Hospitalier Universitaire de Poitiers, Poitiers, France.

**OBJECTIVES:** Dexamethasone (DM) is a glucocorticoid used in paediatric populations to treat acute lymphoblastic leukemia. Given the impossibility of infants before six years to swallow capsules, and the dose individualized by body weight or body surface area, a liquid formulation has to be used. No liquid DM formulation is commercially available in Europe. In the USA and in Canada, DM is available in several liquid formulations. But they either contain alcohol or their strengths are lower than desirable. The aim of this work was to prepare an alternate oral liquid formulation.

**METHODS:** A stability-indicating assay, using U.V. high performance liquid chromatography (HPLC), has been developed and validated. DM acetate powder (pharmaceutical-grade substance) was used to prepare a suspension of 5 mg/mL concentration using a 1:1 mixture of Ora-Sweet®:Ora-Plus® as liquid vehicles. Six batches of this suspension were placed in a light-resistant type I glass vial. Three of them were kept refrigerated and the others stored at room temperature. DM concentrations were determined at day 0, 7, 14, 30 and 60. After agitation, solutions were also visually inspected for colour and clarity. Moreover, the pH of the different solutions was assessed.

**RESULTS:** At day 0, the mean DM concentration was  $5.14 \pm 0.17$  mg/mL. Whatever, the storage condition has no significant impact on DM degradation over the 2 months storage (97.8% and 95.9% of the initial concentration remaining for formulations kept refrigerated and formulations kept at room temperature, respectively). No visual modification or difficulty of re-suspending was observed throughout the storage period and no significant pH modification occurred (from 4.4 to 4.2).

**CONCLUSIONS:** Consequently, in our conditions, oral suspension of DM acetate (5mg/mL) is stable for at least 60 days. This formulation is appropriate to provide an easy to use paediatric dosage form for oral DM administration.

**338E. Sub-optimal dosing patterns of ACE inhibitors in pediatric cardiology patients.** S. Lucy Roche, M.B., Ch.B., Kathryn E. Timberlake, Pharm.D., Mervin Balasingam \*, Paul Kantor, M.B.B.Ch., DCH, FRCP; The Hospital for Sick Children, Toronto, Ontario, Canada.

**OBJECTIVES:** Pediatric dosing recommendations for captopril suggest starting with a low initial dose and up-titrating to a target dose. However, wide ranges are quoted for maintenance doses and no guidance is given on the best method to reach maintenance dose. We sought to describe the use of captopril in a pediatric hospital by (1) surveying the cardiology department to determine their opinions of

captopril dosing; and (2) to compare survey results to the actual dosing patterns and side effects of captopril in children.

**METHODS:** Fifty consecutive pediatric cardiology in-patients starting captopril were identified between 2005/09/01 and 2007/03/19. Charts were reviewed to determine the course of captopril up-titration, incidence of side effects, captopril dose at discharge and 8 weeks after discharge. Departmental surveys were used to define a target dose of captopril of >2.7mg/kg/day.

**RESULTS:** At the time of discharge, 30/50 patients remained on captopril, but only 6/30 (20%) reached target dose. One additional patient reached target dose 8 weeks after discharge. Eight of 30 (26%) were on less than half the target dose. Asymptomatic, self-limiting hypotension was recorded in 11/50 (22%) patients within 2 hours of a dose increase. When compared to baseline, serum creatinine and potassium did not change appreciably in any patients. Median age on admission was 2.7 (IQR 1–5.9) months. The median length of hospital stay after the first dose of captopril was 19 (IQR 10–38) days.

**CONCLUSIONS:** Captopril dosing of pediatric cardiology patients is sub-optimal at the time of hospital discharge and remains so at 8 week follow-up. Physicians remain uncertain about the optimal dose of captopril and how best to achieve it. This uncertainty, and not the occurrence of side-effects, was likely a limiting factor in achieving target doses of captopril within our patient population.

Poster presented at Association for European Paediatric Cardiology Meeting, Venice, Italy, 21–24 May, 2008.

**339E. Nutritional status (NS) influence on the outcome of pediatric liver transplant patients.** *Anna Carollo, Pharm.D., Piera Polidori, Pharm.D. Silvana Bavetta, Pharm.D., Roberta Di Stefano, Pharm.D., Alessio Provenzano, Pharm.D., Francesca Venuti, Pharm.D., Maria Grazia Sidoti, Pharm.D., Valentina Zampardi, Pharm.D.; ISMETT, Palermo, Italy.*

**OBJECTIVES:** Malnutrition (M) is a multifactorial process in children with chronic liver disease and carries an increased risk of morbidity and mortality. Maintaining optimal NS can prevent further derangement of liver function: increasing metabolic energy and improving the immunology status. In fact, M adversely affects on the outcome of surgical patients (pts). In this study we intend to demonstrate how the NS can influence the outcome of liver transplant (LTx) in the pediatric population.

**METHODS:** We evaluated 74 pediatric pts over 24 months from 2006 to 2007 who underwent LTx at ISMETT. The age of the pts ranged between 18 months and 12 years. The causes of the LTx were: 43% biliary atresia, 10% hepatoblastoma, 10% acute fulminant hepatitis, 7% graft non function, 5% autoimmune hepatitis and 25% other. Upon admission, the pts undergo a nutritional screening by a multidisciplinary team (physicians, clinical pharmacists and dietitians) who assess the NS and establish a customized nutritional plan. Clinical pharmacist, based on the patient clinical needs, develops an appropriate nutritional program.

**RESULTS:** Of the 74 pts assessed immediately before the LTx, 14 were between 3–5 percentile weight/height (wt/ht): severe M, 20 were between 10–25: moderate M, 30 between 25–50:normal NS and only 5 pts were above 50:good NS. Of the 14 pts between 3–5percentile wt/ht, there were 2 deaths and 7 pts underwent redo-LTx and the average length of stay (LOS) was 50 days. Of the 20 pts between 10–25percentile wt/ht only 2 underwent redo-LTx and 12 had post-surgery complications, the average LOS was 30 days. Of the 35 pts between 25–50percentile wt/ht there was 1 death and 7 pts had complications post-surgery while the average LOS was around 30 days.

**CONCLUSIONS:** As the results show, the NS can effectively be a prognostic indicator in the LTx and the evaluation of NS along with appropriate nutritional support are important key-factors that contribute to the success of LTx.

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**340. Osmolality of oral medications used in the neonatal intensive care unit.** *Carla K. Findlater, Pharm.D., Dolores Iaboni, B.Sc.PhM, Hari Joshi, B.Sc.; Sunnybrook Health Sciences Centre, Toronto, Ontario Canada.*

**OBJECTIVES:** Hyperosmolality of oral medications and enteral formulas has been implicated as a cause of necrotizing enterocolitis (NEC) and

other gastrointestinal illness in premature neonates. Osmolality less than 400 mOsm/kg is recommended for oral alimentation formulas, but no recommendation exists for medications. Manufacturers do not publish osmolality and many oral medications in the Neonatal Intensive Care Unit (NICU) are extemporaneously compounded therefore osmolality is not available. The purpose of this study was to determine the osmolality of common oral medications used in the NICU.

**METHODS:** A total of 48 oral solutions were evaluated as determined by usage in the NICU. Osmolality was determined by freezing point depression using the Advanced Osmometer Model 3300. Measurements of full-strength preparations were performed in triplicate unless osmolality exceeded the range of the osmometer (>3,000 /kg). When osmolalities of full-strength preparations exceeded the range of the osmometer, the solution was diluted with distilled water to 4%, 10%, 16% and 20%. Full-strength osmolality was then estimated using least squares regression calculations.

**RESULTS:** The osmolality of 48 oral preparations ranged from 13 to >3,000 mOsm/kg. Only 5 full-strength solutions had measured osmolalities under 400 mOsm/kg. Remaining solutions required dilution to obtain acceptable osmolalities. Highest estimated osmolality of a full-strength commercial preparation was 12,085 mOsm/kg, with 40 preparations >1,000 mOsm/kg.

**CONCLUSIONS:** Most proprietary and extemporaneous oral medications for neonates are significantly hyperosmolar as determined in this study. The results provide a guide for dilution of hyperosmolar oral medications to acceptable osmolalities to minimize osmotic load. This will allow for better treatment of premature neonates for conditions in which only oral medications are available and in premature neonates particularly susceptible to NEC.

**341. A descriptive evaluation of asthma outcomes and asthma quality of life in patients seen by pharmacists in a BreathMobile facility.** *Allison M. Chung, Pharm.D., BCPS, AE-C; Auburn University, Department of Pharmacy Practice; University of South Alabama, Department of Pediatrics, Mobile, Alabama, USA.*

**BACKGROUND:** The BreathMobile is a mobile asthma specialty clinic which travels to various area schools (elementary, middle and high school). Since the inception of the BreathMobile, pharmacists have been an integral part of the program: identifying obstacles to adherence, assessing and educating on inhaler technique; providing comprehensive medication education; assessing technique, compliance and adherence; and administering pediatric asthma quality of life (PAQLQ) surveys.

**OBJECTIVES:** To describe development, assessment and evaluation of pharmacist participation in an active BreathMobile clinic.

**METHODS:** A retrospective analysis was conducted to describe and evaluate the activities of the BreathMobile and the pharmacists involved. All data was obtained during the regular BreathMobile clinic visits and entered in the Asma-Trax database. Data was analyzed directly from this database.

**RESULTS:** After 2 years of the BreathMobile program, 508 patients have been evaluated for asthma in 30 schools across the county. Demographically, 41% were female, 55% were African American and age ranged from 1–20 years old (median=11 years). Of the 508 patients seen, 443 were diagnosed with asthma whom accounted for 895 clinic visits. The asthma patients ranged in severity from mild intermittent to severe persistent. Of the 182 patients who had evaluable follow-up visits, 43% improved in their asthma classification, 39% remained stable and 18% worsened. Pharmacists assessed patient medication education and inhaler technique in 113 patients. The Pediatric Asthma Quality of Life (PAQLQ) was surveyed in 120 patients. The mean total PAQLQ score was 109 (range, 29–159). In each of the 3 domains, the mean score was 38.5 for emotional, 24.4 for Activities, and 45.9 for symptoms. Thirty-two patients have taken the PAQLQ more than once. Of these patients the mean change was 0 and ranged from -43–59.

**CONCLUSIONS:** Pharmacist involvement in the BreathMobile program appears to be beneficial but needs a more systematic analysis.

**342. Elevated liver enzymes in neonates receiving amphotericin B in a teaching hospital in South Africa.** *Andries GS Gous, Pharm.D., Natalie Schellack, B.Pharm., Maria Chale, M.Med. (Paed), Linda Mothobi, M.Med. (Paed); University of Limpopo (Medunsa Campus), Pretoria, South Africa.*

**OBJECTIVES:** This study described the unexpected elevation of liver function tests (LFTs) in 9 neonates receiving amphotericin B. These patients were diagnosed with fluconazole resistant *Candida krusei*.

**METHODS:** The use of amphotericin B (sodium deoxcholate formulation) was monitored for 20 patients in the Neonatal ICU at Dr. George Mukhari Hospital. Amphotericin was dosed at 0.1 mg/kg/day administered over 4 hours. These patients were followed prospectively for the duration of therapy. Demographic, clinical and laboratory data were recorded. Amphotericin B side-effects were monitored and accumulative dosages were calculated.

**RESULTS:** Of the 20 patients an increase in LFTs were noted in 9 patients. The average percentage increase from baseline for the LFTs was: Alkaline phosphatase 81% (n=9), ALT 269% (n=7), AST 208% (n=9), GGT 102% (n=4) and Total Bilirubin 188% (n=7). One patient presented with clinical signs and symptoms of hepatotoxicity. Raised LFTs decreased when the dosing intervals were extended. Increased values were noted again with reintroduction of the normal amphotericin B dose confirming amphotericin B as a possible cause. A median cumulative dose of amphotericin B over a period of 17 days (5–48 days); until the first negative culture was obtained; was 20.6 mg (7.4 mg–58.9 mg) for the nine patients.

**CONCLUSIONS:** Possible hepatotoxicity was noted in neonates treated with amphotericin B. Although the majority of the patients did not present with clinical signs and symptoms it might be necessary to monitor LFTs more regularly with amphotericin B therapy.

**343. Rendering Pharmaceutical care in a neonatal intensive care unit at a teaching hospital in South Africa.** *Natalie Schellack, B.Pharm., Andries G.S Gous, Pharm.D.; University of Limpopo (Medunsa Campus), Pretoria, South Africa.*

**OBJECTIVES:** The aim of this presentation is to describe the provision of pharmaceutical care (PC) in a neonatal ICU. The provision focussed on the role of the pharmacist in assessing prescribing patterns, recognising and recording drug related interventions, and the time involved in providing PC.

**METHODS:** The design of the study was mainly quantitative and non-experimental data were collected prospectively. The study commenced with the introduction of pharmaceutical care rounds with the attending paediatrician. Patient demographics, pharmaceutical care interventions and the researcher's time providing PC were recorded.

**RESULTS:** The data were collected from 98 patients over eight months. A total of 522 interventions were performed and documented. The number of interventions per patient ranged from 1 to 23 with a median number of 4.5. Untreated medical conditions (112; 21%), therapy not tailored to patient needs (63; 12%), medicines without indications (58; 11%) and comparative efficacy constituted the most common category of interventions. Extensive attention was given to the use and monitoring of amphotericin B and amikacin. Through the interventions aminophylline was identified as the most problematic medicine and its use was then compared with caffeine. A PC risk assessment sheet based on the interventions was developed. This sheet enables other health care professionals to refer patients to the pharmacist, and also enables the pharmacist to prioritise patients according to their health care needs.

**CONCLUSIONS:** A pharmacist can play an important role in improving patient care in the NICU through the provision of pharmaceutical care. The PC risk assessment sheet can be used to request a PC consultation, integrating the pharmacist as a part of the health care team.

**344. Therapeutic drug monitoring of a once daily dosage regimen of Amikacin for Neonates at a teaching hospital in South Africa.** *Natalie Schellack, B.Pharm., Andries G.S Gous, Pharm.D.; University of Limpopo (Medunsa Campus), Pretoria, South Africa.*

**OBJECTIVES:** Although the amikacin is part of the ward protocol; therapeutic drug monitoring was not performed. Therapeutic drug monitoring was initiated to ensure adequate peak concentrations for efficacy and prevent high trough levels to prevent toxicity.

**METHODS:** Patients were chosen in the ward for therapeutic drug monitoring according to clinical indications, and a risk profile. Amikacin was administered at a loading dose of 25 mg/kg and a maintenance dose of 20 mg/kg once a day. Peak and trough levels were obtained for 30 patients. Blood specimens were taken one hour after infusion to obtain a peak concentration and immediately before the next

dose for trough concentrations. This was done after at least three days of therapy. The amikacin data obtained from the laboratory were analysed using a one compartment open pharmacokinetic model namely the Sawchuk-Zaske method to calculate the different pharmacokinetic parameters.

**RESULTS:** The pharmacokinetic data obtained indicated mean and median peak and trough values that were within the reference range. The mean and median  $t_{1/2}$  were also within the reference ranges, however the mean and median volumes of distribution were higher than the reference range and the mean clearance in this population was twice as fast as the reference values. Birth asphyxia, respiratory distress, hypothermia, hyaline membrane disease, congenital pneumonia and congenital cardiac conditions were identified as conditions that presented with out of range pharmacokinetic parameters.

**CONCLUSIONS:** The standard once-daily dose administered to the neonates resulted in peak and trough levels within the reference ranges for the majority of the patients; however therapeutic drug monitoring is still needed for patients with specific conditions.

**345. Determining the comparative efficacy of aminophylline and caffeine in the prevention of apnoea of prematurity (AOP), in the Neonatal Intensive Care Unit at a teaching hospital in South Africa.** *Natalie Schellack, B.Pharm., Andries G.S Gous, Pharm.D., Patience M.B Mawela, M.Med. (Paed); University of Limpopo (Medunsa Campus), Pretoria, South Africa.*

**OBJECTIVES:** Apnoea of prematurity (AOP), is defined as cessation of breathing that lasts for more than 15 seconds. The study aimed to compare the efficacy and safety profiles of aminophylline (IV) versus caffeine (oral) in the prevention of episodes of AOP.

**METHODS:** Demographic, clinical and laboratory data were collected prospectively. Patients were enrolled randomly. The aminophylline regimen used was; loading dose 6 mg/kg/IV then 2.5 mg/kg/dose IV administered every 8 hours. The caffeine regimen was: loading dose 10 mg/kg, with a maintenance dose of 2.5 mg/kg daily. One blood specimen for caffeine or aminophylline concentration was taken.

**RESULTS:** Thirty-one evaluable patients (aminophylline 16, caffeine 15) were enrolled. The two groups were statistically comparable for gestational age, birth weight, gender, admission criteria and Apgar scores determined at 5 minutes. Serum concentrations were within range for both study groups. The median pulse rate (for two days) and median respiratory rate (five days) were significantly higher in the aminophylline. The number of patients with aspirates more than 30 % of total feeds, was higher in the caffeine population but not statistically significant. Apnoeic attacks were recorded in four study patients, three (19%) of whom received aminophylline and one (7%) patient on caffeine.

**CONCLUSIONS:** Fewer cardiovascular and respiratory side effects and apnoeic attacks occurred in the caffeine population. The oral administration of caffeine is also an advantage. The findings of the study indicated that caffeine is an effective alternative for aminophylline in preventing AOP.

**346. An evaluation of the effectiveness of British National Formulary for Children dosing recommendations for vancomycin in critically ill children.** *Adam B. Sutherland, M.Pharm., M.Sc.,<sup>1</sup> Christopher Todd<sup>2</sup>; (1)Pharmacy Department, Royal Hospital for Sick Children Glasgow, Glasgow, United Kingdom; (2)Royal Hospital for Sick Children, Glasgow, United Kingdom.*

**OBJECTIVES:** To ascertain if dosing recommendations for vancomycin as published in the British National Formulary for Children (BNF-C) 2008 produce initial trough levels within the stated range in the BNF-C (10–15mg/L) Secondary outcomes—do physicians on PICU follow the BNF-C guideline; is there an increased risk of renal impairment using this higher dosing regimen.

**METHODS:** All doses (in mg/kg) and first trough levels in patients >1month in age treated with vancomycin on a large PICU in a six month period were collected retrospectively. Baseline serum creatinine, peak serum creatinine and creatinine after the last dose of vancomycin were also reviewed.

**RESULTS:** 27 treatment episodes were reviewed. Only 9 episodes followed BNF-C dosing guidelines. 11/27 (40.7%) first trough levels

were <10 mg/L, and 10/27 (37%) were >20 mg/L. Mean trough level was 12.5mg/L (range 3.3–31.7 mg/L, median 10 mg/L). There was no significant difference in distribution of trough levels between those treated on the correct dose, and those not. No patient experienced a significant deterioration in renal function (definition: 50% increase in SCr over baseline) 3 patients demonstrated an improvement in SCr over the treatment course. There was no correlation between dose, or high trough levels and worsening renal function.

**CONCLUSIONS:** This is a small scale, underpowered study. Results suggest that BNF-C dosing guidelines produce trough levels 8–12mg/L. There is a suggestion that higher doses and trough levels would be tolerated. Larger pharmacokinetic studies are planned.

**347. Smart-pumps in the neonatal and pediatric intensive care unit: drug incompatibilities and occlusion alarms.** *Caroline Fonzo-Christe, Ph.D.*,<sup>1</sup> Amalys Kiener, M.Sc.,<sup>1</sup> Nathalie Bochaton, Nurse,<sup>2</sup> Patrick Regard, Engineer,<sup>3</sup> Peter C. Rimensberger, M.D.,<sup>2</sup> Pascal Bonnabry, Ph.D.<sup>1</sup>; (1)Pharmacy, University Hospitals of Geneva (HUG), Geneva, Switzerland; (2)Neonatal and Pediatric Intensive Care Unit, HUG, Geneva, Switzerland; (3)Biomedical Service, HUG, Geneva, Switzerland.

**OBJECTIVES:** IV drugs are often infused simultaneously in ICU. Incompatibilities may lead to precipitates occluding catheters. Occlusion alarms should alert nurses of an overpressure in the catheter to prevent clinical consequences (bolus release, over-infusion, extravasation). The objectives are to evaluate experimentally the occurrence of occlusion alarms when incompatible drugs are infused simultaneously (test A) and to determine their incidence in ward (test B).

**METHODS:** Test A: Smart pumps (Module DPS, base intensive Orchestra' Fresenius Kabi), pressure alarm level at 300 mmHg, in-line filters (0.2 microns Posidyne Neo PALL, IV Star CODAN). Y-site infusion during 24 h of furosemide (F) and midazolam (M) at incompatible concentrations for 5, 10 and 20 kgBW (respectively F 0.5 and M 1 mg/ml; F 1 and M 2 mg/ml; F 2 and M 4 mg/ml). Four infusion rates tested with or without filters:  $F_{min}$  0.05 and  $M_{min}$  0.03 mg/kg/h,  $F_{max}$  0.85 and  $M_{max}$  0.3 mg/kg/h,  $F_{min}$  and  $M_{max}$ ,  $F_{max}$  and  $M_{min}$ . Test B: Data extraction of infusion events during 206.5h on two smart pumps (5 patients).

**RESULTS:** Test A: Rapid formation of a precipitate in the stopcock in all conditions. No occlusion alarm during the 24 h Y-site infusion of F and M at 0.5 and 1 mg/ml respectively and only at maximal infusion rates (after 15 min without and 1h15 with filter) at higher concentrations. Test B: 119 infusion alarms over 206.5 h (29% occlusion alarms, no clinical consequences). Only one alarm consecutive to drug incompatibility (rifampin and TPN); no alarm during infusion of incompatible drugs (furosemide and milrinone).

**CONCLUSIONS:** Occlusion alarm at 300 mm Hg is not an efficient way to avoid risks consecutive to incompatibilities when low infusion rate are used. To prevent any clinical consequences, it is either necessary to change the pressure management (lower alarm levels) or to use in-line filters systematically.

**348. The use of azithromycin for the treatment of pediatric acute asthma exacerbations.** *Kalen B. Porter, Pharm.D., BCPS, AE-C, Caitlin Bowers, Pharm.D.* student; University of Georgia College of Pharmacy, Augusta, Georgia, USA.

**OBJECTIVES:** To determine the role of azithromycin in the treatment of acute asthma exacerbations in pediatric patients.

**METHODS:** A retrospective evaluation of all pediatric patients admitted to the Medical College of Georgia's Children's Medical Center with a diagnosis of asthma from August 1, 2007–July 31, 2008 was conducted. Patients who did and did not receive azithromycin during their hospital stay were compared for asthma score, length of stay, asthma treatments received during hospitalization, asthma severity, and presence of infection.

**RESULTS:** Approximately 350 patients were admitted to the hospital with a diagnosis of asthma from August 1, 2007–July 31, 2008. Data collection is currently ongoing. Of the first 50 patients analyzed, there were 35 patients who did not receive azithromycin and 15 patients who did receive azithromycin. Twelve of the 15 patients (80%) who received azithromycin had respiratory symptoms compared to 24 of the 35 patients (69%) in the group who did not. There were 2 readmissions in the azithromycin group compared to 7 in the group who did not receive

azithromycin. The mean length of stay was 2.6 days (azithromycin) versus 1.6 days (no azithromycin).

**CONCLUSIONS:** The results of this study will lead to a prospective evaluation of the role of azithromycin in the treatment of acute asthma exacerbations in pediatric patients.

**349. Development of rescue anti-emetic guidelines for management of chemotherapy-induced nausea and vomiting in paediatric patients.** *Julia Zingel, M.Sc., M.R.Pharm.S.*,<sup>1</sup> Janet Ferguson, M.Sc., M.R.Pharm.S.,<sup>2</sup> Moira Kinnear, M.Sc., M.R.Pharm.S.,<sup>3</sup> B. Julienne Johnson, Ph.D., M.R.Pharm.S.,<sup>1</sup> Stephen Hudson, M.Pharm., F.R.Pharm.S.<sup>1</sup>; (1)Strathclyde Institute of Biomedical Sciences, University of Strathclyde, Glasgow, United Kingdom; (2)NHS Lothian Pharmacy Service, Royal Hospital for Sick Children, Edinburgh, Edinburgh, United Kingdom; (3)Strathclyde Institute of Biomedical Sciences, University of Strathclyde; NHS Lothian Pharmacy Service, Edinburgh, United Kingdom.

**OBJECTIVES:** To develop evidence-based rescue anti-emetic guidelines for the management of chemotherapy-induced nausea and vomiting (CINV) in paediatric patients with haematological/oncological malignancies. To apply qualitative research to improve existing local anti-emetic guidelines at the Haematology/Oncology Department within the Royal Hospital for Sick Children in Edinburgh (RHSCE).

**METHODS:** An extensive literature search on anti-emetics and the management of CINV in paediatrics was undertaken and current local anti-emetic guidelines from the RHSCE and three other UK paediatric Haematology/Oncology centres were reviewed. Semi-structured questionnaires were designed and issued to doctors, pharmacists and nurses with expertise in paediatric haematology/oncology practicing at the RHSCE to obtain their opinions on the local anti-emetic guidelines and the information regarding their practice in management of breakthrough/delayed and refractory CINV in paediatric patients. A multidisciplinary team discussion took place to validate the draft guidelines.

**RESULTS:** The revised guidelines included updated prophylactic sections for acute and delayed CINV and a rescue anti-emetic therapy section for breakthrough and refractory emesis for all CINV phases. A treatment flow chart and information table for drugs used in the management of CINV were added. Recommendations concerning implementation and subsequent evaluation of the effectiveness of these guidelines were made.

**CONCLUSIONS:** The revised anti-emetic guidelines provide a decision support system for clinicians and other healthcare professionals in applying evidence-based anti-emetic treatment strategies for the management of CINV into their practices and support the use of appropriate individualised care to each patient.

**350. Evaluation of a caffeine protocol in a neonatal intensive care unit.** *Marijo Kraisinger, Pharm.D.*,<sup>1</sup> *Kristen M. Jones, Pharm.D.*,<sup>1</sup> *Mya Wilson, Pharm.D.*,<sup>2</sup> *Hilton Bernstein, M.D.*<sup>1</sup>; (1)Disney Children's Hospital at Florida Hospital, Orlando, Florida, USA; (2)University of Maryland, Baltimore, Maryland, USA.

**OBJECTIVES:** The goal was to evaluate a protocol that was implemented at Disney Children's Hospital at Florida Hospital to assist with appropriate monitoring of caffeine levels. The hypothesis was there would be no difference in the average number of caffeine levels drawn before and after implementation of the protocol. In addition, the secondary hypothesis was a decrease in caffeine level monitoring would not increase apnea episodes.

**METHODS:** A retrospective chart review of 90 consecutive neonatal intensive care unit (NICU) patients was conducted between January 2007 and February 2008. Data was collected for 45 patients prior to and following initiation of the protocol. Infants were included if they had a birth weight less than 1500 grams and received caffeine therapy for at least 1 month. Infants were excluded if they had any cardiac or congenital abnormalities. Standard doses of caffeine were used with a loading dose of 20 mg/kg and a maintenance dose of 5–8 mg/kg/day.

**RESULTS:** There was a statistically significant decrease in the average number of levels obtained after implementation of the caffeine protocol ( $p < 0.001$ ). The average number of apnea spells between the groups was similar ( $p = 0.92$ ). Protocol adherence occurred in 59% of the events. In

addition, adverse effects were documented in only a few infants but were minimal in this study.

**CONCLUSIONS:** Implementation of a caffeine monitoring protocol decreases the number of caffeine levels and reduces health care cost without compromising efficacy and safety.

**351. Pharmacist role in the education about labial adhesion to custodian of girls.** *Betty A. Torres, Pharm.D., Mirza Martínez, Pharm.D., Lydia Gonzalez, Pharm.D., Elga Vega, Ed.D.; University of Puerto Rico, School of Pharmacy, Medical Sciences Campus, San Juan, Puerto Rico.*

**OBJECTIVES:** Validate information about labial adhesion that will be used to educate custodians of girls diagnosed with this condition that will attend the University Intramural Gynecological Services.

**METHODS:** Descriptive pilot study conducted by Pharm.D. students. It included twenty seven custodians of girls 3 to 5 years old. Three interventions were made. The first one consisted of: an educational intervention; a pre and post test to evaluate knowledge about labial adhesion; treatment and prevention of recurrence; a questionnaire that collected data about feminine hygiene patterns of the girls; and evaluation of participants about the educational intervention. In the second and third intervention participants were called in order to document changes in feminine hygiene patterns of the girls that were emphasized during the first educational intervention. They used a questionnaire consisted of ten items important in feminine hygiene.

**RESULTS:** In the pre-test only 12% of the custodians of girls demonstrated knowledge about labial adhesion. After the educational intervention the post-test showed an increased to 56%. Before the educational intervention, 89% of custodians supervised the hygiene patterns of girls. At the end of the intervention this percentage increased to 100%. Ninety six percent expressed satisfaction with the educational intervention.

**CONCLUSIONS:** The educational intervention about labial adhesion was an effective technique in the education about labial adhesion to custodians of girls. The intervention increased the participant's knowledge about labial adhesion. There was a positive impact on girl's hygiene patterns since an increase in healthy hygiene conducts were documented. This educational intervention represented a good opportunity for the pharmacist to educate custodians about a condition that is common in girls. The validate information will be use by a clinical pharmacist to educate custodian of girls with labial adhesion in the gynecologic clinic.

**352. Decrease in prescribing errors with preprinted physician order form for admissions to the neonatal intensive care unit.** *Dolores Iaboni, B.Sc.Pharm, Carla Findlater, Pharm.D., Ali Estifae, M.Sc., IS, Renata Gorecki, Advanced Pharmacy Technician; Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada.*

**OBJECTIVES:** Handwritten medication prescriptions are common in the inpatient setting and are a frequent source of error. The purpose of this study was to determine the impact of the design and implementation of a preprinted order form for admission on the incidence of prescribing errors in a Neonatal Intensive Care Unit (NICU).

**METHODS:** During a one month period, an audit of all admission orders for NICU was performed using 25 criteria for prescribing errors. A multidisciplinary team designed a preprinted order form to be used upon admission to NICU. This order form was approved by all of the appropriate hospital committees. An orientation of the form to NICU staff was conducted followed by a post-implementation audit. This second audit was performed for a 2-month period following implementation using the same criteria. Rates of prescribing errors before and after implementation were compared using the StatsDirect<sup>®</sup> calculator. Next steps include a staff survey to assess the convenience and contribution to patient safety.

**RESULTS:** With the implementation of the preprinted form, the rate of total prescribing errors decreased significantly from 25% to 5% ( $p < 0.0001$  for  $\chi^2$  test), with significant differences found in legibility, absence of recorded gestational age, absence of documentation of mg/kg dosing, and use of non-approved abbreviations.

**CONCLUSIONS:** The implementation of a preprinted order form for NICU admissions significantly decreases the number of prescribing errors and minimizes handwritten admission orders; thereby suggesting an improvement in patient medication safety.

**353. Implementation of a standardized electronic medication use guide in the neonatal intensive care unit.** *Dolores Iaboni, B.Sc.Pharm, Ali Estifae, M.Sc., IS, Carla Findlater, Pharm.D.; Sunnybrook Health Sciences Centre, Toronto, Ontario Canada.*

**OBJECTIVES:** The Institute of Medicine states that healthcare organizations should make effective use of well-designed technologies. Neonatal Intensive Care Units (NICUs) are highly vulnerable to medication errors, especially during the prescribing and administration phases of the medication process. ISMP also recommends that all healthcare workers have ready access to institution-specific references incorporating standardized doses accepted by the institution. Therefore, the development of a standardized electronic medication guide for the NICU was undertaken. The system is designed to be accessible to all staff, evidence-based, multi-dimensional and easily updated.

**METHODS:** Current dosing guidelines were reviewed by pharmacists to ensure that the current available evidence and institution-specific information was reflected. Staff with advanced computer training designed a format for an electronic medication guide. Using a PDF format with hyperlinks, the updated NICU dosing guidelines formed the basis of the document. Medications were linked with instructions for preparation of medications, Y-site compatibility calculator, medication use policies, treatment algorithms and other related appendices. The guide is updated quarterly incorporating new drugs, new doses (based upon evidence-based reviews), and changes in dosage forms.

**RESULTS:** The electronic medication guide was installed on all desktop computers in the NICU and the dedicated Pharmacy satellite. Next steps include evaluation of the role of this tool in improving patient medication safety.

**CONCLUSIONS:** The development of the NICU standardized electronic medication guide has provided the NICU with an accessible, easily updated, evidence-based reference guide for medication use within the NICU.

**354. Prevention of medication errors by clinical pharmacist and the Computerized Decision Support System (CDSS) in a neonatal intensive care unit.** *Sook Hee An, M.S.,<sup>1</sup> Jae Youn Kim, Ph.D.,<sup>1</sup> Young Cheon Song, Ph.D.,<sup>1</sup> Hyesun Gwak, Ph.D., Pharm.D.<sup>2</sup>; (1)Department of Pharmacy, Asan Medical center, Seoul, South Korea; (2)Ewha Womans University, Seoul, South Korea.*

**BACKGROUND:** Neonates are at risk for medication errors attributable to individualized dosing calculation by age and weight. To prevent medication errors, development of computerized decision support system (CDSS) by clinical pharmacist was required in neonatal intensive care unit (NICU).

**OBJECTIVES:** To study the impact of CDSS and clinical pharmacist on selected NICU.

**METHODS:** We developed the CDSS for neonates, named CDSSN. Information about usual dosage by individual patients' age and weight was provided. The warning message was popped up on computer screen when high risk prescriptions (overdose and underdose) were given. The neonatal clinical pharmacist reviewed the alerted prescriptions and monitored subsequent medication use. We evaluated the effect of the CDSSN and clinical pharmacist on medication safety.

**RESULTS:** This study included 45,110 prescriptions in NICU during 8 months. The 296 medication errors were prevented by CDSSN and clinical pharmacist. The 238 overdose and 58 underdoses were prevented. Of these corrected prescriptions, the 10-fold dosage was 99 prescriptions and the 0.1-fold dosage was 38 prescriptions.

**CONCLUSIONS:** The CDSSN and clinical pharmacist prevent medication errors that may caused adverse drug events and support the appropriate medication use in NICU.

**355. Evaluation of voriconazole levels in pediatric bone marrow and cord blood transplant patients.** *Kathryn R. Matthias, Pharm.D.,<sup>1</sup> Heidi A. Hadley, Student,<sup>1</sup> Susanne Cassie, R.N.,<sup>2</sup> Michael L. Graham, M.D.<sup>1</sup>; (1)The University of Arizona, Tucson, Arizona, USA; (2)University Medical Center, Tucson, Arizona, USA.*

**OBJECTIVES:** Voriconazole levels obtained from pediatric bone marrow or cord blood transplant (BMT) patients were evaluated in relation to voriconazole doses and potential confounding variables.

**METHODS:** A retrospective study was performed to evaluate the dosing of voriconazole and voriconazole levels in BMT patients under the age of 14 at a tertiary acute care medical center between July 2006 and June

2008. All included patients had received at least four consecutive doses of voriconazole for prophylaxis of invasive fungal infections prior to initial voriconazole level. Evidence of fungal infections and potential complications of voriconazole therapy were also evaluated in each patient.

**RESULTS:** More than 300 voriconazole levels were evaluated in 28 BMT patients ranging in age from <1 to 13 years. Based on the patients' actual body weight and height, voriconazole doses ranged from 6.8 to 40 mg/kg/day (median 12 mg/kg/day) and 172 to 858 mg/m<sup>2</sup>/day (median 324 mg/m<sup>2</sup>/day). Dosing of voriconazole was scheduled every 12 hours in all patients except for one patient with every 8 hour dosing. The majority of levels (87%) were obtained after intravenous doses. Trough voriconazole levels ranged from <0.1 to 10 µg/mL; the majority of levels (71%) were <1 µg/mL while only 11% were >2 µg/mL. The majority of levels >2 µg/mL correlated with an acute decrease in renal function. Fungal infections (all *Zygomycosis species*) during the transplant period were documented in 3 patients.

**CONCLUSIONS:** Voriconazole trough levels >1 µg/mL were not consistently obtained in pediatric BMT patients based on every 12-hour dosing despite significant increases in dose.

**356. Implementing universal indomethacin prophylaxis to reduce pulmonary hemorrhage in a neonatal intensive care unit.** *Betsy Walters Burkey, Pharm.D., BCPS, David Dolcini, RRT-NPS, Jeffery Pietz, M.D., Babu Achanti, M.D., Erin Clifford Stepka, M.D., Ph.D.;* Fairview Hospital/A Cleveland Clinic Hospital, Cleveland, Ohio, USA.

**OBJECTIVES:** Our neonatal intensive care unit had an increase in pulmonary hemorrhage in the very-low-birth-weight population over the course of two years leading into 2007. The decision was made to universally administer indomethacin prophylaxis to all infants born under 1000 grams to attempt to reduce our pulmonary hemorrhage rate.

**METHODS:** Our data collection resides within the Vermont Oxford Network (VON) and additional information necessary will be collected from individual electronic charts. The NICU has followed a strict feeding protocol for twenty-plus years and prior to this practice change, maintained almost 100% avoidance of any early non-steroidal anti-inflammatory drugs or steroids for any indication. This has been attributed to the very low rate of necrotizing enterocolitis in comparison to other NICUs within the VON. The intraventricular hemorrhage prophylaxis dose of 0.1 mg/kg of indomethacin intravenously was given every 24 hours for 3 doses to all infants below 1000 grams.

**RESULTS:** It was determined that in order to detect a 13% reduction in pulmonary hemorrhage, a total of 110 babies in each arm would be needed to achieve 80% power with a 0.05 significance level. The incidence of pulmonary hemorrhage prior to administration of indomethacin was 20%. One year post intervention, we have given indomethacin to 29 babies below 1000 grams born and have had an overall pulmonary hemorrhage rate of 10.3% (relative reduction of 51%). We have had only one case of confirmed necrotizing enterocolitis, but have begun to investigate our incidence of feeding intolerance.

**CONCLUSIONS:** We expect to continue collecting data until 2010 to have enough infants unless interim analysis indicates an unacceptable increase in bowel injury.

**357. Evaluation of the effectiveness, safety, dosing and cost with intravenous ibuprofen lysine for patent ductus arteriosus in a community hospital.** *David N. Copelan, Pharm.D., MPA, FASHP;* Southern Regional Medical Center, Riverdale, Georgia, USA

**OBJECTIVES:** Evaluate the effectiveness, safety, dosing and costs of Ibuprofen lysine (IBU) for neonates with patent ductus arteriosus (PDA) within a community-based setting.

**METHODS:** A retrospective medication-use evaluation was performed for all patients receiving IBU for PDA from 8/1/06 to 9/30/08 at Southern Regional Medical Center. A chart review was performed to identify birth date, GA, age in days of first dose, number of doses, resolution, and date of ductal closure. Safety involved lowest urine output (UOP) and highest serum creatinine (SCr) during the 5 days after IBU, and any IVH (via cranial ultrasound) or NEC during hospital stay. IVH rate was compared vs. institutional rates over the last 3 yrs. Descriptive statistics were employed and a cost minimization analysis was performed using an acquisition cost of \$494/dose.

**RESULTS:** Data were obtained from 44 infants. The mean GA was 26.98 wks (range: 23–36 wks), with 63% of infants <27 wks. The mean age at 1st dose was 3.16 days (range: 1–7). PDA closure rates were 86.5% overall, 81% for <27 wks, and 100% for ≥27 wks. Closure occurred in 59.4% of those after the 1st dose and another 34.4% after the 2nd dose. UOP <1.0 mL/kg/hr and SCr >1.5 mg were seen in 6.8% and 13.6% respectively. NEC was seen in 4.5% of infants. IVH (all grades) was reported in 48% of infants; whereas the institutional 3-year rate was 41% overall and 57% in infants <27 wks. The mean number of IBU doses was 1.47 (range 1-3) translating to a mean cost of \$726.18.

**CONCLUSIONS:** Closure rates, renal effects, and NEC rates with IBU appear similar to previous experience. Closure occurred with 1 or 2 doses, translating to lower IBU costs. The IVH rate, though high, fell within reported institutional rates and will require further evaluation.

**358. Lysosoma storage diseases (LSDs): the development of synergies between hospital pharmacists and physicians in order to develop pertinent care plans.** *Michelangela Fabbrocini, Hospital-Pharmacist, Maria Teresa Carbone, Department of Paeditrcs, Vincenzo Giordano, Setting and Planning-Manager, Alfonso Bernardo, Setting and Planning-Manager, Salvatore Nardi, Urgency and Internal Medicine, Paolo Bellis, Urgency and Internal Medicine, Antonio Correr, Department of Paediatrics, Nicola Silvestri, Medical-Director; ASL NA 1, Napoli, Italy.*

**OBJECTIVES:** Rare diseases are life-threatening or chronically-debilitating diseases with a low prevalence and a high level of complexity. Lysosomal Storage Diseases (LSDs) are a group of approximately 40 rare inherited metabolic disorders occurring with incidences of less than 1:100,000, however, as a group, the incidence is about 1:5,000/10,000. Enzyme Replacement Therapy (ERT), modifying and attenuating the phenotype and disease progression, has given an important contribution to improve the QoL of patients affected by LSDs. The treatment is invasive and onerous. With the intention of making more approachable the administration of ERTs, patients were given the opportunity to choose the nearest ASL's hospital, instead of Prescribing Centers (PCs).

**METHODS:** ASL-NA-1 has named a Rare-Diseases-Team composed of a Hospital Pharmacist, Manager and Referee Physicians for Paediatric and Adult diseases and Hospital Setting/Planning Managers. Aims of this Team are: assist patients/families affected by a rare disease; integrate knowledge developing a Care-Plan which includes the delivery of Pharmaceutical-Care; administer therapies; monitor rare diseases/therapies, in order to grant pertinence of prescriptions and share therapy protocols.

**RESULTS:** Since July-2008 the Team enlisted 5 patients; 3 of them were paediatric patients affected by Hunter-Syndrome (Mucopolysaccharidosis-Type-II), Pompe-Disease (acid α-glucosidase deficiency) and non-neuronopathic-(Type-1) or chronic-neuronopathic-(Type-3) Gaucher-Disease. In all cases was required ERT; EMEA drugs approved are respectively idrusulfase and alglucosidase-alfa (as Orphan-Drugs, alglucosidase alfa under "Exceptional Circumstances") and imiglycerase. After flanking the PC's Physicians, the Paediatric-Team began to administer therapy as intravenous 4 hours infusions every 7/15 days, followed by 2 monitoring hours (cardiac/respiratory activity and reactivity) during which patients were entertained in a dedicated resting/recreating area.

**CONCLUSIONS:** The Care Plan will be a starting point in the development of synergies between ASL's hospitals and PCs, and moreover, between Physicians and hospital Pharmacists in order to share protocols and opinions regarding rare diseases. The first Rare Disease Team's goal was to grant ERT to those patients who preferred to access ASL's hospitals, but it is already working on clinical audits, patient's booklets and a web-information-site with an ask/answer question section.

**359. Survey of the prevalence of use of complementary and alternative medicines in a pediatric oncology population.** *Preeti Singh, M.B.B.S., M.P.H., student,<sup>1</sup> Tracy Hagemann, Pharm.D.,<sup>2</sup> Kapil Saxena, M.D.,<sup>3</sup>* (1)University of Oklahoma College of Public Health, Oklahoma City, Oklahoma, USA; (2)The University of Oklahoma College of Pharmacy, Oklahoma City, Oklahoma, USA; (3)University of Oklahoma, College of Medicine, Oklahoma City, Oklahoma, USA.

**OBJECTIVES:** Complementary and alternative medicine (CAM) is generally defined as diverse medical practices, systems and products that are used along with or in place of conventional medicine. Published studies in adults have demonstrated that persons using CAM typically are educated, have chronic diseases and are insured. The prevalence of CAM in pediatric oncology patients has been reported as ranging from 41% to 84%. Reports in the literature have shown that approximately 50% of CAM therapies used are not reported to the health care provider, and 85% of children using CAM are concurrently enrolled in a clinical trial for their primary cancer. The primary purpose of this study is to identify the extent and patterns of use of CAM in children within the pediatric oncology clinics at The Children's Hospital at OU Medical Center. Secondary objective is to ascertain whether health professionals are informed about the patients' use of these products. Third objective is to identify perceived barriers to sharing information about use of CAM with health care providers.

**METHODS:** A live face-to-face 25-point questionnaire survey was administered to pediatric oncology patients (or their caregivers). Patients included those undergoing active treatment and those who presented to our off-therapy long-term follow-up clinic. The questions asked included demographics, use of herbal products, dietary supplements, chiropractic, relaxation techniques, prayer, nutrition, acupuncture, massage, aromatherapy, music therapy, special diets, Ayurvedic, and vitamins. Patients were also asked whether any CAM therapies had helped them, where they received their information about CAM and if they had notified their healthcare provider. If the provider was not informed, questions further probed any perceived barriers.

**RESULTS:** A total of 91 patients were enrolled and surveyed.  $\chi^2$  analysis was used for categorical variables and analysis of variance for continuous variables.

**CONCLUSIONS:** Results will be presented.

**360. Banding of antibiotic doses for neonates.** *Amanda Bevan, B.Sc. (Hons), D.Pharm., Philip Hayes, B.Sc. (Hons), Ailsa Hutchinson, B.Sc. (Hons); Southampton University Hospitals NHS Trust, Southampton, United Kingdom.*

**OBJECTIVES:** This service was developed to enable antibiotics to be administered locally to babies on the postnatal wards.

**METHODS:** A range of dose bands for cefotaxime was designed. The procedure for prescribing included a guide on the timing of doses to be given twice daily at specific times. Having set times has allowed a drug round service to be developed. A range of dose syringes were made by pharmacy to enable each band to be made up of one or two syringes. Two nurses from the Neonatal Unit conduct a ward round twice a day to administer the antibiotics. The syringes are stored in the fridge on the Neonatal Unit and are carried to the ward for the drug round. An initial audit was carried out for workload calculation. Babies who are admitted to the neonatal unit have their doses calculated on an individualised basis.

**RESULTS:** The dose bands range from 150 mg up to 400 mg, doses are prescribed at 9 am and 7 pm, these times fit best with staff availability from the neonatal unit. Syringes are made in 150 mg and 200 mg strengths and are made weekly. The number of syringes required per week varies. The system has removed the need for babies to be transported from the post-natal wards to the neonatal unit for their antibiotics and has made the giving of antibiotics on the postnatal wards much easier. There have not been any reported problems with the use of banded doses of antibiotics in this group of patients.

**CONCLUSIONS:** Dose banding and the use of pre-filled syringes for newborn babies is a viable and efficient method for antibiotic treatment. Having antibiotics prescribed at set times has enabled the administration to be carried out as a drug round. It may be considered for other drugs in other areas within the hospital in the future.

**361. Microbiologic stability of neonatal parenteral nutrition supplied as all-in-one admixtures.** *Grazia Mingolla, Pharmacy, Anna Bianca Calzona, Pharmacy, Giovanni Guarany, Pharmacy, Gerardo Miceli Sopo, Pharmacy, Roberto Tazza, Pharmacy; Sandro Pertini Hospital, Rome, Italy.*

**OBJECTIVES:** Many newborn infants in the Neonatal Intensive Care Unit cannot obtain adequate nutritional intake via the gastrointestinal

tract, so they require parenteral nutrition. Parenteral Nutrition Solutions (all-in-one admixtures) for premature neonates of Casilino General Hospital (P.O.ASL Roma B) are prepared in Sandro Pertini Hospital's Clinical Pharmacy, under the responsibility of pharmacists. The aim of this study was to examine the microbiology stability of all-in-one admixtures.

**METHODS:** Stability studies were carried out on 31 all-in-one admixtures. Stability assays consisted of the assessment of the admixture's LAL test, Bacteriological test (*E. Coli*, *P. aeruginosa*, *S. Enterici*, *Aureus*, *Bacillus Cereus*, etc.). For the measurements, the admixtures were stored at 2 different temperatures, 2–8°C (storage) and 25°C (compounding), and then analyzed at a starting time, 24 hours, 48 hours, 72 hours and after compounding.

**RESULTS:** The investigation was held from May 2006 to May 2007. 313 all-in-one admixtures were set among which 31 (10%) were analysed. The 31 all-in-one parenteral admixtures for neonates were shown to be microbiology stable under analysis conditions, and there were no contaminations.

**CONCLUSIONS:** The manual preparation of parenteral admixtures for neonates didn't alter microbiologic stability of the admixtures. The specific procedure will be published in the guidelines of Parenteral Nutrition preparation for Pediatric Patients.

**362. From laboratory to bedside and back again The use of blood spot analysis in paediatric care.** *Sangeeta Tanna, B.Sc., Ph.D.,<sup>1</sup> Graham Lawson, B.Sc. Ph.D.,<sup>1</sup> Hussain Mulla, B.Sc., Ph.D.,<sup>2</sup> Hitesh Pandya, M.B.ChB., M.D.<sup>2</sup>; (1)Leicester School of Pharmacy, Faculty of Health and Life Sciences, De Montfort University, Leicester, United Kingdom; (2)Children's Hospital and Centre for Therapeutic Drug Evaluation of Drugs in Children, University Hospitals of Leicester NHS Trust, Leicester, United Kingdom.*

**OBJECTIVES:** A dried blood spot (DBS) sampling system for newborns was investigated as a means of using small volume samples for measuring drug levels to obtain pharmacokinetic (PK) information and therefore to enable optimal paediatric patient care. We describe the development and validation of a micro-analytical technique for the determination of captopril, used for the treatment of paediatric heart failure, from DBS collected on Guthrie card. The stability of this simple format for blood samples was investigated.

**METHODS:** A rapid sensitive liquid-chromatography ion trap mass spectrometry method with selected ion monitoring was developed to determine captopril levels in DBS. The stabiliser 1,4 dithiothreitol was used both to pre-treat the Guthrie cards and as part of the extraction medium in order to enable the determinations of low levels of captopril extracted from the DBS.

**RESULTS:** The extraction efficiency for the recovery of captopril from spiked blood spots was demonstrated to be  $90 \pm 10\%$ . Validation showed good precision and linearity with a limit of detection of 10 pg in the DBS, 4ng/ml in whole blood or 40 ng/kg body weight. This method was applied to blood spots on Guthrie card taken from a neonate patient previously administered 1 mg/kg captopril orally. The amount of captopril in the DBS was 1.8 ng which equates to 88 ng/ml in whole blood or 7.04  $\mu\text{g/kg}$  body weight.

**CONCLUSIONS:** The DBS method offers a way to enable paediatric PK studies for captopril. The small volume (20  $\mu\text{l}$ ) of blood required combined with the simplicity of the extraction procedure and analytical technique together with the demonstrated stability makes this a useful procedure for monitoring captopril concentrations for paediatric PK studies and possibly other clinical trials. This method could also be adapted to determine the levels of other drugs and may facilitate assessing medication compliance and therapeutic monitoring in a routine clinical setting for paediatric patients.

**363E. A Cross-sectional study comparing variation in body surface area and chemotherapy dosing in pediatric oncology using two different methods.** *Wasil A. Jastaniah, M.D., FRCP(C), Mohammed A. Aseeri, B.Sc., Pharm.D.; King Abdul Aziz Medical City, Jeddah, Saudi Arabia.*

**OBJECTIVES:** Standardizing Body Surface Area (BSA) determination is essential for avoiding variation in chemotherapy dosage calculations. In this study we compared variation in BSA calculation using weight and

height by the Mosteller formula with weight alone using recently adapted table in a pediatric oncology center.

**METHODS:** A Cross-sectional study of pediatric oncology patients presenting to the pediatric oncology clinic over a week period of time.

**RESULTS:** One hundred consecutive pediatric oncology patients presented to the clinic. The mean BSA calculated by the Mosteller formula was 0.83 m<sup>2</sup> (SD 0.24) and the mean BSA determined by the table (based on weight alone) was 0.82 m<sup>2</sup> (SD 0.25). The mean variation in dosing between the two methods was 1.64% (SD 3.4). Only 13 out of 100 patients (13%) had equal dosing using both methods and 21 out of 100 patients (21%) had dosing variation greater than 5%. When comparing both methods, using paired *t*-test, the difference was statistically significant ( $t_{(99)} = 3.99$  and  $P < 0.001$ ).

**CONCLUSIONS:** Significant differences in BSA-based chemotherapy dosing exist in our center. The Mosteller method should remain the standard until prospective studies are performed to determine the significance of this dosing variability on toxicity and survival outcome.

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**364E. Development of a pharmacist-based pediatric anticoagulation program.** Elora Hilmas, Pharm.D., BCPS; Alfred I duPont Hospital for Children, Wilmington, Delaware, USA.

**OBJECTIVES:** Joint Commission requires that all organizations that provide anticoagulation therapy meet the requirements of National Patient Safety Goal (NPSG) 3E. Through the use of innovative new processes, surveillance, and computerized tools, pharmacists will play a central role in the implementation of this goal at our institution.

**METHODS:** Through various pharmacy-based initiatives, we target patients on anticoagulants, provide dosing, monitoring, and document the efficacy of these agents. This program will be fully implemented by January 2009. It is currently implemented in a pilot phase.

**RESULTS:** The pharmacist-based pediatric anticoagulation program consists of several components: a daily surveillance report, a computerized anticoagulation therapy calculator and monitoring sheet, auto-generated lab reports that print in the pharmacy, documentation binders, pharmacist involvement with discharge counseling, and competency exams for all pharmacists. Pharmacists run daily reports that show patients that are receiving the target medications and will then provide the prescriber with assistance with the dosing and monitoring of the medication according to our hospital guidelines, which were based on the 2004 Chest guidelines for antithrombotic therapy in children. A computerized dosing nomogram and monitoring sheet for each target medication was developed, which assists with the complicated calculations required for dose adjustments in pediatrics. In addition, anticoagulation lab results have been directed to print in our pharmacy to prompt pharmacists to provide advice for appropriate dose changes. A new pharmacy consult was developed to allow prescribers to request a pharmacist to provide discharge counseling. Finally, pharmacist interventions are cataloged in an anticoagulation binder to allow the auditing of the program elements and to determine if pharmacy involvement facilitates the achievement of desired patient outcomes.

**CONCLUSIONS:** Through the use of several innovative processes and tools, we have been able to address the majority of the components of the NSPG 3E with a pharmacist-run anticoagulation program.

Presented at the 17th Pediatric Pharmacy Conference and Annual Meeting, Baltimore, Maryland, October 2-5, 2008.

**365. Rectal paraldehyde in the management of convulsive status epilepticus in children.** Andrew G Rowland, M.D., Andrea M. Gill, M.Sc., B.Pharm., Briar Stewart, M.D., Richard E Appleton, M.D.; Alder Hey Children's NHS Foundation Trust, Liverpool, United Kingdom.

**OBJECTIVES:** To undertake a prospective study to describe the use of rectal paraldehyde in children with status epilepticus.

**METHODS:** Data collection forms were designed and distributed to 4 hospitals in the North West of England's Regional Epilepsy Network. Over 12 months nursing staff completed a form for each dose of rectal paraldehyde administered and returned them to the Pharmacy Department. Information collected included age of the child, dose of paraldehyde, other anti-convulsants used to terminate the seizure, cessation of the seizure and any respiratory depression occurring.

**RESULTS:** Data was available for 53 episodes in 30 patients. Patients

were aged from 5 months to 16 years (mean 6.12 years, median 5.91 years) and received a dose of 0.08 ml/kg to 0.83 ml/kg (mean dose 0.65 ml/kg, median 0.79 ml/kg). Twelve episodes occurred in the Emergency Department, 10 in critical care and 31 in inpatient wards. Thirty five (66%) of the children had a pre-existing diagnosis of epilepsy. Rectal paraldehyde terminated the seizure in 33 (62%) episodes. Paraldehyde terminated the seizure within 10 minutes in 23 (70%) of the 28 episodes where this was recorded. No respiratory depression was recorded. Rectal paraldehyde was used first-line in 19 (36%) episodes, 16 with a pre-existing diagnosis of epilepsy. A benzodiazepine was used before paraldehyde in 58% of episodes. In 27 of the 33 episodes (82%) where paraldehyde terminated the seizure, no further rescue anticonvulsants were required.

**CONCLUSIONS:** This prospective, descriptive study of rectal paraldehyde in children with convulsive status epilepticus is unique despite this was recorded. No respiratory depression was recorded. Rectal paraldehyde was used first-line for the majority of patients, paraldehyde was effective within an appropriate time frame in patients who had not responded to other anticonvulsants.

**366. Good approach to treatment of disseminated Lymphangiomatosis.** Vesna Rosovic-Bazijanac, M.Pharm., V. Rozmanic, Prof., K. Manestar, Prof., S. Banac, Prof., D. Miletic, Prof., N. Cace, Prof., V. Ahel, Prof.; Klinicki Bolnicki Centar Rijeka, Rijeka, Croatia.

**OBJECTIVES:** Lymphangiomatosis has been characterized as a rare pathological condition in which multiple lymphangiomas appear in various body constituents and can involve the skeletal system, connective tissue, and visceral organs which can obstruct, compress or destroy vital structures. Etiology of this disorder is unknown.

**METHODS:** Our patient was 9-year-old girl with lymphangiomatosis of soft tissue. Her disease presented with edema of neck and both lower part of legs. Diagnosis was made by MRI and ultrasound of both lower part of legs and neck. The neck biopsy revealed dilated lymphatic channels of soft tissue of the neck. The patient received interferon alfa-2b, 3 million U/m<sup>2</sup>/daily. Significant clinical and radiological improvements were observed. After the first month of therapy the dosage was reduced to 2 million U/m<sup>2</sup>/daily for three times a week because of fever, nausea and vomiting. In the fourth month of therapy with interferon thyroid dysfunction occurred - autoimmune thyroiditis.

**RESULTS:** Improvement of disease was marked after clinical and radiological findings two months later and cost benefit was confirmed: Intron A' 18 million U = 110 Euro x 19/year = 2 090 Euro = 174.16 Euro monthly

**CONCLUSIONS:** Our observations suggest that intrferon alfa-2b may be an effective treatment of disseminated lymphangiomatosis but significant toxicity has also been observed.

**367E. Extended-interval gentamicin administration in neonates greater than 34-weeks gestational age.** Gladys M. El-Chaar, Pharm.D.,<sup>1</sup> Susana Castro-Alcaraz, M.D.,<sup>2</sup> Tingnong Supaswud, M.D.<sup>2</sup>; (1)St. John's University College of Pharmacy and AHP and Schneider Children's Hospital of the NS-LIJ HS department of pharmacy, Jamaica, New York, USA; (2)Schneider Children's Hospital of the North Shore-Long Island Jewish Medical Center, New Hyde Park, New York, USA.

**OBJECTIVES:** Extended-interval gentamicin administration (EIGA) has been adopted in neonates to maximize the drug's pharmacodynamics and minimize its toxicity. Neonatal guidelines for EIGA dosing derived from the literature remain complicated. Our aim was to simplify them. Our hypothesis is that using a uniform gentamicin dose of 5 mg/kg IV every 36 hours for all neonates will reduce the number of elevated trough serum gentamicin concentrations (defined as  $\geq 2$  mg/L), from approximately 50% (from a retrospective chart review) to 10%. A sample size of 23 neonates in each group was needed to detect this difference. Other objectives were to improve gentamicin's pharmacodynamics and safety while simplifying its dosing.

**METHODS:** This prospective, randomized, controlled study compared traditional dosing (control group) to EIGA (study group) in neonates >34 weeks gestational age (GA). Another study arm of neonates  $\leq 34$  weeks GA is still in progress. Traditional dosing entails using a loading dose and multiple daily dosing. Inclusion criteria: neonates >34 weeks

GA and <6 months postnatal age. Exclusion criteria: neonates previously enrolled or endocarditis. Hearing screens and renal function parameters were closely monitored.

**RESULTS:** 46 neonates were enrolled, 23 in each group. Overall, elevated trough concentrations are reported in 0% vs. 39% in the EIGA and traditional groups, respectively.  $C_{max}$  and AUC achieved were  $10.9 \pm 1.86$  mg/L vs.  $6.83 \pm 1.33$  mg/L and  $161.38 \pm 29.11$  vs.  $89 \pm 2$  6.38 mg/hr/L in the EIGA and traditional groups, respectively. One patient in the traditional group failed the hearing screen whereas none did in the EIGA group. One child in the EIGA group had transient elevation in serum creatinine levels. None of the patients had a documented gram-negative sepsis.

**CONCLUSIONS:** A gentamicin dose of 5 mg/kg IV every 36 hours in neonates >34 weeks GA improved the drug's pharmacokinetics and possibly pharmacodynamics, was simple, and did not increase the incidence of adverse effects.

Presented at the 2008 Pediatric Academic Society and Asian Society for Pediatric Research Joint Meeting, May 2008.

**368. Free versus total cortisol levels in treatment of adrenal insufficiency in the newborn.** Varsha Bhatt-Mehta, M.S., (CRDSA), Pharm.D., FCCP, John D Barks, M.D.; University of Michigan, Ann Arbor, Michigan, USA.

**OBJECTIVES:** Determine the relationship between total and free cortisol levels in newborn infants with relative adrenal insufficiency.

**METHODS:** A non-interventional study of residual plasma from blood collected for routine laboratory tests of infants receiving intravenous Hydrocortisone (HC) for treatment of pressor resistant hypotension due to presumed adrenal insufficiency. Residual plasma for free cortisol (FC) concentrations at baseline prior to IVHC administration per a predesigned dosing protocol was collected from the clinical laboratory and frozen at  $-80^{\circ}\text{C}$  until analysis (LC-MS). Demographic data and baseline total cortisol level values measured routinely to guide HC treatment, analyzed by the clinical pathology laboratory using radioimmunoassay methods (RIA), were collected from the patient's medical record.

**RESULTS:** 36 pairs of Total vs. Free baseline HC were available for analysis. The Mean ( $\pm$  SD) GA, PNA, BW and treatment WT were  $29.1 \pm 5.7$  weeks,  $1.78 \pm 3.36$  weeks,  $1.49 \pm 1.27$  kg and  $1.65 \pm 1.25$  kg, respectively. The correlation between free and total cortisol levels was strong ( $r^2=0.8$ ) for concentrations  $\leq 10$  ng/mL. However this correlation became much weaker at higher concentrations.

**CONCLUSIONS:** Cortisol is highly protein bound and may provide variable total serum cortisol values in premature and term infants secondary to fluctuating protein concentration as a result of prematurity, malnutrition and critical illness. Free cortisol values are a more reliable indicator of adrenal insufficiency but not easily measured routinely. The results of this study suggest good correlation between free and total cortisol levels at low cortisol values. However, total cortisol levels under stress conditions or during HC treatment are much higher and do not correlate well with free cortisol levels. Routine RIA methods may not reflect true cortisol levels under stress or during treatment of relative adrenal insufficiency.

**369E. Use of olanzapine for emergency management in the agitated pediatric patient.** Brenda E. Darling, Pharm.D.,<sup>1</sup> Mercedes Uribe, M.D.,<sup>2</sup> Maria Stephan, M.D.<sup>3</sup>; (1)Children's Medical Center, Dallas, Texas, USA; (2)UT Southwestern Medical Center, Dallas, Texas, USA; (3)UT Southwestern Medical Center, Dallas, Texas, USA

**OBJECTIVES:** Treatment of agitation (AG), posing a safety risk to the patient (pt) and caregiver, is problematic in pediatrics. Benzodiazepines are the mainstay of treatment in most emergency pts. Olanzapine (OL), is an alternative used in AG adult psych patients. This use is considered off-label in children. We present the first study describing the use of OL in pediatric pts presenting with AG, violence or psychosis to the emergency department (ED).

**METHODS:** A 3-year retrospective study of pts <18 yrs of age given OL for treatment of AG in a pediatric ED was performed. Data obtained included: age, race, PMH, PE, VS, medication (med) given, drug effect, adverse events, and disposition.

**RESULTS:** 63 pts were identified: aged 3–17 yrs. 67% were <13 yrs. 70% male, 57% Caucasian, 80% had psych diagnoses. Concurrent meds

included: risperidone 18%, valproic acid 17%, quetiapine 16%. Chief complaints were: altered mental status (AMS) (6.3%), violent behavior/AG (85%), suicidal (9.5%). PE revealed: AMS (3.2%), AG (82%), violent (75%), combative (25%). 14% pts required physical restraints. 100% were given OL orally. 80% received 5 mg of OL. 37% required a second med (OL-86%, haloperidol-13%, lorazepam-1%). 5 pts had minor alterations in VS. 71.5% reported decreased agitation with 1 dose of OL. 1pt developed hypotension, resolving with IVF. There were no statistical differences between pts with and without known psych disease or concurrent neuroleptic med use with respect to drug doses, efficacy, or adverse events.

**CONCLUSIONS:** OL appears to be a safe and effective orally administered drug in the treatment of the AG/violent pediatric patients. No patient developed a serious adverse event. Limitations were: retrospective study, small patient number, difficulty determining drug effect, and long-term outcomes. Prospective studies are needed to verify this result. We recommend caution in the use of OL in pts taking neuroleptic drugs and in those with undifferentiated AMS.

Presented at the North American Congress of Clinical Toxicology, Toronto Canada, September 11–16, 2008.

**370. Once-daily aminoglycoside dosing versus thrice or twice-daily dosing in cystic fibrosis patients: A comparison using pharmacokinetic simulations.** Jeanette D. Straight, Pharm.D., Sarah C. Erush, Pharm.D., BCPS, Talene A. Metjian, Pharm.D.; The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, USA.

**OBJECTIVES:** The use of once daily aminoglycoside dosing (ODD) has become increasingly common in hospitalized adult patients and in some pediatric patient populations. Despite studies in adults, concluding that ODD of aminoglycosides is as safe and effective as traditional dosing, ODD remains a controversial issue in the treatment of pediatric cystic fibrosis (CF) patients. The purpose of this study was to analyze simulated serum tobramycin levels for ODD, twice daily (BID), and thrice daily (TID) dosing in anticipation of determining an optimized aminoglycoside dosing regimen for pediatric CF patients based on estimated serum tobramycin levels.

**METHODS:** Serum tobramycin levels of standardized ODD, BID, and TID doses were calculated using pharmacokinetic parameters established from preexisting data on TID dosing of tobramycin in 140 pediatric CF patients from December 2003 to September 2006.

**RESULTS:** Results demonstrated that 54.5% of the patients had undetectable serum levels at 12 hours with ODD. These patients tended to be younger, weigh less, and were more commonly female. Compared to TID dosing, BID dosing provided significantly more peaks at goal, while maintaining troughs less than  $2 \mu\text{g/mL}$ .

**CONCLUSIONS:** The results of this study indicate the need for further data on BID versus ODD in pediatric CF patients. Long-term studies on the susceptibility patterns of microorganisms in CF patients using ODD are also recommended.

**371E. Improving and reducing first dose antibiotic turnaround time for pediatric patients.** Abigail A. Dee, Pharm.D.,<sup>1</sup> Brian Kelly, Pharm.D.,<sup>1</sup> Christian Hampp, Ph.D.,<sup>2</sup> Carole Kimberlin, Ph.D.<sup>2</sup>; (1)Shands at University of Florida, Gainesville, Florida, USA; (2)University of Florida College of Pharmacy, Gainesville, Florida, USA.

**OBJECTIVES:** Antibiotic timing is used as a quality standard for hospital accreditation and is an important quality measure. The study aim was to identify barriers in the process of first dose antibiotic administration on the pediatric floors at Shands at the University of Florida and to identify interventions to improve turnaround time to less than one hour.

**METHODS:** This was a quasi-experimental study of pediatric patients less than 18 years of age initiated on intravenous antibiotics. Every order for a first dose intravenous antibiotic was assessed on all pediatric floors between October 24, 2008 and November 13, 2008. Orders that did not meet overall turnaround time goal of less than or equal to 1 hour were identified. A root cause analysis (RCA) was performed to identify reasons for delayed antibiotic administration. Barriers identified in the RCA were used to develop interventions to improve compliance with the 1-hour turnaround time to greater than 80%. Lastly, a post-intervention period analysis following the interventions will be performed to document changes in compliance rates.

**RESULTS:** During the assessment period, 30 out of 47 total physician orders for a first dose intravenous antibiotic did not meet the one-hour overall turnaround goal. Of these orders, 100% (30/30) did not have 'STAT', 'now', or 'first dose antibiotic' indicated on the physician order. Causes of antibiotic delay were divided into medical staff (12%), clerk (33%), pharmacy (19%), nursing (24%) and other (12%). Areas of planned interventions include education and executing an alert system. The post-intervention analysis will be performed following the implementation of these interventions.

**CONCLUSIONS:** System barriers were identified to help the institution meet quality standards. Several interventions will be incorporated at specific points in the system to help in improving antibiotic timing. Final results are pending and will be completed in March.

Presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition sponsored by University HealthSystem Consortium (UHC), Orlando, FL, December 6, 2008.

**372. Immune globulin therapy: a report of adverse events associated with immune globulin therapy at a children's medical center.** *Weng Man Lam, Pharm.D.,<sup>1</sup> Kelley R. Norris, Pharm.D., BCPS,<sup>2</sup> Kalen B. Porter, Pharm.D., BCPS, AE-C<sup>3</sup>; (1)The University of Georgia, College of Pharmacy and MCG Health, Augusta, Georgia, USA; (2)MCG Health, Inc., Augusta, Georgia, USA; (3)University of Georgia College of Pharmacy, Augusta, Georgia, USA.*

**OBJECTIVES:** The use of immune globulin therapy (IVIG) is expanding for pediatric patients. The purpose of the study was to determine the frequency of IVIG-related adverse events being reported and characterize the details surrounding those events (timing and dose of premedications given prior to IVIG infusion, rate and titration of infusion, type of adverse event).

**METHODS:** A retrospective chart review of pediatric patients receiving IVIG therapy during July 2007 to August 2008 in the Medical College of Georgia Children's Medical Center (CMC) was conducted. Data collection included indication for use (FDA-approved or unlabeled uses), dosing, infusion rate, premedications, and adverse events reported in the University Health System Consortium (UHC) Patient Safety Net Event Report and Pharmacy Adverse Events Report.

**RESULTS:** Forty one patients received a total of 111 IVIG infusions. The average dosage of IVIG was 1.2 grams/kg/dose. The average number of IVIG doses per course was 1.5. Twelve out of 41 patients (23%) experienced at least one IVIG-related adverse event, with two patients having a total of six symptoms at one time. Due to the severity of the IVIG-related adverse events, one patient was admitted to the pediatric intensive care unit and two patients were admitted to the hospital. Three out of 41 patients (7.3%) did not receive diphenhydramine and antipyretic premedications. The average starting infusion rate was 0.51 ml/kg/hour and average maximum infusion rate was 2.61 ml/kg/hour. There were 13 initial infusions that followed the manufacturer's infusion protocol. Two adverse events cases were reported to University of Health System Consortium (UHC) Patient Safety Net Event Report and Pharmacy Adverse Events Report.

**CONCLUSIONS:** More education of physicians and nurses regarding the ordering and administration of IVIG is required. An intervention should be performed by pharmacists if inappropriate infusion rates are ordered by physicians.

**373E. Establishing pediatric specific training and competency documentation for pharmacy technicians at a Women's and Children's facility.** *Melissa O'Neill, Pharm., D., Dianna K. Proulx, Pharm.D., Lindsay Lester, Pharm.D.; Huntsville Hospital, Huntsville, Alabama, USA.*

**OBJECTIVES:** Pharmacy technicians who work in special populations, such as pediatrics, should have specific training regarding the concerns and hazards pertinent to that special population. With increasing coverage of hospital errors causing serious harm, including death, in pediatric patients across the nation, the need to appropriately train and educate hospital staff is even more urgent. The purpose of this study is to establish a thorough training program and document the competency of all pharmacy technicians working at Huntsville Hospital Women's and Children's Pharmacy.

**METHODS:** A computer based test was established that contains

information pertinent to the technicians' job functions, as decided by the Women's and Children's pharmacists. Test questions will be randomly compiled from a pool of questions each year to minimize duplication. The pharmacy technicians were required to take a pre-test, followed by a post-test after receiving educational material. Technicians must obtain a 100% pass rate on the post-test to be considered competent to work within the Women's and Children's pharmacy. The number of times a technician must take the post-test in order obtain a 100% will be recorded.

**RESULTS:** Test scores will be analyzed to determine if more educational information is necessary for the pharmacy technicians to adequately perform their job. An analysis will be preformed to see if length of employment, part-time, or full time status have an impact on scores. Pharmacists and technicians will be surveyed to determine how the training can be improved for future years.

**CONCLUSIONS:** The average pre-test score was 81.6% (52–96%). IV room technicians scored an average of 14% higher than non-IV room technicians (90% vs. 76%). Technicians are currently completing educational training. This competency training program should decrease the risk of medication errors within the pharmacy and help ensure patient safety.

*Presented at ASHP*

**374. Medication preferences at different age bands in paediatrics.** *Graciela M. Calle, Principal, Pharmacist, Eduardo A. Lagomarsino, Principal Pharmacist, Gabriel H. Mato, Chief Pharmacist, Patricia Elmeaudy, Directorate; Hospital de Pediatria Prof. Dr. Juan P. Garrahan, Buenos Aires, Argentina.*

**OBJECTIVES:** This study documents the preferred formulations and flavors in pediatric out-patients at Hospital de Pediatria Garrahan, Buenos Aires, Argentina; this is a 600 beds tertiary public pediatric hospital providing complex care to children (acute and chronic). There is a lack of data about the appropriateness of pediatric formulations specifically in our country. There are many drugs with no suitable formulation and palatability for children which affects negatively compliance. The objective was to quantify and classify preferences in palatability and types of formulations for different age bands in order to accomplish the formulations which better address children's health needs.

**METHODS:** We conducted a survey in our out-patient pharmacy on February 2007 on 338 pediatric patients if possible or their parent/guardian depending on age and mental status of the patient. This was a prospective observational study; data was collected by 3 pharmacists and reviewed by a paediatric specialist. Data was recorded using Microsoft Excel version 1998, classified by frequency of age bands, gender, type of preferred formulation and flavour (strawberry-vanilla-others).

**RESULTS:** We conducted a survey on 338 children (49% male, 51% female); respondent (child 33%, parents 67%); less than a year: 19%, 1–5 years: 35%, 6–12 years: 32%, more than 12 years: 14%. Preference for liquid formulations: less than a year 95%; 1–5 years 100%; 6–12 years 67%, more than 12 years 37%. In all age bands we found preference on strawberry: less than 1 year: 77.9%; 1–5 years: 75%; 6–12 years: 71.3%; more than 12 years: 60%. Syrups were preferred between liquids by all age bands: 73%.

**CONCLUSIONS:** Liquid formulations were preferred even by children up to 12 years, possibly because of swallowing difficulty in patients with high complexity pathologies. We assume syrup has greater acceptance than other liquid formulations. Further investigations are needed to develop appropriate paediatric formulations.

**375E. Clinical development of the HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) etravirine for the pediatric population.** *Thomas N. Kakuda, Pharm.D.,<sup>1</sup> Rekha Sinha, M.D.,<sup>2</sup> Ingeborg Peeters, B.S.,<sup>2</sup> Rebecca Mack, M.S.,<sup>1</sup> Katrien Janssen, M.S.,<sup>2</sup> Aleidis Lasure, Pharm.D.,<sup>2</sup> Katia Boven, M.D.,<sup>1</sup> Richard M. W. Hoetelmans, Pharm.D., Ph.D.<sup>2</sup>; (1)Tibotec Inc., Yardley, Pennsylvania, USA; (2)Tibotec BVBA, Mechelen, Belgium.*

**OBJECTIVES:** Etravirine is a next generation NNRTI approved for use in combination with other antiretrovirals for the treatment of HIV-1 infected treatment-experienced adults. Pediatric development for etravirine commenced with a Phase I open-label trial in HIV-1 infected

treatment-experienced children to determine the weight-based dose of etravirine with the objective of achieving exposures comparable to those in adults.

**METHODS:** Children between 6 and  $\leq 17$  years with at least two consecutive viral loads  $< 50$  copies/mL on a stable lopinavir/ritonavir-containing regimen were enrolled; concomitant NNRTI use was disallowed. The trial was conducted in two sequential stages. In both stages, etravirine was added to the current regimen for 7 days followed by a morning dose and 12-hour pharmacokinetic assessment on Day 8. Etravirine was dosed 4 mg/kg bid in Stage I and 5.2 mg/kg bid in Stage II. **RESULTS:** Twenty-one children were enrolled into each stage; pharmacokinetics were available for 19 and 20 children in Stages I and II, respectively. The mean (SD)  $C_{max}$  in Stage I and II, respectively, was 495 (453) ng/mL and 757 (680) ng/mL;  $C_{min}$  was 184 (151) and 294 (278) ng/mL; and  $AUC_{12h}$  was 4050 (3602) and 6141 (5586) ng•h/mL. Pharmacokinetic parameters in Stage II were more comparable to adults (mean [SD] population derived  $C_{min}$  was 393 [391] ng/mL and  $AUC_{12h}$  was 5506 [4710] ng•h/mL,  $n=575$ ). Etravirine was generally safe and well tolerated. Two subjects (11.8%) reported rash in Stage I which resolved without any sequelae; rash was not reported in Stage II.

**CONCLUSIONS:** Based on the pharmacokinetics and safety, the proposed dose of etravirine in children 6 to  $\leq 17$  years is 5.2 mg/kg bid. Further pharmacokinetics, safety and tolerability of etravirine in this population is ongoing in the Phase II trial PIANO. Based on 24-week data from PIANO, subsequent trials will enroll children between 2 months to  $< 6$  years old.

Presented at the 16th Conference on Retroviruses and Opportunistic Infections, Montreal, Canada, February 8–11, 2009

**376E. Optimal dosing of once-daily aminoglycosides in pediatric patients with normal renal function.** Jennifer N. Ashton, Pharm.D.,<sup>1</sup> Lisa M. Taylor, Pharm.D., BCPS,<sup>1</sup> Robert Lawrence, M.D.,<sup>2</sup> Elvin T. Price, Pharm.D.;<sup>3</sup> (1)Shands at the University of Florida, Gainesville, Florida, USA; (2)University of Florida College of Medicine, Gainesville, Florida, USA; (3)University of Florida College of Pharmacy Department of Pharmacy Practice and Center for Pharmacogenomics, Gainesville, Florida, USA.

**OBJECTIVES:** To determine the efficiency of a once-daily aminoglycoside dosage in pediatric patients aged 1 month to 18 years with normal renal function in achieving tobramycin or gentamicin peak serum concentrations in a targeted range of 15 to 25  $\mu\text{g/ml}$  while maintaining a trough less than 1  $\mu\text{g/ml}$ . Secondary objectives include determining variables that affect the pharmacokinetics of once daily aminoglycosides in pediatric patients, to determine pharmacokinetic parameters, including elimination rate constant ( $k_e$ ), volume of distribution ( $V_d$ ), half-life, maximum concentration ( $C_{max}$ ), minimum concentration ( $C_{min}$ ), and estimated drug free interval, and to assess nephrotoxicity.

**METHODS:** Retrospective chart review of patients greater than or equal to 1 month and less than or equal to 18 years of age who received gentamicin or tobramycin 7.5 mg/kg/dose intravenously (IV) every 24 hours followed by post 2- and 8-hour serum drug concentrations between January 1, 2005 and October 31, 2008. Exclusion criteria include patients without a 2 or 8-hour serum concentration and/or prior history of renal dysfunction. Patient demographics, aminoglycoside dosage information and serum concentrations, and renal function information (urine output, serum creatinine) will be collected. Descriptive statistics will be used to describe demographic information and aminoglycoside treatment regimen. In addition, regression analysis will be used to identify patient subgroups for which an alternative initial dose is required to achieve a  $C_{max}$  between 15 and 25  $\mu\text{g/ml}$ .

**RESULTS:** To be presented.

**CONCLUSIONS:** To be presented.

Presented at the University HealthSystem Consortium, Orlando, Florida, Dec 6, 2008.

**377. A mnemonic developed for pediatric databases.** Per Nydert, M.Sc., Pharm.; Karolinska University Hospital, Stockholm, Sweden.

**OBJECTIVES:** Data from drug databases are often connected with regards to numbers identifying commercial products (e.g., NDC National Drug Code) or single substances. Since a substantial amount of the drugs used in pediatrics are lacking an identifying number

(extemporaneous, reconstituted or licensed drugs) there is a need for an alternative mnemonic.

**METHODS:** The drug database for the neonatal ward at Karolinska 2008 was used to investigate the number of drugs that needed a new mnemonic. A multi-layer information structure was created to be able to use part or the whole mnemonic at different levels. The levels of prescribing, administration, reconstitution, pharmacy ordering and statistical output was investigated.

**RESULTS:** Two hundred twenty-two drug preparations and 160 substances were used in the database, 156 (70%) was commercially available, 45 (20%) extemporaneously prepared and 21 (10%) unlicensed. Of those 87 (39%, 45% of the commercial available) had to be reconstituted before administration. That means that 131 (59%) lacked a proper identifying number with regard to the final product. A mnemonic consisting of 25 characters was created, incorporating standardized information with regards to the substance, administration route, pharmaceutical form, administration strength, unit and compounding information. To connect to the stand alone database with administration and dosing information only 12 characters, incorporating substance, pharmaceutical and administration form, are used. To extract data to the ordering, statistical and compounding system the full code is used.

**CONCLUSIONS:** Before this study all data was connected by automatically generated number for each post. Today the mnemonic allows the database to be connected in a comprehensive, structural way to different sources of information as well as easy sharing of drug data among international pediatric hospital pharmacies.

**378E. Prevalence of venous thromboembolism in a pediatric hospital.** Elizabeth J. Beckman, Pharm.D., BCPS,<sup>1</sup> Karen S. Hudmon, Dr.P.H.,<sup>2</sup> Iftekhar D. Kalsekar, Ph.D.,<sup>3</sup> Holly M. Knoderer, M.S., M.D.,<sup>4</sup> Jennifer L. Morris, Pharm.D., BCPS;<sup>5</sup> (1)Riley Hospital for Children, Indianapolis, Indiana, USA; (2)Purdue University, West Lafayette, Indiana, USA; (3)Butler University, Indianapolis, Indiana, USA; (4)Indiana University School of Medicine, Indianapolis, Indiana, USA; (5)Purdue University, Riley Hospital for Children, Indianapolis, Indiana, USA

**OBJECTIVES:** Development of venous thromboembolism (VTE) in children is considered rare; however, the incidence is suspected to be grossly underreported. The purpose of this study is to identify VTE prevalence and proposed risk factors in a large, pediatric, urban health system.

**METHODS:** This investigation was a retrospective cohort analysis of pediatric patients who developed a VTE from September 2002 to August 2007. Cases were identified from ICD-9 discharge diagnosis or by radiographic evidence. Controls were matched in a 2:1 (control:case) fashion on gender and admitting service. Demographics and proposed risk factors will be analyzed comparing cases to controls using appropriate inferential statistical tests and logistic regression will be utilized to assess for independence of risk factors.

**RESULTS:** Prevalence was calculated to be 1.5 VTE/1000 admissions per year. Sixty-nine cases were matched to 138 control subjects. Case population was 54% females with a median age of 8.5 years (1 month–17 years). Median length of stay and time to VTE were 55.8 days (3–379 days) and 16.4 days (0–112 days), respectively. Proposed risk factors identified in the case population included indwelling venous catheters (96%), acute immobilization (90%), systemic infection (56%), surgery (39%), malignancy (22%), trauma (13%), estrogen therapy (3%). Two or more proposed risk factors were found in 46 patients (66%). Data collection for control subjects is ongoing. Final results are pending.

**CONCLUSIONS:** The calculated prevalence of VTE is three times higher than previously published data. Preliminary analysis of the case group demonstrates indwelling venous catheters and acute immobilization were the most commonly identified proposed risk factor. The majority of case subjects had multiple proposed risk factors ( $\geq 2$ ) which may demonstrate an additive effect of proposed risk factors.

Presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting, Orlando, Florida, USA, Dec 6–11, 2008.

**379. Treatment of hyperammonemia in paediatrics: interest of Ammonul®: a case report.** Mélina Raimbault, Resident,<sup>1</sup> Armelle Junchat, Resident,<sup>1</sup> Géraldine Senon, Dr.,<sup>1</sup> Anne De La Guernne, Dr.,<sup>2</sup> Laure

Cosson, Resident,<sup>3</sup> Véronique Meteier, Dr.,<sup>1</sup> Lucie Chevremont, Resident,<sup>1</sup> François Labarthe, Dr.,<sup>3</sup> Philippe Meunier, Dr.;<sup>1</sup> (1)Pharmacy Department, Clocheville Hospital, Tours, France; (2)Pharmacy Department, Bretonneau Hospital, Tours, France; (3)Paediatric Department, Clocheville Hospital, Tours, France.

**OBJECTIVES:** Ammonia is normally produced from the catabolism of amino acids and ammonium is converted into urea in urea cycle. Genetic urea cycle disorders, most commonly ornithine transcarbamylase defect (OTC), can cause hyperammonemia. Hyperammonemia can cause neurotoxicity, which early clinical signs are lethargy and vomiting. We describe the treatment of hyperammonemia crises in a child.

**METHODS:** We report the case of a three year-old boy suffering from OTC deficiency (X-linked inherited disorder) diagnosed at birth, who was admitted for metabolic crises (ammonemia level 279  $\mu\text{mol/L}$ , normal: 25–40  $\mu\text{mol/L}$ ). Clinical presentation associated lethargy and vomiting.

**RESULTS:** An oral treatment with sodium benzoate (60 mg/kg x 4/d prescribed, only one dose administered) and sodium phenylbutyrate granules (Ammonaps® 100 mg/kg x 4/d, one administration) was started associated with a low-protein diet but no clinical improvement was observed after 4h. The treatment was switched to a venous infusion of sodium benzoate and sodium phenylacetate 10%/10% (Ammonul®, recently available in France) with a loading dose of 2.5 mL/kg over 2h, as recommended. Numerous vomiting led to stop the enteral nutrition. Because of vomiting, the dose of Ammonul® was decreased before the end of the loading dose to maintenance dose infusion (2.5 mL/kg/24h) over 24h. Vomiting disappeared with the lower dose of Ammonul®, which allowed the reintroduction of enteral nutrition. Despite the decrease of the dose, ammonia level was normalized (17  $\mu\text{mol/L}$ ) after 4h of treatment with Ammonul®.

**CONCLUSIONS:** In this case, we report a well-known side effect of Ammonul® but which frequency and intensity surprised the physicians. Its efficiency on hyperammonemia is indisputable even if the dose had to be decreased in this case. The association with an antiemetic agent could have an interest with the administration of Ammonul®. Ammonaps®, oral form is not suited to young children with severe metabolic crises, whereas Ammonul®, intravenously administered can be used in emergency in spite of the presence of vomiting.

**380. International cooperation must be improved in treating paediatric.** Xavier Cartan, Resident,<sup>1</sup> Armelle Junchat, Resident,<sup>1</sup> Géraldine Senon, Dr.,<sup>1</sup> Hélène Bourgoïn-Herard, Dr.,<sup>2</sup> Agnès Rousseau, Dr.,<sup>1</sup> François Labarthe, Dr.,<sup>3</sup> Pierre Castelnaud, Pr.<sup>4</sup> Philippe Meunier, Dr.;<sup>1</sup> (1)Pharmacy Department, Clocheville Hospital, Tours, France; (2)Pharmacy Department, Trousseau Hospital, Tours, France; (3)Paediatric Department, Clocheville Hospital, Tours, France; (4)Neuropaediatric Department, Clocheville Hospital, Tours, France.

**OBJECTIVES:** When a drug is not marketed in France, the French authorities require using priority commercial drugs when available even if the market authorization in from a foreign country. Then the French agency safety of health products must issue a Temporary Authorisation of Use (TAU) to allow the purchase. If it is not possible, capsules can be prepared by the hospital pharmacy from powder preferentially, or from pills if the powder is not available. Paediatric treatments are particularly concerned. The hospital pharmacists were recently requested by physicians who diagnosed a congenital myasthenia in a 6 months child. This pathology is a rare genetic disease that leads to neuromuscular failure. The aim of this work is to describe the French pharmaceutical difficulties to implement the regulations whereas paediatric treatment of this pathology exists.

**METHODS:** The child was first treated by subcutaneous neostigmin 6 times/day. Clinical state was improved but an oral therapy was rapidly discussed for the particular patient comfort. Pharmaceutical team realized a scientific review to find an appropriate galenic form for treatment.

**RESULTS:** Oral treatment by pyridostigmin is decided regards to litterature. No oral form of pyridostigmin is available in France. Oral form of Mestinon® is available in the, USA but its importation is not possible, so no TAU is asked. Different dosages of pyridostigmin capsules are prepared by the hospital pharmacy to allow adapted titration and avoid secondary events. This solution is not satisfactory because pyridostigmin powder is very hydrophilic which leads to

difficulties preparations and control results regularly do not comply after dosing (24% of nonconformity for 62 series of 100 capsules).

**CONCLUSIONS:** Many progresses have to be made for paediatric pharmaceutical care. Importation of commercial drugs is unfortunately difficult even if this way which should first be envisaged. The international cooperation must be improved in treating paediatric, especially between Europe and America.

**381. Pharmaceutical intervention in the nutritional care of a paediatric patient.** Lucie Chevremont, Resident,<sup>1</sup> Méline Raimbault, Resident,<sup>1</sup> Géraldine Senon, Dr.,<sup>1</sup> Caroline Paulin, Student,<sup>1</sup> François Labarthe, Dr.,<sup>2</sup> Anne Jourdain, Dr.,<sup>3</sup> Pascal Blouin, Dr.,<sup>3</sup> Stéphanie Prévot, Dr.,<sup>1</sup> Philippe Meunier, Dr.;<sup>1</sup> (1)Pharmacy Department, Clocheville Hospital, Tours, France; (2)Paediatric Department, Clocheville Hospital, Tours, France; (3)Paediatric Oncology Department, Clocheville Hospital, Tours, France.

**OBJECTIVES:** We report the case of a paediatric patient suffering from malnutrition and describe the role of the pharmacist to adapt the nutrient intake (NI).

**METHODS:** Analysis of the case and of the corrective actions.

**RESULTS:** Tom is a 12-year-old boy suffering from a myeloblastic acute leukaemia treated by chemotherapy. Since his birth, he presents -2 Standard Deviations (SD) (weight and size). At admission in the Oncology Unit, he was suffering from malnutrition (23.9 kg, 133 cm, -2SD) due to his leukaemia. One month after, considering an intestinal occlusion and his anorexia (-2 kg since hospitalization) due to refractory leukaemia, the oncologist initiated a total parenteral nutrition (TPN). For two weeks, Tom received industrial ternary TPN. After 4 days of prescription, the pharmacist detected non adapted NI of amino-acid (5.3 g/kg/d, max 3 g/kg/d) and potassium (6 mmol/kg/d, max 5 mmol/kg/d), and he informed oncologists who lowered the rate of amino-acid. As the child has lost weight (-3.1 kg from the beginning of TPN: 18.8kg) the pharmacist intervened after one week of this new TPN formula. Tom has lost 5.1 kg since admission. The nutritionist, contacted by the oncologist after the pharmacist's advice, concluded that NI were appropriate for a 12-year-old child but not for a patient suffering from malnutrition. Because of his chemo-induced diabetes (asparaginase+dexamethasone), the oncologist wanted to wait for increasing the level of glucose to know if it was a diabetes or glucose intolerance. The nutritionist advised to increase the level of glucose (9 to 13 g/kg, +1 g/day), along with that of insulin, protein and lipid to reach sufficient NI. Two weeks after the change of the prescription, Tom is in complete remission for his leukaemia and has put on 2.2 kg.

**CONCLUSIONS:** Despite the marketing authorization of the industrial bags, they are not automatically adapted to children. This case emphasizes the importance of cooperation between health professionals in the interest of patients.

**382. A retrospective analysis of factor VIIa use in pediatric patients.** Kristen G. Turner, Pharm.D.<sup>1</sup>, A. Jill Thompson, Pharm.D., BCPS<sup>2</sup>; (1)Spartanburg Regional Medical Center, Spartanburg, South Carolina; (2)Medical University of South Carolina, Charleston, South Carolina, USA.

**OBJECTIVES:** Off-label factor VIIa use has not been extensively studied in the pediatric population. We report a retrospective analysis of the clinical characteristics and outcomes of pediatric patients receiving off-label factor VIIa at a tertiary medical center over a 3-year period.

**METHODS:** Pharmacy distribution software was used to identify pediatric patients who received factor VIIa from January 1, 2003 to March 30, 2006. Medical records were reviewed and the following data were collected; patient demographics, indication, dose, adverse effects, clinical outcome, blood product administration, and coagulation laboratory findings. Patients were excluded from analysis if the indication for factor VIIa administration was hemophilia.

**RESULTS:** Thirty-three patients were identified and 27 patients (12 male, 15 female) met inclusion criteria. The median age of our patient population was 9 months (range: 2 days to 17 years). The majority of doses were administered for a surgical procedure or due to liver disease. The overall survival rate of patients receiving factor VIIa was 78% with 74% of all patients achieving hemostasis after treatment. All of the patients who failed to achieve hemostasis later died. The patients in this analysis received 1–4 doses with an average dose of 71 micrograms/kg.

The median baseline INR for our patient population was 1.83 (range: 0.83 to >12). Post-dose, the median INR decreased to 1.24 (range: 0.64–5.67). Three cases of thrombotic complications potentially attributable to factor VIIa were identified in our population.

**CONCLUSIONS:** Factor VIIa is an effective agent when used off-label in pediatric patients. Safety and dose optimization should be further studied in this population.

**383E. License status of drugs involved in neonatal and paediatric medication errors.** Sharon Conroy, B.Pharm., M.R.Pharm.S., Ph.D.; University of Nottingham, Derby, United Kingdom.

**OBJECTIVES:** Use of unlicensed (UL) and off label (OL) drugs in children is common and leads to well documented problems. This study explored whether there is a relationship between medication errors in hospital in-patients and license status of the drugs involved.

**METHODS:** Forms reporting medication errors in the Derbyshire Children's Hospital over three years were analysed for the nature of the error and the license status of the drugs. This was compared to the overall license status of drugs used on the wards.

**RESULTS:** UL drug use in children was more likely to be associated with errors. 7% of all prescriptions on paediatric wards are UL. Errors associated with UL use however, ranged from 12% (prescribing) to 25% (dispensing) and overall 17%. UL drug use in neonates was also more likely to be associated with errors. The error rate ranged from 26% (administration) to 83% (dispensing), with 38% overall, whereas UL drug use in neonates is only 10%. The risk of errors did not appear to be increased with the use of OL medicines. In children the error rate ranged from 4% (prescribing) to 25% (dispensing), with 10% overall, whereas OL drug use is estimated to be 23%. In neonates the error rate ranged from 17% (dispensing) to 43% (administration), with 38% overall, whereas OL drug use in neonates is estimated to be 55%. Twenty (13%) errors were considered to have caused moderate harm and 12 (60%) of these involved UL and OL drugs.

**CONCLUSIONS:** Use of UL drugs increased error risk. This was highest in neonates and those <2 years, but applied across all ages. It was particularly associated with dispensing errors but also with prescribing and administration errors. OL drug use did not appear to increase the risk of errors, but was prominent in errors causing moderate harm.

Presented at the Neonatal and Paediatric Pharmacists Group annual conference, Birmingham, UK. November 14–16, 2008

**384. Retrospective observational comparison study of poractant alpha and beractant in preterm infants with very low birth weight (<1500 grams) with respiratory distress syndrome.** Morgan K. Reynolds, Pharm.D.; Baystate Medical Center, Springfield, Massachusetts, USA.

**OBJECTIVES:** Pulmonary surfactants along with respiratory support are the main treatments for infants suffering from respiratory distress syndrome. Studies have shown that patients who received poractant required fewer ventilator days, spent fewer days in the hospital, required fewer oxygen days and had lower oxygen concentration (FiO<sub>2</sub>) values. Proposed factors that are responsible for these outcomes are: (1) Poractant has the highest phospholipid concentration and a potent initial dose (2) the amount of surfactant protein B (SP-B) is higher in poractant and (3) beractant contains more surfactant protein C (SP-C). On February 12, 2008, Baystate Medical Center removed beractant from the formulary and replaced it with poractant. It is the goal of this study to determine the effectiveness of poractant when compared to beractant in an observational setting. The primary objective of this study is to compare the mean FiO<sub>2</sub> values of beractant and poractant during the first 72 hours after initial treatment.

**METHODS:** Infants with birth weight <1500 grams born at Baystate Medical Center between February 12, 2007 and February 12, 2009 who received either beractant or poractant will be analyzed. Exclusion criteria will be defined as patients transferred into Baystate Medical Center or patients that were transferred out to another level 3 NICU. Key data to be collected will include: date/time of birth, birth weight, gestational age, race, gender, APGAR score at 1 and 5 minutes, date/time/dose of surfactant and any repeat doses, FiO<sub>2</sub> values for the first 72 hours, number of respirator days (non-invasive mechanical ventilation [NIMV]), number of days on oxygen therapy (nasal cannula), length of stay, date/time/cause of death (if occurs), and listing

of complicating medical conditions such as patent ductus arteriosus (PDA), pneumothorax (PNX), persistent pulmonary hypertension, intracranial hemorrhage, and pulmonary hemorrhage.

**RESULTS:** Research in progress

**CONCLUSIONS:** Research in progress.

**385. Timing of initial palivizumab dosing and subsequent hospitalization for respiratory syncytial virus infection.** Kirsten H. Ohler, Pharm.D., BCPS, Jennifer T. Pham, Pharm.D., BCPS; University of Illinois at Chicago, Chicago, Illinois, USA.

**OBJECTIVES:** Optimal timing of the first dose of palivizumab to infants at high risk for respiratory syncytial virus (RSV) infection who have been hospitalized since birth is unclear. Historically, monthly palivizumab was administered to infants in the neonatal intensive care unit (NICU) at University of Illinois Medical Center at Chicago (UIMCC) beginning in October regardless of their anticipated discharge date. Therefore, patients may have received from one to six inpatient doses of palivizumab. Beginning in November 2007, infants received only one dose prior to discharge. This study evaluated if this change affected the incidence of RSV hospitalizations.

**METHODS:** Infants who received palivizumab in the NICU from 10/01/2005 to 4/30/2008 and were followed at UIMCC clinic were included. Patient demographics, details of palivizumab doses, and RSV hospitalizations were documented. Patients were grouped as follows: group 1 from 10/01/2005 to 06/30/2007 and group 2 from 11/01/2007 to 4/30/2008.

**RESULTS:** A total of 277 neonates received palivizumab; 163 were evaluated (group 1 = 111, group 2 = 52). Reasons for exclusion were follow-up care was not at UIMCC clinic (n=75) and failure to follow-up (n=24). The mean gestational age was 29.7 weeks (23.6–40) and 30.3 weeks (23.6–39.7) in group 1 and 2, respectively. Five-hundred nineteen doses of palivizumab were administered; 248 of which were inpatient doses. Group 1 received 190 inpatient doses; 86 of which would not have been administered based on the new practice change. This would result in an estimated cost-savings of \$129,000. Seven patients were hospitalized for RSV infection; 5 in group 1 and 2 in group 2. No patient died due to RSV.

**CONCLUSIONS:** Limiting palivizumab administration to one inpatient dose prior to hospital discharge was no less effective in preventing RSV hospitalizations and is a potential cost-saving strategy when compared to historical practice.

**386. A question of weight: do obese children need higher than standard dose of enoxaparin for VTE prophylaxis?** Teresa Lewis, Pharm.D., BCPS,<sup>1</sup> Peter N. Johnson, Pharm.D., BCPS,<sup>1</sup> Ashley Nebbia, Pharm.D. Candidate,<sup>1</sup> Marny Dunlap, M.D.<sup>2</sup>; (1)The University of Oklahoma College of Pharmacy, Oklahoma City, Oklahoma, USA; (2)University of Oklahoma College of Medicine, Oklahoma City, Oklahoma, USA.

**OBJECTIVES:** Young age may be a protective risk factor for venous thromboembolism (VTE) prevention. However, obese adolescents have been found to have the greatest VTE risk compared to younger children. Enoxaparin 0.5 mg/kg/dose SQ BID is one regimen for VTE prophylaxis in children. The challenge of weight-based dosing of low molecular weight heparins (LMWH) in overweight children lies in determining a ceiling dose. Clinicians must weigh efficacy versus increased adverse events (AE).

**METHODS:** We present two adolescents who required larger than usual adult doses of enoxaparin to achieve the American College of Chest Physicians recommended anti-FXa range of 0.1–0.3 U/mL for VTE prevention.

**RESULTS:** Patient A was a 16-year-old male (358.6 kg; BMI 105.92 kg/m<sup>2</sup>). Enoxaparin 40 mg (0.11 mg/kg/day) once daily SQ was initiated for VTE prophylaxis. This dose correlated with an anti-FXa <0.02 U/mL. Dose adjustments were required to achieve target anti-FXa values (Table 1). He received three months of prophylaxis. The only AE noted was ecchymosis at the injection site, two months into therapy. Patient B was a 16-year-old male (294 kg; BMI 89.6 kg/m<sup>2</sup>). He was admitted to the PICU for status asthmaticus. Enoxaparin 40 mg (0.13 mg/kg/dose) SQ BID was initiated for VTE prophylaxis. This correlated with an anti-FXa of 0.05 U/mL. Dosage adjustments were needed to achieve target anti-FXa values (Table 1). The adolescent received 8 days of therapy and tolerated dosage increases with no AE.

Table 1.

	Enoxaparin Dose (mg/kg/day)	Anti-FXa Value (U/mL).
Patient A	0.11	<0.02
	0.24	0.06
	0.36	0.05
	0.55	0.15
	0.59	0.17
Patient B	0.29	0.05
	0.32	0.13

**CONCLUSIONS:** Our findings suggest that obese adolescents may require larger than usual adult doses to obtain target anti-FXa values for VTE prophylaxis. Despite requiring larger than usual adult doses of enoxaparin, both patients tolerated the therapy well without increased AE.

**387. Comparison of levalbuterol and racemic albuterol based on cardiac adverse effects.** *Laura LoCastro, Pharm.D.*; University of the Sciences in Philadelphia, Philadelphia, Pennsylvania, USA.

**OBJECTIVES:** To compare the cardiac safety of levalbuterol and racemic albuterol based on changes in heart rate.

**METHODS:** The medical records of patients who received either racemic albuterol or levalbuterol via nebulizer for 3 consecutive doses between January 2006 and December 2008 will be reviewed. Children aged 1 month to 12 years admitted to the general pediatric unit who received either racemic albuterol or levalbuterol via nebulizer given in three consecutive treatments will be included. Patients will be excluded due to lack of data (i.e., missing pre or post-dose heart rate, age), underlying chronic cardiac condition (i.e., arrhythmias, Wolff-Parkinson-White Syndrome), intubation, concurrent administration of beta blockers, vasopressors, or racemic epinephrine, and bronchodilator therapy administered less frequent than 4 hours. The documented heart rate will be collected prior to the bronchodilator therapy and after therapy. Patients will be stratified by baseline tachycardia and no baseline tachycardia. Tachycardia will be defined as heart rate greater than the 98th percentile for age. The primary outcome will be percent change in heart rate from pre to post dose. Secondary outcomes will be incidence of tachycardia post bronchodilator therapy, and number of patients with a greater than 10% change in heart rate. Descriptive data will be analyzed by  $\chi^2$  and nominal data will be compared using student *t*-test. Repeated measures ANOVA will be used to analyze the primary endpoint. Based on the primary endpoint, the sample size required for 80% power is 17 patients per treatment group assuming a change of 15% between groups with a standard deviation of 15.

**RESULTS:** In progress.

**CONCLUSIONS:** In progress.

**388. Description of an Antimicrobial Stewardship Program in a pediatric hospital.** *Leslie M. Stach, Pharm.D.*,<sup>1</sup> *Mary Anne Jackson, M.D.*,<sup>1</sup> *Theoklis E. Zaoutis, M.D.*,<sup>2</sup> *Jason G. Newland, M.D.*,<sup>1</sup>; (1)Children's Mercy Hospital, Kansas City, Missouri, USA; (2)Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, USA.

**OBJECTIVES:** The Infectious Diseases Society of America has published guidelines for the development of a multi-disciplinary Antimicrobial Stewardship Program (ASP). We describe the characteristics and findings of a newly instituted ASP at a tertiary care children's hospital.

**METHODS:** A prospective cohort study was utilized to evaluate an ASP program at a 317 bed free standing children's hospital. On 3/3/08 an ASP was initiated to monitor the following antibiotics: 3rd and 4th generation cephalosporins, carbapenems,  $\beta$ -lactam/ $\beta$ -lactamases, fluoroquinolones, vancomycin, linezolid, tobramycin, amikacin, and aztreonam. An infectious diseases (ID) clinical pharmacist reviews patients who have received any of these antibiotics for 2 calendar days and confers with an ID physician. Data obtained include: antibiotic dose & frequency, indication, types of recommendations made by the program and if recommendations are followed.

**RESULTS:** The ASP performed 1701 reviews on 1240 patients who received 1971 monitored antibiotics. The ASP made 495 recommendations in 414 (24%) of the reviews. Antibiotics most frequently reviewed were ceftriaxone or cefotaxime (947), vancomycin (323) and ceftazidime (204). The treating service was most commonly a general pediatric (323), hospitalist (272), hematology/oncology (289),

NICU (204) or PICU (170) team. Predominant diagnoses included presumed sepsis- 403, pneumonia-175, urinary tract infection-142 or fever and neutropenia 125. The ASP focused 75% of recommendations on de-escalation, narrowing, shortening duration or discontinuing therapy. Physicians agreed with 84% of the ASPs initial recommendations and followed through in 97% of cases where recommendations were made.

**CONCLUSIONS:** A multi-disciplinary ASP has been successfully developed, implemented, and accepted at a children's hospital. The main recommendations are discontinuing antibiotics, shortening duration, or narrowing therapy. Future work will evaluate antibiotic cost savings and antimicrobial resistance.

**389. Counseling low health literacy parents at hospital discharge: methodology developed by the pediatric clinical pharmacy team at the University Hospital of São Paulo University, Brazil.** *Monica C. S. Ricci, M.Pharm.*,<sup>1</sup> *Carlos P. Rodrigues, Pharmacy*,<sup>1</sup> *Karen E. Andrade, Pharmacy Student*,<sup>2</sup> *Regina T. Goto, Pharmacy Student*,<sup>2</sup>; (1)University Hospital of University of Sao Paulo, Sao Paulo, Brazil; (2)Faculdade de Ciencias Farmaceuticas, University of Sao Paulo, Sao Paulo, Brazil.

**OBJECTIVES:** As many as 68% of adults in Brazil either cannot read or possess minimal reading skills. Health literacy includes the ability to read and comprehend health care information. Patients who do not understand labels on medicine containers or prescription directions may use wrong dosages or schedules of administration. Some consequences include longer hospital stays, increased visits to the emergency department, increased cost and patients being labeled by health team as noncooperative or noncompliant. Because all of these situations were observed at the University Hospital of University of São Paulo, the pediatric clinical pharmacy team developed and improved counseling abilities directed to low literacy parents of pediatric patients at hospital discharge. The objective of this work is to describe the improvements on the methodology for counseling pediatric patient parents with low health literacy at hospital discharge.

**METHODS:** Improvements on counseling techniques and printed materials were analyzed since September 2003, when this practice was initiated, until December 2008. Impressions of pharmacists about how easy and fast were for parents to comprehend information was considered.

**RESULTS:** The pharmacists improved the mechanisms adopted to identify limited health literacy, as well as simplified the printed materials and the method of marking the correct dose on syringes used by parents to administer oral liquid medicines. Pharmacists observed that printed materials were easier to understand when medication schedules were modified from the "table" format, which demands ability in correlating columns and arrows, to an easier one, which shows medications identified by different colors near pictograms related to the time of administration. Labeling each medication with a different color was always the most effective way of identify the correct medicine.

**CONCLUSIONS:** Consideration of literacy level is fundamental to a successful counseling session. Implementation of effective counseling should consider the development of printed materials adequate to the needs of the caregivers.

**390. Design and evaluation of a gentamicin dosing protocol in the neonatal intensive care unit at Mission Hospitals.** *Melissa A. Gervase, Pharm.D.*,<sup>1</sup> *Karl Ruch, Pharm.D.*,<sup>2</sup> *Neena Varughese, Pharm.D.*,<sup>3</sup> *Beth Addington, Pharm.D.*,<sup>4</sup>; (1)Duke University Hospital, Durham, North Carolina, USA; (2)Mission Hospitals, Asheville, North Carolina, USA; (3)Pitt County Memorial Hospital, Greenville, North Carolina, USA; (4)Greenville Hospital System University Medical Center, Greenville, South Carolina, USA

**OBJECTIVES:** Gentamicin is commonly used with ampicillin as empiric therapy for early-onset neonatal sepsis. Appropriate therapy in this population is complicated by the lack of consensus on a dosing regimen. The objective of this study is to design and evaluate an institution-specific gentamicin dosing protocol for patients <7 days postnatal age.

**METHODS:** This is a 3-phase, retrospective, observational, analysis of pharmacokinetic monitoring of approximately 2400 neonatal intensive care unit (NICU) patients. Phase I consisted of an evaluation of patient pharmacokinetics and the creation of an institution-specific gentamicin dosing protocol. Phase II evaluated peak and trough levels in protocol-

dosed patients over a 30-month period. Phase III assessed changes made to the protocol based on phase II results.

**RESULTS:** Phase I found that pharmacokinetic parameters significantly correlated with gestational age (GA). As a result a new dosing regimen was implemented (fixed 3.5 mg/kg dose, frequency based on GA, and levels drawn at 72 hours). In phase II, mean peak and trough concentrations in protocol-dosed patients were  $8.2 \pm 1.9$  and  $1.1 \pm 0.5$  mcg/mL, respectively, and 76% of patients had target levels (peak 6–10, trough  $\leq 1.5$ ). Subanalysis found that significantly more patients 30–34 weeks GA had elevated levels as compared to patients 35–37 weeks GA, so adjustments to the protocol were made. In phase III, 93% of patients evaluated achieved target levels. Mean levels obtained were  $7.98 \pm 1.07$  (peak) and  $0.69 \pm 0.26$  (trough).

**CONCLUSIONS:** Through the development of this protocol, we were able to accurately dose gentamicin in the majority of our neonatal patients. Furthermore, eliminating first-dose pharmacokinetic workup avoided lab draws in many of the patients started on gentamicin.

**391E. Stress ulcer prophylaxis in critically ill pediatric patients receiving intravenous famotidine and esomeprazole: a pH-based dose adjustment study.** *Laura Hayn, Pharm.D., Elizabeth Farrington, Pharm.D., BCPS, FCCP, FCCM; University of North Carolina Hospitals, Chapel Hill, North Carolina, USA.*

**OBJECTIVES:** To evaluate the efficacy and safety of IV famotidine and esomeprazole in critically ill pediatric patients in the prevention of clinically significant stress ulceration.

**METHODS:** All patients admitted to the pediatric intensive care unit (PICU) at a single center will be evaluated for study inclusion. Exclusion criteria includes renal insufficiency, hepatic insufficiency, nasogastric tube (NG) feeds, gastric bleed, or H2 blocker or proton pump inhibitor therapy prior to admission. Patients admitted to the PICU have an NG tube placed, and stress ulcer prophylaxis therapy will be initiated by the admitting physician. NG aspirates will be obtained at baseline, then at 1 hour, 6 hours and 12 hours following each dose. The pH will be measured with pH indicator paper. All patients will be treated with either famotidine (0.5 mg/kg/dose IV Q 12 hours, max initial dose 20 mg) or esomeprazole (1 mg/kg/dose IV Q 12 hours, max initial dose 40 mg). No dose adjustments will be made until at least 24 hours after the first dose is administered. If pH is  $\geq 4$  after 24 hours of therapy, the dose will not be changed. If pH is  $< 4$  after 24 hours of therapy, the dose will be doubled to famotidine 1 mg/kg/dose IV Q 12 hr or esomeprazole 2 mg/kg/dose IV Q 12 hr. Therapy will be considered successful when gastric pH is  $\geq 4$  with no dose adjustment necessary. Gastric acid measurements will be discontinued in all patients with stable gastric acid suppression (pH  $\geq 4$  for at least 48 hours). Clinically significant bleeding will be evaluated with the use of a composite endpoint (required surgery due to gastric bleed, blood transfusion due to gastric bleed, overt gastric bleeding followed (within 24 hrs) by decrease in systolic blood pressure).

**RESULTS:** Data collection and evaluation is currently being conducted.

**CONCLUSIONS:** Conclusions will be presented at the ACCP/ESCP meeting.

Presented at the ASHP Midyear Clinical Meeting Orlando, FL December 2008

**392. Descriptive study of hepatotoxicity Associated with highly active antiretroviral therapy in pediatric patients.** *Wanda Maldonado-Davila, B.S.Pharm., Pharm.D., Ricardo Lopez, Pharm.D., Jose A. Soto, Pharm.D., Luis D. Pagan, Pharm.D., Ines Esquilin, M.D.; University of Puerto Rico, San Juan, Puerto Rico.*

**OBJECTIVES:** To describe the incidence, type and frequency of dyslipidemias in the HIV infected patients treated in the Pediatric AIDS Clinic of the University of Puerto Rico.

**METHODS:** A retrospective medical record review of pediatric patients receiving Highly Active Antiretroviral Therapy (HAART) at this clinic was performed. Laboratory data for total cholesterol and triglyceride values were recorded and the criteria set forth by The Harriet Lane Handbook 17<sup>th</sup> Edition were used to define normal values.

**RESULTS:** A total of 81 records of patients who were receiving HAART were evaluated, and 69 (34 boys and 35 girls) were included in the study. The ages of the patients ranged from 0 to 23 years. Of the 69

patients included in the study, 46 (66.7%) showed elevated total cholesterol and triglycerides values that could be associated to antiretroviral therapy. Of the 46 patients with dyslipidemia, 39 (84.8%) patients showed triglyceride levels above the upper normal limit. Of these 46 patients, 7 patients (15.2%), or 10.1% of all patients evaluated in the study, demonstrated elevated total cholesterol levels. Although dyslipidemia was associated with a variety of antiretroviral regimens, the HAART more frequently used by the patients with elevated triglycerides and total cholesterol was the regimen containing: lamivudine + stavudine + nelfinavir (19.6 % of patients).

**CONCLUSIONS:** These results suggest that the incidence of dyslipidemia in the population described is higher than the general pediatric population. Elevated triglyceride values was the lipid disorder more commonly associated with HAART in the pediatric population studied. Additional clinical studies with larger cohorts are needed to propose alternatives for patients who develop dyslipidemia while receiving HAART.

**393. Reintubation in preterm infants treated with surfactant increases in-hospital costs: a pharmaco-economic analysis.** *Robert Segal, M.D.,<sup>1</sup> Carlos G Guardia, M.D.,<sup>1</sup> Phillip Simmons, M.S.,<sup>1</sup> Fernando R. Moya, M.D.,<sup>2</sup> Walter T. Linde-Zwirble, B.S.,<sup>3</sup> James L. Doherty, B.S.<sup>3</sup>; (1)Discovery Laboratories, Inc., Warrington, Pennsylvania, USA; (2)South East Area Health Education Center, Warrington, Pennsylvania, USA; (3)ZD Associates LLC, Perkasie, Pennsylvania, USA.*

**OBJECTIVES:** Reintubation in preterm infants after surfactant replacement therapy (SRT) for prevention of RDS may be associated with excess morbidity and mortality and likely increases in-hospital costs. The objective of this analysis was to quantify pharmaco-economic consequences associated with subsequent reintubation after extubation following SRT.

**METHODS:** We conducted a pharmaco-economic analysis of 1546 infants who were reintubated after initial successful extubation vs. those who remained extubated through 36 weeks PMA, following prophylactic SRT in two recent clinical trials (SELECT, Moya 2005; STAR, Sinha 2005). Cost variables were based on average 2007 costs per day in the NICU either on mechanical ventilation (MV; U.S. \$2,260) or off MV (U.S. \$1,380), derived from a database of average costs for treating 244 preterm infants with severe RDS.

**RESULTS:** Overall extubation rates exceeded 80% for all surfactant treatment groups (lucinactant, colfosceril palmitate, beractant and poractant alfa;  $p=NS$ ). Despite statistically significantly higher mortality rates in reintubated infants vs. those who remained extubated (18% vs. 0.5%, respectively,  $p<0.05$ ), those requiring at least one reintubation compared with those who remained extubated were observed to have significantly more days on MV (mean [SD]: 21.9 [17.9] vs. 8.2 [14.8], respectively;  $p<0.001$ ), and longer total in-hospital stay (50.2 [19.2] days vs. 48.1 [13.3] days, respectively;  $p=0.017$ ). The additional average cost per infant associated with reintubation was \$33,860, based on average costs associated with additional days on MV (\$30,962) and off MV (\$2,898).

**CONCLUSIONS:** In preterm infants receiving SRT, subsequent reintubation following successful extubation significantly increases in-hospital costs vs. those infants who remain extubated, primarily due to excess costs associated with MV. Measures to reduce need for reintubation in preterm infants receiving SRT should significantly impact both clinical outcomes and the costs associated with treating these infants.

**394E. Safety and efficacy of dietary supplements for use in ADHD.** *Pratish C. Patel, Pharm.D.,<sup>1</sup> Pranavkumar P. Patel, Pharm.D.,<sup>2</sup> Viet H. Nguyen, Pharm.D.,<sup>2</sup> Kevin J. Gregerson, Pharm.D.<sup>2</sup>; (1)University of Tennessee Le Bonheur Children's Medical Center, Memphis, Tennessee, USA; (2)Nova Southeastern University, West Palm Beach, Florida, USA.*

**OBJECTIVES:** Attention-deficit hyperactivity disorder (ADHD) affects 5% to 10% of school-aged children in the U.S. and is considered to be one of the most common disorders of childhood. The purpose of this review was to identify the safety and effectiveness of complementary and alternative medicines in the treatment of ADHD.

**METHODS:** A literature search was performed using secondary databases such as PubMed, IPA, MANTIS, EMBASE, MDCConsult, and

Alt-HealthWatch. Search topics included the use of herbal, nutritional, natural, alternative, complementary, dietary, and nutraceutical supplements in the treatment of ADD/ADHD.

**RESULTS:** There are many natural supplements used to treat or augment the treatment of ADHD. The only supplement that has shown evidence of proven efficacy and safety in children is zinc, as demonstrated in two double blind placebo-controlled trials (n=44 and n=400) and a case control study (n=43). Outcome measures included the Conners' Parent and Teacher ADHD Rating Scale, an investigator developed ADHD scale, and serum zinc concentrations, respectively. Other products that have been used and have shown positive benefits in children with ADHD are magnesium with vitamin B6 (n=76), and ginseng with *Ginkgo biloba* (n=36). Outcome measures in these studies were serum magnesium and blood ionized calcium, Conners' Parent Rating Scale, and serum ferritin levels and Conners' Parent Rating Scale, respectively.

**CONCLUSIONS:** There are clinical trials that show dietary supplements to be safe and efficacious, especially as adjunct therapy, in the treatment of ADHD. Studies demonstrated potential efficacy of zinc, American ginseng with *Ginkgo biloba*, as well as magnesium with vitamin B in the reduction of ADHD symptoms such as cognition, socialization, and behavior.

Presented at the Annual Meeting of the Florida Pharmacy Association, Marco Island, FL, June 23–27, 2008

**395. Retrospective case-controlled study of poractant alfa versus beractant in the treatment of respiratory distress syndrome in preterm infants.** Jennifer T. Pham, Pharm.D., BCPS; University of Illinois at Chicago, Chicago, Illinois, USA.

**OBJECTIVES:** Beractant has been the surfactant of choice for the treatment of respiratory distress syndrome (RDS) in preterm infants in the neonatal intensive care unit (NICU) at the University of Illinois Medical Center (UIMCC) since 1990. Recent studies reported a faster weaning of ventilator support and a decreased dose requirement in Poractant-treated infants. In March 2007, beractant was replaced with poractant at UIMCC. This case-controlled study evaluated if there were any differences in respiratory outcomes between surfactants.

**METHODS:** Infants who received either surfactants from 01/01/2006 to 10/31/2008 were included. Patient demographics, number of doses, age at extubation, and complications associated with RDS were recorded.

**RESULTS:** A total of 153 neonates, matched 2:1 beractant: poractant by gestational age (GA) received surfactant (n=51 poractant, n=102 beractant). Mean GA was 28.6 weeks  $\pm$  12.73 and 28.7 weeks  $\pm$  11.31 in poractant-and beractant –treated groups, respectively. Mean number of doses was 1.63  $\pm$  1.41 and 1.27  $\pm$  0.71 (poractant vs. beractant groups, respectively). Fifty-four percent of poractant-treated infants received  $\geq$  2 doses compared to 35% with beractant (p=0.024) resulting in a higher mean cost per poractant-treated patient (\$759.27  $\pm$  71 vs. \$479.8  $\pm$  91). Initial extubation after treatment was more successful with poractant (55% vs. 36%, p=0.037). Mean age at final extubation was younger with beractant (9 days vs. 35 days). The incidence of bronchopulmonary dysplasia (BPD) was higher with poractant (53% vs. 32%, p=0.022). Overall mortality was similar in both groups.

**CONCLUSIONS:** Although initial extubation was greater in the poractant-treated group, the mean age at final extubation is less in those treated with beractant. The number of doses required and the incidence of BPD are significantly higher in poractant-treated group. Additionally, if >1 dose is required, beractant appears to be more cost-effective.

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