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American College of Clinical Pharmacy
2002 Spring Practice and Research Forum/
Updates in Therapeutics
April 7-10 • 2002
Savannah Marriot Riverside
Savannah • Georgia

ABSTRACTS

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2002 Spring Practice and Research Forum/ Updates in Therapeutics April 7–10, 2002

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Encore Presentations: Abstracts marked with an "E" are Encore Presentations. Encore Presentations undergo the same peer review process as do Original Presentations, but may have been presented elsewhere or published in abstract form only prior to the 2002 Spring Practice and Research Forum/Updates in Therapeutics. For Encore Presentations, the abstract title, authors, and original citation (if provided) are published in *Pharmacotherapy*. The full abstract will be published in the meeting program book.

ORIGINAL RESEARCH

These papers describe original research in therapeutics, pharmacokinetics, pharmacodynamics, pharmacoconomics, pharmacoepidemiology, and pharmacogenomics.

Administration

1. Use of surrogate markers to evaluate medication errors leading to hyperkalemia. *Anthony T. Gerlach, Pharm.D.*; Ohio State University Medical Center, Columbus, OH.

PURPOSE: Voluntary reporting grossly underreports the occurrences of medication errors. The Institute of Safe Medication Practices suggests using alternative methods to provide more information and yield better information to improve medication safety. The purpose of the study is to assess the usage of dextrose 50% syringes (D50) and sodium polystyrene sulfonate (SPS) as surrogate triggers for medication errors leading to hyperkalemia.

METHODS: A retrospective review was conducted during the month of March 2001, at a university medical center. All patients admitted to the medical center were included except neonates. Patients were identified from the pharmacy and laboratory computer systems. Any patients that had serum potassium greater than 6.0 mg/dl and were billed for D50 or SPS were reviewed for demographics, indication and were assessed for potential medication errors.

RESULTS: During March 2001, 2769 patients were admitted and 14,169 serum potassium levels were measured. One hundred thirty nine patients were billed for D50 and 41 for SPS. Fifteen patients with hyperkalemia were given SPS including five patients who also received D50. Fourteen patients received D50 and/or SPS for hyperkalemia due to renal failure and one patient for a medication error.

CONCLUSION: The use of pharmacy billing data for D50 and SPS does not adequately correspond to medication errors. Medication errors are difficult to identify and more accurate surveillance systems are needed.

Adverse Drug Reactions/Drug Interactions

2. Renal impairment is a risk factor for bleeding with enoxaparin in cardiac patients. *Meshal AlMutairi, Pharm.D., R.Ph.*, Abdulhamid AlBisher, M.S., Khalid AlNemer, Pharm.D., Kris Malmquist, R.Ph., BCNSP; Prince Sultan Cardiac Center, Riyadh, Saudi Arabia.

PURPOSE: Enoxaparin, a low-molecular weight heparin, is partially cleared renally. However, little published information is available regarding enoxaparin's use in patients with renal insufficiency. This prospective observational study compared incidence of bleeding complications in 190 cardiac patients receiving enoxaparin therapy for 48 hours or longer with creatinine clearances (CrCl) ≥ 30 ml/min versus patients with CrCl < 30 ml/min.

METHODS: Data collected included demographic information, indications,

dosage, duration, renal function parameters, bleeding events, and other adverse effects. Bleeding events were divided into major (i.e., >2 g/dl hemoglobin decrease with corresponding signs or symptoms; intracranial bleeding; bleeding leading to transfusion of 2 units or more of blood; retroperitoneal bleeding; or gastrointestinal bleeding) or minor bleeding (bleeding that did not meet major bleeding criteria (i.e., hematoma, bleeding at injection site, etc.).

RESULTS: Our study included 135 patients (71.1%) with CrCl of ≥ 30 ml/min and 55 patients (28.9%) with CrCl < 30 ml/min. Average age: 62.4 ± 12.1 years; average weight: 69.8 ± 12.03 kg. Average dose: 56.1 ± 8.4 mg. Bleeding complications occurred in 27.9% of patients (18.4% minor and 9.5% major). An increase in total bleeding in patients with CrCl < 30 ml/min was seen vs those with CrCl ≥ 30 ml/min (45.5% vs 20.7%, $p < 0.001$). In patients with CrCl < 30 ml/min, major bleeding episodes occurred more frequently (23.6% vs 3.7%, $p < 0.001$).

CONCLUSION: Renal impairment is a significant risk factor for bleeding with enoxaparin. Clinical trials focusing on patients with renal impairment are needed to define guidelines for using enoxaparin safely in these patients.

3. The occurrence of new onset diabetes mellitus in patients exposed to atypical antipsychotics. *Carie D. Hatch, Pharm.D.*, Rex W. Force, Pharm.D., FCCP, BCPS, Julie M. Johnson, Pharm.D., Paul S. Cady, Ph.D., Vaughn L. Culbertson, Pharm.D., Craig M. Kelley, B.S.; Idaho State University, Pocatello, ID.

PURPOSE: Recently, there have been several case reports that associate the use of atypical antipsychotics with new onset diabetes mellitus. Currently, limited data are available and further investigation is needed to substantiate a relationship. This study was conducted to determine if new onset diabetes mellitus is associated with the use of atypical antipsychotics.

METHODS: The study population, aged 18-65, was drawn from Idaho's Medicaid program from 1993 to 2001. Case patients were defined by new diagnosis of diabetes mellitus, impaired glucose tolerance and/or new start on an antidiabetic medication. Controls consisted of patients without the diagnosis of diabetes mellitus, impaired glucose tolerance, or use of an antidiabetic agent. Patients were matched by age, gender, and disease severity. The use of atypical and typical antipsychotics in ≥ 8 of the last 12 months prior to diabetes diagnosis was determined.

RESULTS: 3.1% (135/4407) of new diabetic patients were receiving atypical antipsychotics, whereas 2.1% (277/13221) of control patients were receiving atypical antipsychotics (OR=1.48, 95% confidence interval [CI], 1.20-1.82, $p=0.0002$). New-onset diabetic patients were not more likely to be using typical antipsychotics (OR=0.83, CI, 0.64-1.09, $p=0.18$).

CONCLUSIONS: The development of diabetes mellitus is associated with the use of atypical antipsychotics. Although the results of this study may not fully delineate the relationship between atypical antipsychotics and new onset diabetes mellitus, clinicians should monitor patients for this complication.

4E. Predicting subsequent infusion-related reactions from responses to initial doses of amphotericin B lipid complex. *Tara L. Belden, Pharm.D.*, *Richard H. Drew, Pharm.D., MS, BCPS*, John R. Perfect, M.D.; Duke University Medical Center, Durham, NC; Campbell University, Buies Creek, NC.

Presented at the 31st Annual Southeastern Regional Conference of Pharmacy Practice Residencies, Athens, GA, April 27-28, 2000.

5. Vancomycin-induced thrombocytopenia: a rare case report. *Roy Guharoy, Pharm.D.*, Frederick Rose, M.D., David Duggan, M.D., Jeanna Marraffa, Pharm.D., Syed Nazeer, M.D.; University Hospital, SUNY-Upstate Medical University, Syracuse, NY.

PURPOSE: We report a rare case of vancomycin-induced thrombocytopenia. **CASE REPORT:** A 50-year-old male with sub acute bacterial endocarditis underwent mitral valve replacement surgery and was started on vancomycin. His platelet count (PC) decreased from $346 \times 10^3/\text{mm}^3$ to $1 \times 10^3/\text{mm}^3$ on postoperative day (POD) 4 and a differential diagnosis of heparin-induced thrombocytopenia versus drug-induced thrombocytopenia was entertained. Anti-heparin antibodies were detected in the serum on day 5. Patient did not have any signs of bleeding. PC remained less than $5 \times 10^3/\text{mm}^3$ despite two platelet transfusions on POD 5. He developed pericardial tamponade from hemorrhage, which required drainage. A trial of intravenous gammaglobulin lead to fever and chills and the infusion was not completed. Vancomycin was changed to clindamycin on POD 8 and prednisone therapy was started. On POD 11, the patient's clinical condition improved and PC increased from $3 \times 10^3/\text{mm}^3$ to $32 \times 10^3/\text{mm}^3$ without any bleeding. On POD 19, PC was $424 \times 10^3/\text{mm}^3$ and patient was scheduled for discharge on Vancomycin for a total of six weeks. Improvement was attributed to prednisone. A vancomycin 1 gram dose was given at the hospital and PC dropped to $164 \times 10^3/\text{mm}^3$ one hour after the completion of infusion and $58 \times 10^3/\text{mm}^3$ twelve hours later. Vancomycin was discontinued and clindamycin and prednisone were restarted. On POD 21, PC increased to $105 \times 10^3/\text{mm}^3$ and he was discharged on warfarin, prednisone and clindamycin.

CONCLUSION: Vancomycin has been reported as a rare cause of thrombocytopenia. We suspect that the thrombocytopenia in this patient was due to Vancomycin.

6. Evaluation of patients' recorded allergies to drugs. *Patrick J. McDonnell, Pharm.D., Olga Geyfman, Jane Shafir, Inessa Shukher; Temple University, Philadelphia, PA.*

PURPOSE: This study assessed the recorded allergy history of patients evaluating validity, manifestations, and outcomes in drug therapy of this record.

METHODS: Drug allergy histories were evaluated from the period of January 2001 through May 2001 at a 180-bed community hospital. Evaluation of 202 patients revealed 348 drug allergies in these records (96 patients had multiple drug allergies listed). Each patient's record for allergy history was triple checked based on what was recorded in the pharmacy's patient medication profile (PMP), the patient's medical chart, and patient interview by the investigators. This data was examined to established discrepancies, validity of the allergy, change in patient drug therapy, and adverse outcomes.

RESULTS: Discrepancies between recorded allergy history between the medical chart and the pharmacy computer system were seen in 37 allergies recorded (10.6%). No manifestations of the recorded allergy were listed on the PMP. Only 8.9% (31/348) of allergies had manifestations listed in the patient's chart. From the patient interviews, 60.5% (209/348) of what was recorded as an allergy was deemed as being true allergic reactions. 35.1% (122/348) of the recorded allergies were not considered to be true allergic reactions, but rather intolerances to a certain drug therapy, and 4.9% (17/348) were cases in which the patient stated in the interview that they were not allergic or aware that this was part of their medical history.

Of the 202 patients in this study, 95 (47.0%) had changes in their drug therapy based on the allergy history. From this group 77.9% (74/95) were deemed to have true allergies and 22.1% (21/95) had their drug therapy changed based on recorded allergy history that was not a true allergy. Forty-one patients that had true drug allergy received drugs that are known to cause cross-sensitization. Seven patients receiving these agents had a new adverse allergic reaction. Details on drug classes regarding validity of recorded allergies, changes in drug therapy, cross-sensitizing agents, and new adverse allergic reactions to follow.

CONCLUSIONS: An incomplete drug allergy history.

7. Fentanyl-associated syndrome of inappropriate antidiuretic hormone secretion. *Heather Kokko, Pharm.D., Philip D. Hall, Pharm.D., Lawrence B. Afrin, M.D.; Medical University of South Carolina, Charleston, SC.*

PURPOSE: To describe a case of syndrome of inappropriate antidiuretic hormone secretion (SIADH) associated with fentanyl.

CASE SUMMARY: A 43 year-old female with advanced pulmonary blastoma complained of lower back pain. Home medications included hydromorphone and benazepril. On admission she was given hydromorphone patient-controlled analgesia (PCA) for acute pain control and dexamethasone due to concern for cord compression. Baseline labs were unremarkable, but magnetic resonance imaging revealed T3 and L3 lesions. Radiotherapy was initiated. In anticipation of discharge, a fentanyl transdermal patch (100 µg/hr) was initiated and PCA was tapered. Two days later, she became progressively confused and fell. Neurologic exam and computed brain tomography were unrevealing, but labs diagnosed SIADH with a serum sodium of 119 mEq/L (normal 136-144) (confirmed on repeat), urine sodium 194 mEq/L, and urine and plasma osmolalities 554 and 245 mOsm/k (280-300), respectively. Fluid restriction was initiated, hydromorphone PCA reinitiated, and fentanyl discontinued. After 36 hours, serum sodium increased to 136 mEq/L. Unsure whether fentanyl or cancer was causative, and unable to find any published reports of fentanyl-associated SIADH, we re-instituted the fentanyl patch two days later. Within 48 hours, serum sodium dropped to 123 mEq/L. Fentanyl was discontinued, fluid restriction reinitiated, and 3% saline begun; serum sodium returned to 132 mEq/L in 48 hours. She was discharged home on oral hydromorphone.

CONCLUSIONS: The repeated temporal relationship between administration of fentanyl and onset of SIADH suggests fentanyl was the causative agent in this case. To our knowledge, this is the first report of fentanyl-associated SIADH.

Analgesia

8E. Analgesic safety and efficacy of diclofenac sodium softgels in postoperative dental pain. *J. Zuniga, C. Phillips, D. Shugars, L. Rogers, J. Lyon, S. Peroutka, J. Swarbrick; University of North Carolina at Chapel Hill, Chapel Hill, NC; aaiPharma, Inc., Wilmington, NC.*

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Cardiology

9. Bleeding complications and analysis of risk factors in patients on warfarin after mechanical heart valve replacement. *SoHyun Lee, MS, Sukhyang Lee, MS, Pharm.D.; Sookmyung Women's University; Korea University Hospital, Seoul, Korea.*

PURPOSE: Warfarin is an anticoagulant for preventing thromboembolic

disorder. Patients on warfarin should be monitored closely because of narrow therapeutic range and bleeding is a common, potentially fatal complication of warfarin therapy. This retrospective study was to evaluate the incidence and risk factors of bleeding in patients on warfarin after mechanical valve replacement.

METHODS: Patients were included if they were on Anticoagulation Consult Service (ACS) after mechanical valve replacement at Korea University Hospital, Seoul, Korea. Pharmacists with referral of physician have managed ACS. Exclusion criteria were an active peptic ulcer or bleeding disorders other than warfarin related risks. Data were collected for patient characteristics, comorbid diseases, bleeding sites and frequency. Bleeding complications were analyzed by patient characteristics, comorbid diseases, ACS follow-up, weekly warfarin dosage, target international normalization ratio (INR) and measured INR.

RESULTS: Total patients for evaluation included 68 outpatients and 786 follow-ups. All follow-ups reported 214 bleeding cases and 572 non-bleeding cases. Incidence of minor bleeding was 13.3% per year and major bleeding was 0.3% per year. Most sites of minor bleeding were gingival, bruising and epistaxis. Major bleedings were hematuria and cerebral hemorrhage. Weekly dosage was higher in the bleeding group compared to non-bleeding group by 1.3 mg (34.9 ± 12.0 vs 32.5 ± 10.8, p=0.013). Measured INR was also higher in the bleeding group (2.44 ± 1.16 vs 2.18 ± 1.13, p=0.004), but distribution of target INR was similar. Under multivariate analysis, significant risks of bleeding were related to female, advanced age, warfarin dosage, measured INR, duration of ACS follow-up. The most significant risks of bleeding in patients with mechanical valve replacement on warfarin were female and advanced age.

CONCLUSIONS: Anticoagulation with warfarin is extensive in the cardiovascular disease. Patients on warfarin are increasing and should be closely monitored for effective prevention of thrombosis and bleeding complications. Bleeding cases were not high but evaluation of risk factors should be assessed individually to maximize benefit and reduce risk of warfarin therapy.

10. Forearm endothelial response in users of smokeless tobacco as compared to cigarette smokers and non-tobacco users. *Mark C. Granberry, Pharm.D., Rhonda Troillett, John Eidt, M.D., Eugene S. Smith, III, M.D.; University of Arkansas for Medical Sciences, Little Rock, AR.*

PURPOSE: Cigarette smoking impairs endothelial function as measured by forearm flow mediated dilation (FMD), however the effect of smokeless tobacco use has not been investigated. This investigation compared FMD in users of smokeless tobacco, cigarette smokers and non-users of tobacco.

METHODS: Healthy volunteers were matched for age, gender, body mass index (BMI), low-density lipoprotein cholesterol (LDL-C) and blood pressure. Brachial artery diameters were obtained from ultrasound images with a 7.0 MHz linear transducer and standard 128XP/10 system. We measured diameters at rest, during reactive hyperemia (endothelium-dependent FMD), and after sublingual nitroglycerin (NTG; endothelium-independent dilation). Two observers unaware of subject status measured vessel diameters. A comparison of the mean percent change from baseline, reactive hyperemia and nitroglycerin was made to determine endothelial response. ANOVA was used to compare differences between the users of smokeless tobacco, cigarette smokers and non-users of tobacco. Vessel diameters in scans of FMD and NTG are expressed as percentages of the first control scan.

RESULTS: Demographic characteristics were similar between groups. Mean brachial artery diameters were 4.7 ± 0.3 mm in non-users (n=4), 4.1 ± 0.5 mm in smokers (n=4) and 4.7 ± 0.5 mm in dippers (n=5). FMD was 13.3 ± 6.5 % in non-users, 4.9 ± 5 % in smokers, and 4.0 ± 0.6 % in dippers (p less than 0.05 for comparison of non-users to both smokers and dippers). NTG-induced dilation was 21.2 ± 3.4 % in non-users, 6.9 ± 3 % in smokers, and 11.8 ± 9 % in dippers (p less than 0.05 for comparison of non-users to both smokers and dippers).

CONCLUSION: FMD measured in our study of smokers as compared to non-users was statistically different and similar to results obtained by others. In addition, we found that tobacco dippers had significantly less FMD than tobacco non-users and was similar to FMD found in the smokers. NTG-induced dilation was also different when smokers and dippers were compared to non-users.

11. Delayed use of β-blocker therapy in heart failure patients. *Mark C. Granberry, Pharm.D., Jason B. Hawkins, Pharm.D., Amy M. Franks, Pharm.D., Eugene S. Smith, III, M.D.; University of Arkansas for Medical Sciences; Central Arkansas Veterans Healthcare System, Little Rock, AR.*

PURPOSE: β-blocker (BB) therapy is considered an integral part of optimal heart failure management. The Heart Failure Society of America practice guidelines recommend BB therapy be initiated after clinical stability is achieved, usually 2-3 weeks after hospital discharge.

METHODS: In this retrospective study, we determined the frequency of BB initiation in heart failure patients after discharge from the Central Arkansas Veterans Healthcare System in Little Rock, Arkansas between October 1996 and March 2001. BB initiation was classified as early (3 months or less), late (after 3 months), or never.

RESULTS: Using ICD9 coding (428.0), 2,030 patients were identified with a heart failure diagnosis and 528 were known to have an ejection fraction of $\leq 40\%$. A total of 383 patients were hospitalized of whom 128 were discharged without BB therapy. We then reviewed the prescription database and found that in 66 patients BBs were never initiated, in 146 patients BBs were initiated late, and BBs were initiated early in 43 patients. When analyzed by year hospitalized, BB initiation occurred early in 2 of 26 patients in late 1996 and 1997 (8%), 11 of 51 patients in 1998 (22%), 13 of 51 patients in 1999 (25%), 9 of 44 patients in 2000 (20%), and 8 of 17 patients in early 2001 (47%). $p=0.005$ when 2001 is compared to all previous years. All 8 patients in 2001 had BBs started while hospitalized.

CONCLUSION: BBs have been frequently used in our patients but initiation is often delayed. Increased early use in 2001 may be attributed to initiation before hospital discharge.

12. The effects of physical exercise on plasma prebeta-1 high-density lipoprotein in exercise trained and sedentary subjects. *Mahtab Jafari, Pharm.D., David Alexander Leaf, M.D., MPH, Julie Kasem, Holden MacRae, Ph.D., Patricia O'Connor, Ph.D., Mary Malloy, M.D., John Kane, M.D., Ph.D.; University of California at Irvine, Irvine, CA; University of California at Los Angeles, Los Angeles, CA; Greater Los Angeles Healthcare System, Los Angeles, CA; Pepperdine University, Malibu, CA; University of California at San Francisco, San Francisco, CA.*

PURPOSE: The exercise-induced impact upon HDL metabolism is recognized as a major mechanism of coronary artery disease risk reduction. Prebeta HDL subparticle species play a pivotal role in initiating reverse cholesterol transport. This study examines the effect of acute physical exercise on plasma prebeta HDL levels in physical exercise trained and untrained subjects.

METHODS: 19 healthy men ($n=11$) and women ($n=8$) not receiving lipid-altering medications were classified as exercise trained (Group A, $n=9$), or sedentary (Group B, $n=10$). Following an overnight fast subjects completed dietary surveys, body fat distribution, and had blood drawn for measurements of plasma lipids, lipoproteins, apolipoprotein A-I (Apo A-I), and absolute and percent prebeta HDL. Each subject completed cardiopulmonary exercise stress (CPX) testing to VO_{2peak} followed by a 2.5 mile course of run-jogging. Laboratory measurements were repeated immediately post-exercise.

RESULTS: No differences were noted between groups for age, percent body fat, dietary cholesterol, dietary fat, or other measurements of pre-exercise plasma lipids and lipoproteins except higher plasma HDL-C levels in group A (54.8 ± 11.2 mg/dl) than Group B (43.3 ± 8.7 mg/dl; $p=0.024$), and greater VO_{2peak} levels in Group A (52.8 ± 6.8 ml O_2 /kg/min) than Group B (45.0 ± 7.3 ml O_2 /kg/min; $p=0.026$). For all subjects combined exercise significantly increased absolute plasma prebeta HDL (0.096 ± 0.057 to 0.130 ± 0.065 μ g/ml; $p=0.012$) and decreased plasma HDL-triglycerides (23.3 ± 10.8 to 12.5 ± 5.6 mg/dl; $p=0.011$).

CONCLUSIONS: Our findings indicate that prebeta HDL and HDL-triglyceride metabolism are significant components of the acute exercise-related impact on reverse cholesterol transport in both trained and sedentary individuals.

13. Implementing lisinopril in a diabetic patient population with coronary artery disease: a practical application of the heart outcomes prevention evaluation (HOPE) trial by clinical pharmacy staff. *Karen J. Emmerich, Pharm.D., Tammy R. Lousberg, Pharm.D., BCPS, Marsha A. Raebel, Pharm.D., BCPS, FCCP, John A. Merenich, M.D.; Kaiser Permanente of Colorado, Denver, CO.*

PURPOSE: Based on the HOPE trial, the objective of this study was to increase the percentage of diabetic patients with coronary artery disease (CAD) on angiotensin-converting-enzyme inhibitors (ACEI) therapy, increasing to goal or highest tolerated dose by the Clinical Pharmacy Cardiac Risk Service (CPCRS).

METHODS: The study population included hospitalized patients screened by a pharmacist using strict exclusion criteria. Eligible patients were initiated on lisinopril 5 mg daily upon discharge and titrated to goal (≥ 20 mg daily). Serum creatinine, potassium, and blood pressure were measured at baseline, at each dosage titration, and two weeks after goal was reached.

RESULTS: There were 95 patients in the historical control and 101 patients in the study population. Among controls, 20% were at goal, 37% were taking a suboptimal dose, 18% were excluded from treatment, and 25% were eligible but not taking lisinopril. In the study group at baseline, 37% were at goal and therefore not titrated, 15% were on a suboptimal dose, 34% were excluded from treatment, and 12% were eligible but not on therapy. After the titration period, 53% of patients were at goal, 13% were on a suboptimal dose, and 34% were not candidates for ACEI. The most common reasons for exclusion were renal insufficiency, cough, and baseline hypotension. Changes in potassium, creatinine, and blood pressure were not significant.

CONCLUSION: Literature consistently shows treatment gaps with implementing therapies proven beneficial in clinical trials. CPCRS more than doubled the number of patients on goal dose of ACEI therapy, a treatment shown to decrease morbidity and mortality.

14. The need for improved blood pressure control within the African-American population: a multisite assessment. *Anne Frechette, RN, BSN,*

James Jackson, Pharm.D., Paul Godley, Pharm.D., Scott Sabrsula, Pharm.D., Pamela Coyle-Toerner, MHHA, Bruce Weiss, M.D.; Applied Health Outcomes, Tampa, FL; Scott & White, Temple, TX; Firstcare, Amarillo, TX; Queen City Physicians, Cincinnati, OH; AvMed Health Plan, Gainesville, FL.

PURPOSE: As many as 30% of all deaths in African American (AA) men and 20% of all deaths in AA women are attributed directly to hypertension. Recognizing this, our goal was to evaluate the level of risk, treatment patterns, and blood pressure (BP) control within the AA population.

METHODS: A broad based hypertension quality improvement initiative within 11 managed care and physician groups from January 1999-April 2001 yielded a database representing over 6 million lives. From this database, 7,192 medical charts of patients with hypertension (HTN) were randomly selected. Of the 5,529 available charts reviewed with a confirmed diagnosis of HTN, a sub-population of AA patients was identified to assess risk factors, target organ damage, BP control per JNC-VI standards ($<140/90$ for general population, $<130/85$ for diabetic population), and antihypertensive regimen.

RESULTS: Four hundred thirty-five AA patients with hypertension were identified. The majority of patients were female (66%). Mean age was 60 and over 77% had two or more cardiovascular risk factors. The most prevalent target organ damage was angina (15%), followed by stroke or TIA (10%). The most commonly prescribed antihypertensive agents were CCBs (42.3%), diuretics (41.6%) and ACEIs (33.1%), with over 64% receiving 2 or more agents concurrently. When assessing BP control, 35% met the JNC-VI goal.

CONCLUSIONS: Risk within the AA population is high and blood pressure control remains a challenge. These data confirm that more aggressive approaches, including multi-drug therapy, are needed to reach goal BP.

15. Stated criteria for statin selection are discordant with drug choice. *Julie M. Johnson, Pharm.D., Rex W. Force, Pharm.D., FCCP, BCPS, Vaughn L. Culbertson, Pharm.D., Paul S. Cady, Ph.D.; Idaho State University, Pocatello, ID.*

PURPOSE: To evaluate newly-initiated lipid-lowering therapy in patients previously taking cerivastatin (Baycol[®]) in light of survey results of prescribers' rationale for new medication choice.

METHODS: A Medicaid database of prescription claims was used to identify patients with a recent prescription for Baycol. Providers were notified by mail one week after Baycol's recall with patient information, educational materials, and a survey. They were asked to rank their desired criteria for an alternative from the following: proven clinical outcomes, safety, cost, and sample availability. Two months later the database was queried to determine changes in lipid-lowering therapy. Large, controlled trials were the basis for defining "proven clinical outcomes."

RESULTS: Eighty prescribers received letters regarding 100 patients. Thirty-five responded, and cited the following criteria as "most important" in choosing an alternative: proven clinical outcomes 54%, safety 26%, and cost 9%. Planned alternative was atorvastatin 57%, simvastatin 14%, and pravastatin 10%. Review of the database 2 months later showed that 13 patients were unavailable for follow-up, 15 had no lipid-lowering therapy, 1 had begun colestipol, and 71 were receiving statins. Of the 71 on statins, the individual agents were as follows: atorvastatin 58%, simvastatin 23%, pravastatin 15%, fluvastatin 3%, and lovastatin 1%. Proven clinical outcomes were greatest for pravastatin, followed in descending order by simvastatin, lovastatin, atorvastatin, and fluvastatin, according to review of the medical literature.

CONCLUSION: The criteria physicians claimed "most important" in choosing a statin was not supported by their choice of agent. Fifteen percent of patients had received no alternative lipid-lowering therapy.

16. Factors influencing the activity of antiplatelet agents in stroke patients. *Edith Nutescu, Pharm.D., Larisa M. Humma, Pharm.D., Lucy A. Fashingbauer, BS, Carolyn Pham, Cathy M. Helgason, M.D.; University of Illinois at Chicago, Chicago, IL.*

Platelet aggregation is important in stroke pathophysiology. Antiplatelet agents are recommended after an ischemic stroke to prevent a recurrent event. However, up to 25% of patients are resistant to antiplatelet therapy as assessed by ex-vivo effects of antiplatelet drugs on platelet aggregation.

PURPOSE: To identify factors that affect the activity of antiplatelet therapy post-stroke.

METHODS: Forty-one stroke patients taking single antiplatelet therapy who had in-vitro platelet aggregation studies done were identified. Demographic characteristics, medical histories, smoking status, and concomitant drugs were compared between 19 patients with complete inhibition (CI) and 22 patients with partial inhibition (PI) of platelet aggregation. Continuous variables were compared between groups with the Student's unpaired *t*-test and nominal variables were compared by chi square analysis or Fisher's exact test.

RESULTS: Sixteen patients in each group were taking aspirin; median dose 325 (81-975) mg/day in the PI group and 325 (81-650) mg/day in the CI group. The remaining patients were taking clopidogrel 75 mg/day. There were no significant differences in age (mean \pm SD: 68 \pm 14 vs 63 \pm 9 years); race (white/black/Hispanic: 8/10/4 vs 6/9/4); weight (mean \pm SD: 74 \pm 15 vs 85 \pm 21 kg); history of HTN (77% vs 84%), dyslipidemia (82% vs 79%), or diabetes

(18% vs 16%); number of current smokers (2 vs 5); or number taking statin therapy (17 vs 13) between the PI and CI groups, respectively.
CONCLUSION: We did not identify any environmental factors that affected in-vitro antiplatelet drug activity. These data suggest that other factors, such as genotype, may influence the activity of antiplatelet agents in stroke patients.

17E. Differences exist between GP IIb/IIIa inhibitors: results of the National GP IIb/IIIa Inhibitor Study. Patrick L. McCollam, Pharm.D., David A. Foster, Ph.D., Jeffrey S. Riesmeyer, M.D., Susan L. Dennett, Ph.D.; Eli Lilly and Co., Indianapolis, IN; Solucient Inc., Ann Arbor, MI.

Published in Am J Cardiol 2001;88(5):11G-12G.

18E. Cholesterol screening of adults in the U.S.: role of sociodemographic factors. Christopher R. Bartalos, D.O., Chao Sun, M.D., MPH, Jacqueline S. Marinac, Pharm.D.; University of Health Sciences, Kansas City, MO; Medical Center of Independence, Independence, MO.

Presented at the Annual Meeting of the American College of Cardiology, Atlanta, GA, March 17-20 2002.

19E. Thrombolytic fibrin specificity influences activated partial thromboplastin time prolongation. James P. Tsikouris, Pharm.D., Craig D. Cox, Pharm.D., Kenneth C. Jackson, Pharm.D., Jose A. Diaz, M.D., Gary E. Meyerrose, M.D., Charles F. Seifert, Pharm.D.; Texas Tech University, Lubbock, TX.

Presented at the 51st Annual Scientific Session of the American College of Cardiology, Atlanta, GA, March 17-20, 2002.

20. β -blockers decrease heart rate and inhibit exercise tachycardia regardless of antihypertensive effect. Brian J. Puckett, Pharm.D., Daniel F. Pauly, M.D., Ph.D., Issam Zineh, Pharm.D., Julie A. Johnson, Pharm.D.; Virginia Commonwealth University at the Medical College of Virginia, Richmond, VA; University of Florida, Gainesville, FL.

PURPOSE: Only 40% to 70% of patients achieve adequate blood pressure (BP) control with β -blockers alone. It is unclear if this variability exists for the heart rate (HR) lowering effect of these agents. In this study, we sought to evaluate the relationship between the negative chronotropic and antihypertensive effects of metoprolol monotherapy.

METHODS: Twenty-eight hypertensive men and women between the ages of 35 and 65 were studied. Baseline studies included 24h ambulatory blood pressure monitoring (ABPM) and treadmill studies. Metoprolol was titrated weekly starting at 50 mg twice daily until response or maximum dose was achieved. Once on a stable dose for ≥ 4 weeks, 24h ABPM and treadmill studies were repeated as at baseline.

RESULTS: Fourteen patients were responders (decrease in DBP $\geq 10\%$) and 14 were nonresponders. Baseline 24h, daytime, and nighttime ABPM data were not different between responders and nonresponders (mean 24h BP=149/92 vs 141/89 mm Hg, mean 24h HR=81 vs 77 bpm; p=NS). Exercise HR (147 vs 149 bpm; p=NS) was also not different. Metoprolol-induced BP changes in responders and nonresponders were different (Δ mean 24h SBP=-13.4% vs -2.2%, DBP=-13.8% vs -3.8%) with mean daily doses of 250 mg vs 293 mg, respectively. However, Δ mean 24h HR (-18.0% vs -13.7%; p=NS) and treadmill study HR values were not different (resting HR=-20.4% vs -20.6%, exercise HR=-31.5% vs -26.5%; p=NS). Blacks (n=7) had less BP reduction than whites (n=21; Δ 24h SBP=-1.4% vs -8.1%, DBP=-4.2% vs -9.3%) yet similar changes in HR (Δ mean 24h HR=-15.1% vs -16.7%, exercise HR=-29.7% vs -28.8%).

CONCLUSION: Our data suggest that metoprolol reduces resting HR and inhibits exercise tachycardia irrespective of the magnitude of blood pressure lowering. Thus, in clinical situations where β -blockers are used for their negative chronotropic effects, one would expect less interpatient and racial variability in this response than in the antihypertensive response.

21E. β -adrenergic receptor polymorphisms and antihypertensive response to β -blocker therapy. Brian J. Puckett, Pharm.D., Daniel F. Pauly, M.D., Ph.D., Issam Zineh, Pharm.D., Julie A. Johnson, Pharm.D.; Virginia Commonwealth University at the Medical College of Virginia, Richmond, VA; University of Florida, Gainesville, FL.

Presented at the 103rd Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Atlanta, GA, March 24-27, 2002.

22E. Regional gap junction inhibition increases defibrillation energy requirements. J. Jason Sims, Pharm.D., Kell L. Schoff, BS; University of Wisconsin, Madison, WI.

Presented at the Annual Scientific Sessions of the American College of Cardiology, Atlanta, GA, March 17-20, 2002.

Critical Care

23E. Using brain microdialysis to detect drug penetration in severe brain injury patients. Gretchen M. Brophy, Pharm.D., BCPS, Eljim P. Tesoro,

Pharm.D., Zhe Tang, Ph.D., H. Thomas Karnes, Ph.D., Egon Doppenberg, M.D., M. Ross Bullock, M.D., Ph.D.; Virginia Commonwealth University, Richmond, VA; University of Illinois at Chicago, Chicago, IL; Virginia Commonwealth University Health Systems, Richmond, VA.

Presented at the 31st Critical Care Congress of the Society of Critical Care Medicine, San Diego, CA, January 27, 2002.

24. Early metabolic changes following traumatic brain injury in pediatric patients. Jimmi Hatton, Pharm.D., Loran Karlosky, BS, Brant Sachleben, BS, Zeinab Abdorahman, MS, Henrich Warner, M.D., Benjamin Warf, M.D.; University of Kentucky Chandler Medical Center, Lexington, KY.

PURPOSE: Metabolic changes following TBI in adults include hyperglycemia, hypoalbuminemia, increased cytokines, anergy, reduced insulin-like growth factor 1 (IGF1), increased energy expenditure (EE) and nitrogen excretion (UUN). The hypothesis of this investigation was that TBI children do not differ from TBI adults in the metabolic response to brain injury.

METHODS: Within 48 hours of injury, patients (2-17 years) suffering severe TBI were prospectively studied. Baseline anergy response, EE, UUN, albumin, glucose, Interleukins 6, 8, 10, and IGF-1 were measured.

RESULTS: Thirty-two patients (21 males) with a mean age of 11.9 ± 4.1 years were enrolled. Three patients were withdrawn secondary to death or significant change in clinical condition. Mean admission Glasgow Coma Scale score was 6.5 ± 0.98 . Study procedures were often interrupted due to clinical circumstances. EE measured in nineteen evaluable patients was not significantly higher than predicted (mean EE=1610 \pm 370 kcal/d; 28 ± 5.1 kcal/kg). UUN was 9.2 ± 4.8 g (0.17 ± 0.04 g/kg/d). Albumin= 3.0 ± 0.7 g/dl; glucose= 162 ± 57.4 g/dl. Anergy panels were negative in 22/25 patients. Cytokine concentrations were elevated in 25/25 IL-6, 5/13 IL-8, 8/15 IL-10 patients. IGF-1 concentrations were reduced in 10/26 patients and appeared more frequently in females.

CONCLUSIONS: In this small study, the younger TBI patients did not demonstrate increased EE or UUN within 72 hours of injury. Hyperglycemia, hypoalbuminemia, and immunocompetence changes were evident. Endogenous marker profiles were not identical to those reported in adult TBI. Further studies are needed to characterize TBI in children.

25. Validating the use of ICD-9-based search strategies to identify patients with severe sepsis who may be candidates for drotrecogin alfa (activated) therapy. Salmaan Kanji, Pharm.D., Madeline Betancourt, Pharm.D., James A. Kruse, M.D., John W. Devlin, Pharm.D., BCPS; Detroit Receiving Hospital; Wayne State University, Detroit, MI.

PURPOSE: Estimating drotrecogin alfa (activated; D) use is challenging as there is no specific ICD-9 code for severe sepsis (SS) and not all patients with SS will be candidates for D. The search strategy reported by Angus et al. [AS] using concomitant ICD-9 codes for infection and organ dysfunction has been used by many institutions to predict SS incidence and D utilization. (Crit Care Med 2001) However, the AS does not account for SIRS, consider the temporal relationship between infection, organ dysfunction and SIRS, nor identify patients for whom D may be contraindicated. We attempted to validate the use of the AS at our 340-bed, urban, level-one, trauma center as a strategy to estimate the incidence of SS and D use.

METHODS: All patients discharged from our institution over a one year period meeting the AS criteria were electronically identified. For the first two month period, consecutive patient records were reviewed to determine: 1) incidence of SS based on both ACCP/SCCM guidelines (Chest 1992) and PROWESS (N Engl J Med 2001) study criteria and 2) potential D use based on both institutional D prescribing guidelines and PROWESS study criteria.

RESULTS: The AS identified 821 patients (6/100 admissions). Review of 104 patient records revealed that only 28 (27%) and 26 (25%) had SS based on the ACCP/SCCM and PROWESS criteria, respectively. Common reasons that SS was not identified included: 1) organ dysfunction criteria not met (79%), 2) SIRS not present (11%), and 3) temporal relationship not evident (8%). Of the patients with SS, 9/26 were candidates for D based on institutional prescribing guidelines and 8/26 based on PROWESS study criteria. Contraindications to D therapy included: 1) bleeding risk (74%) and 2) therapeutic futility (16%). Based on this analysis, it is estimated that 71 courses/year of D will be used at our institution (0.5 courses/100 admissions).
CONCLUSIONS: The AS appears to overestimate the incidence of SS and D utilization. Refinements to the AS criteria should be considered in future evaluative efforts.

26E. Bioavailability of gatifloxacin by nasogastric administration with and without concomitant enteral feeding in critically ill patients. Salmaan Kanji, Pharm.D., Peggy S. McKinnon, Pharm.D., Jeffrey F. Barletta, Pharm.D., James A. Kruse, M.D., FCCM, John W. Devlin, Pharm.D., BCPS; Detroit Receiving Hospital; University Health System; Wayne State University, Detroit, MI.

Presented at the 31st Critical Care Congress of the Society of Critical Care Medicine, San Diego, CA, January 26-30, 2002.

Drug Delivery

27. Using sequential sampling from an individual rat to assess controlled drug delivery. Steven C. Laizure, Pharm.D., D. Chris Watts, B.S., Atul J. Shukla, Ph.D.; University of Tennessee, Memphis, TN.

PURPOSE: The development of controlled-release, parenteral dosage forms is nascent technology that offers important therapeutic advantages over daily oral therapy. Usually, evaluation of controlled-release dosage forms is initially done in rats with only one sample being collected from each animal. The concentration-time profile is constructed under the assumption that all animals have the same clearance and Vss. We present an alternate method in which the pharmacokinetics of the drug is determined after a bolus dose and after implantation of a controlled-release dosage form in an individual rat.

METHODS: A catheter was surgically inserted into the jugular vein and tunneled to subcutaneous tissue in the scapular area where it was connected to a port accessible by inserting a needle through the skin and into the port. Multiple blood samples can be drawn with patency being maintained by flushing with 80% glycerol containing 500 U of heparin per ml. Using this port, blood samples were collected after an IV bolus of nalmefene (5 mg/kg) and after insertion of a biodegradable pellet containing 100 mg of nalmefene. Plasma samples were assayed by high-performance liquid chromatography with electrochemical detection. Pharmacokinetic parameters were estimated after the IV bolus by fitting a two-compartment model to the data. The AUC after implantation of pellet was estimated using the trapezoidal rule. Using these parameters the bioavailability and release rate of nalmefene from the pellet were estimated.

RESULTS: The following table summarizes the results after intravenous bolus:

Rat	Cl (L/h)	Vss (L/kg)	Half-Life (h)
1	3.92	14.42	1.53
2	5.39	11.24	0.65
3	2.39	4.57	0.82
Mean	3.90	10.08	0.88
STD	1.500	5.025	0.467

The AUC in Rat 3 over the 34-day sampling period after implantation of the pellet was 22399 $\mu\text{g/L}\cdot\text{h}$. The average release rate derived from nalmefene concentration and Cl was $72 \pm 41 \mu\text{g/h}$ with concentrations maintained above 13 $\mu\text{g/L}$ over the entire 34-day period. Bioavailability over the 34-day period was 0.54.

CONCLUSIONS: The intravenous data demonstrates that Cl is variable and the assumption necessary when collecting only one sample per rat that Cl is the same in all animals may not be valid. Additionally, only by collecting all samples in an individual rat can drug release rate and bioavailability be evaluated. This method offers significant advantage over a single blood collection from each rat when evaluating drug release from a controlled-release dosage form.

Education

28. Readability of patient education materials at an inner-city hospital. Jacqueline S. Marinac, Pharm.D., Colleen Buchinger, M.D.; University of Health Sciences; University of Missouri at Kansas City; Truman Medical Center-West, Kansas City, MO.

PURPOSE: Determine the readability of a random sample of patient education materials in our outpatient clinics. Previously we determined that approximately half of our patient population was unable to read materials written above the 8th grade level. Experts suggest low literacy materials should use: the active voice, common words and short sentences and visual aids to motivate and reduce text.

METHODS: A random sample of 90 patient education materials was obtained from adult outpatient medicine, OB-GYN and general surgery clinics. The text was analyzed using Microsoft Word™ readability statistics. The Flesch Kincaid score corresponds to the grade level of the reading material. The data are reported as mean (\pm standard deviation [SD]).

RESULTS: The grade level was 8.4 (SD \pm 2.3; range 3.8-12 +). The % of passive voice sentences was 13.7% (SD \pm 11.5; range 0-57%). The number of words/sentence was 15 (\pm 4; range 8-32). 51 were foldout pamphlets, 30 booklets and 9 single pages. 47% contained photographs or visual aids. The sources of the materials included: pharmaceutical industry (28), Missouri Dept of Health (13), National Cancer Institute (6), professional healthcare associations (13), NIH (2), US Dept of Health (4).

CONCLUSIONS: Approximately half of our patients would be unable to read 50% of the patient education materials distributed at our hospital. The written materials frequently used long sentences and the passive voice, both of which are difficult for low literacy persons to understand. Based upon this random sample in our outpatient clinics, we are inadequately prepared to meet the educational needs of our patients using written materials.

29. Impact of the EPOC program on student learning and site productivity. Rowland J. Elwell, Pharm.D., Harold J. Manley, Pharm.D., George R. Bailie, Pharm.D., Ph.D.; Albany College of Pharmacy, Albany, NY; University of Missouri at Kansas City, Kansas City, MO.

PURPOSE: The ACPE's Accreditation Standards and Guidelines recommend that pharmacy students acquire clinical experiences early and as a continuum throughout the curriculum. In our Early Patient-Oriented Care (EPOC) program, students gain such experience while providing clinical pharmacy services to hemodialysis outpatients. Each student is responsible for 3 patients longitudinally over 3 semesters. We assessed the EPOC program by evaluating its impact on student learning and site productivity using published algorithms.

METHODS: Core EPOC activities were identified by preceptors and applied to 2 algorithms that estimate the impact of clerkship activities and produce categorical results representing a continuum of opportunity for students to learn (A=optimal; G=minimal) or to impact site productivity (A=positive; H=negative).

RESULTS: Nine core activities were identified: 1) conduct medication histories, 2) update medication lists, 3) monitor/evaluate drug therapy, 4) provide medication counseling, 5) document pharmaceutical care activities, 6) retrieve patient information, 7) communicate with healthcare providers, 8) participate in classroom discussions, and 9) provide therapeutics/case presentations to peers. All activities produced a learning opportunity score of "A". Site impact scores were "D" for activities 1-7. Activities 8-9 were not evaluated for site impact, as they do not occur at EPOC sites.

CONCLUSION: The EPOC program provides students an optimal learning opportunity while having minimal but positive impact on participating dialysis centers. Efforts are underway to offer similar experiences to more students at our institution.

30. Influence of classroom and clinical experience on the ethical decisions of doctor of pharmacy students. Rowland J. Elwell, Pharm.D., George R. Bailie, Pharm.D., Ph.D.; Albany College of Pharmacy, Albany, NY.

PURPOSE: It has been suggested that ethics education should include theoretical and practical components. Our objective was to compare the effects of classroom discussion and clerkship experience on the ethical decisions of pharmacy students.

METHODS: From 1996 to 2001, students [n=112; median (range) age=23 (22-46) years; 59.8% females] in a required ethics course were presented 5 cases describing ethical dilemmas and asked whether a pharmacist should dispense medications for assisted suicide, sedate an unruly patient, recommend treatment to allow parole, ration drugs, or ask a pharmacist to resign for making an error. Anonymous questionnaires assessed their reactions (yes, no, don't know) at 3 study phases. Phase 1 preceded and phase 2 followed classroom debate. Phase 3 followed 45 weeks of clerkship training. Responses were compared by chi-square (χ^2) analysis.

RESULTS: Phases 1 and 2 responses (n=65) were similar for all cases, except parole (p<0.05). Phase 3 responses (n=39/89; 43.8% response rate) for cases involving assisted suicide, parole, and drug rationing were statistically different (all p < 0.05) from in-class responses. All significant differences were characterized by increased frequency of the "no" response, except parole (phase 3) where "yes" increased. No differences were observed at any phase for the sedation or resignation cases.

CONCLUSION: Practical experience had significant effect on the ethical decisions of pharmacy students. Clerkship training should be recognized and utilized as an important practical component of ethics education.

31E. Using study guides to promote active learning in an advanced pharmacotherapeutics course. Sharon See, Pharm.D., Tina Kanmaz, Pharm.D., Judith Beizer, Pharm.D., Gladys El-Chaar, Pharm.D., Laura Gianni, Pharm.D., Andrew Skirvin, Pharm.D., Michael Torre, M.S.; St. John's University, Jamaica, NY.

Published in *Pharmacotherapy* 2001;21(10):1266.

32E. Gender differences in peak flow meter technique. Christopher K. Finch, Pharm.D., Elizabeth Tolley, Ph.D., Carol C. Chafin, Pharm.D., Christa George, Pharm.D., Muthiah Pugazhenthii, M.D., Alan James, M.D., Timothy H. Self, Pharm.D.; University of Tennessee, Memphis, TN.

Presented at the 3rd Annual World Asthma Conference, Chicago, IL, July 13-16, 2001.

33E. Readability of over-the-counter analgesic medications. Kenneth C. Jackson, II, Pharm.D., Cynthia Raehl, Pharm.D., C.A. Bond, Pharm.D.; Texas Tech University Health Sciences Center, Lubbock, TX; Texas Tech University Health Sciences Center, Amarillo, TX.

Presented at the Annual Scientific Meeting of the American Pain Society, Baltimore, MD, March 14-17, 2002.

Emergency Medicine

34. Phenytoin loading in the emergency department: a prospective, randomized, controlled comparison of oral phenytoin, intravenous phenytoin and intravenous fosphenytoin. Maria I. Rudis, Pharm.D., Kian Azimian, B.S., Stuart P. Swadron, M.D., Michael Orlinsky, M.D.; University of

Southern California; Los Angeles County Medical Center, Los Angeles, CA.

INTRODUCTION: Considerable variability exists in emergency departments (ED) with respect to the practice of phenytoin loading in non-seizing patients with sub-therapeutic phenytoin concentrations.

PURPOSE: We prospectively compared the safety, efficacy and pharmacokinetic profile of three methods of phenytoin administration: intravenous phenytoin (DPH IV), intravenous fosphenytoin (FOS IV) and oral phenytoin (DPH PO) in order to determine the most effective method of loading phenytoin in the emergency department.

METHODS: Patients with known history of seizure disorder and sub-therapeutic concentrations of phenytoin who presented to the ED within 72 hours of a seizure provided written informed consent and were randomized to receive DPH IV 18 mg/kg (50 mg/min), FOS IV 18 mg/kg phenytoin equivalents (PE; 150 mg/min) or DPH PO 20 mg/kg (total dose divided q2h). During study intravenous drug administration, the following were recorded: blood pressure and cardiac rhythm (via continuous monitoring), presence of local effects (e.g., phlebitis, perineal pruritis). For all study arms, neurological effects (e.g., evidence of seizure activity [clinical] nausea, dizziness, nystagmus) were noted. Serial venous blood samples (7 ml/sample) were obtained through a dedicated heparin lock at t=0, 5, 15, and 30 minutes, and 1, 2, 4, 6, 8, 10 and 24 hours after completion of the DPH IV and FOS IV arms and at 0, 1, 2, 4, 6, 8, 10 and 24 hours for the DPH PO arms. A clinical evaluation was carried out at 24 hours for all groups.

RESULTS: A total of 45 patients (37 male and 8 female; DPH IV [n=14], DPH PO [n=16], FOS IV [n=15]) completed the study. There was no difference in the time required to achieve therapeutic levels ($>10 \mu\text{g/ml}$) between DPH IV (mean \pm SE: 0.24 ± 0.30 h) and FOS IV (0.21 ± 0.28 h; $p=NS$). In contrast the DPH PO was predictably slower (5.6 ± 0.28 h; $p < 0.001$). There was no difference in the frequency of hypotension or phlebitis requiring adjustments in infusion rate for DPH IV and FOS IV (1.14 ± 1.74 vs 0.47 ± 0.63 , $p=0.41$) although 14 of 15 (93%) patients receiving FOS IV experienced perineal pruritis. Episodes of nausea were greater in the FOS IV arm vs the other treatment arms (0.93 ± 1.86 vs DPH PO 0.0 ± 0.0 vs DPH IV 0.06 ± 0.25). One seizure occurred in the IV phenytoin arm.

CONCLUSION: Although serum phenytoin concentrations are achieved more slowly in the DPH PO arm, DPH PO may be an effective therapeutic option in the ED since it does not result in any adverse effects and requires less intensive resource utilization than the intravenous administration of either phenytoin or fosphenytoin. A cost analysis is underway.

Endocrinology

35. Treatment of hypothyroidism with a single weekly dose of L-thyroxine. William C. Nicholas, M.D., Brendan S. Ross, M.D., Richard G. Fischer, Pharm.D., Leigh Ann Ramsey, Pharm.D., Rebecca N. Stevenson, R.N., William P. Repogle, Ph.D.; University of Mississippi Medical Center, Jackson, MS.

PURPOSE: To determine whether a single weekly dose of L-thyroxine (T4) will safely maintain control of hypothyroidism.

METHODS: Patients euthyroid on stable T4 doses of $\leq 150 \mu\text{g/d}$, alternatively, received weekly doses equivalent to 7 times their daily doses for 11 weeks. Baseline thyroid function tests (TFTs) and ECGs were obtained. TFTs were repeated 1, 2, 4, and 8 hours after the first consolidated dose of T4, and at weekly intervals to yield 24, 48, 72, 96, and 120 hour post-dose measurements. ECGs were repeated 4 hours after the first weekly dose and at study conclusion.

RESULTS: Twenty patients, 70% women, average age 54 (SD=12) years, completed the study. The mean daily dose of T4 was 1.5 (SD=0.25) $\mu\text{g/kg}$ BW. Mean serum thyroid-stimulating hormone (TSH), free triiodothyronine (FT3) and FT4 levels were comparable ($p > 0.05$). ECGs did not reveal significant heart rate or interval changes; no patient developed atrial fibrillation.

CONCLUSIONS: Single weekly doses of T4 were as effective as daily replacement therapy for hypothyroidism, and would benefit patients with poor compliance or in institutional settings. T4 is an ideal drug for weekly dosing due to its elimination half-life of 7 days. T4 is a prohormone and its conversion to the active hormone T3 in peripheral tissues is autoregulated. This study confirms that these pharmacokinetic and biodynamic properties render weekly dosing of T4 both efficacious and safe.

36. Accuracy of the Bayer DCA 2000+ point of care HgA_{1c} device. Cara Lawless-Liday, Pharm.D., Rex W. Force, Pharm.D., FCCP, BCPS; Idaho State University, Pocatello, ID.

PURPOSE: To determine the reliability of a point of care (POC) device, the DCA 2000+ (Bayer Diagnostics, Elkhart, Indiana USA), for measuring HgA_{1c} with that of a standard laboratory method using the Variant II HPLC system. **METHODS:** Single venous blood samples were obtained from 26 type 2 diabetic patients during routine clinic visits. HgA_{1c} values were then determined for each sample using both the Bayer DCA and the HPLC system. Data were analyzed with SPSS statistical software.

RESULTS: Mean HgA_{1c} values in 26 paired samples were 6.82% (± 0.687) for HPLC and 6.64% (± 0.742) for the Bayer DCA ($p < 0.001$). The mean difference between values was 0.181% (95% CI, 0.113-0.248). These data were closely correlated ($y=1.0543x - 0.551$, $r=0.976$).

CONCLUSIONS: Although the Bayer DCA slightly underestimated the HgA_{1c}, it correlated well with the HPLC system. Rapid determination of glucose control would enable providers to make more informed therapeutic decisions at the point of care.

37. Glucocorticoid replacement therapy in chronic adrenal insufficiency: a patient education intervention to improve disease state knowledge and outcomes. Brendan S. Ross, M.D., Leigh Ann Ramsey, Pharm.D., Richard G. Fischer, Pharm.D., James W. Boutwell, Pharm.D., William C. Nicholas, M.D.; University of Mississippi Medical Center; Jackson, MS.

PURPOSE: To determine the impact of an education intervention on patients receiving glucocorticoid replacement therapy (GCRT) with regard to disease state knowledge and health care outcomes and utilization.

METHODS: The knowledge of patients with chronic adrenal insufficiency (CAI) on GCRT was assessed through a validated survey instrument. Subsequently, a clinical pharmacist conducted a standardized education intervention. Materials for home study and reference were provided. A follow-up assessment was performed at 6 weeks. Clinic and ER utilization and hospitalization rates were documented for 12 months prior to and following the intervention.

RESULTS: Twenty patients were recruited: 80% female, 70% African American and 30% Caucasian, 25% primary and 75% secondary CAI, average age 39.7 (range 22-65) years, average education 11th (SD=2) grade, and mean duration of disease 8.5 (range 1.5-29) years. At 6 weeks post-intervention, a significantly greater percentage of patients were able to successfully complete a 20-item questionnaire regarding CAI (mean prior, 0.60; post, 0.80; $p < 0.01$). Knowledge of self-treatment practices was notably improved. Annualized clinic utilization and contact was greater after the education intervention, than in the previous year (mean prior, 3.9; post, 6.6; $p < 0.01$); however, ER visits were significantly fewer (mean prior, 2.7; post, 1.6; $p < 0.05$). Hospitalization rates were low and not significantly different between the 2 time periods (OR 0.82; 95% CI 0.44 to 1.51).

CONCLUSIONS: Patient knowledge of how to self-treat CAI with GCRT can be significantly improved with a limited education intervention by clinical pharmacists. Such an intervention translates into a more cost-effective utilization of health care resources, and may potentially improve patient outcomes.

38. Use of angiotensin-converting enzyme inhibitors in hypertensive diabetic patients. L. Brian Cross, Pharm.D., C.D.E., Amy L. Herndon, Pharm.D., Gale Hamann, Pharm.D., BCPS, C.D.E.; University of Tennessee, Memphis, TN; Auburn University, Auburn, AB; Regional Medical Center at Memphis, Memphis, TN.

PURPOSE: Patients with diabetes and hypertension have significantly higher incidences of nephropathy and end stage renal disease. Studies have shown that angiotensin converting enzyme inhibitors (ACE-I) slow the progression of nephropathy in hypertensive diabetic patients. The purpose of this study was to determine the prevalence of ACE-I use in hypertensive diabetic patients, and to evaluate the presence of contraindications in patients not receiving an ACE-I.

methods: A retrospective chart analysis was performed of all diabetic patients presenting to the internal medicine clinic at the Regional Medical Center in Memphis for a 2-week period. Charts were reviewed for the diagnoses of both diabetes and hypertension. Patient encounters were reviewed for the documentation of ACE-I use. Patients not receiving ACE-Is were evaluated for the documentation of a contraindication to ACE-I therapy and the documentation of use of angiotensin receptor blockers (ARBs) or nondihydropyridine calcium-channel blockers (NCCBs). Charts were also reviewed for level of blood pressure control.

RESULTS: Seventy-three percent (122) of 167 diabetic patients with hypertension were treated with an ACE-I. Of the remaining 45 (27%) patients not receiving ACE-I therapy, 47% had a documented contraindication, 4% of patients refused ACE-I therapy, and 49% had no documented reason for the lack of ACE-I therapy.

CONCLUSIONS: The prevalence of ACE-I therapy use in hypertensive diabetic patients was greater at this facility than previously shown in similar studies. This study population had a higher percent of diabetic patients meeting blood pressure goals.

39. Conservative versus aggressive sliding scale insulin regimens in hospitalized patients with diabetes. Julie A. Brouil, Pharm.D., John M. Burke, Pharm.D., BCPS, FASHP, FCCP, Jennifer Ormsby, Pharm.D. candidate; St. Louis College of Pharmacy; Forest Park Hospital, St. Louis, MO.

Despite clinical trials discounting the value of sliding scale insulin (SSI) in hospitalized patients, it remains common practice. SSI regimens are often modified to manage hyperglycemia.

PURPOSE: This study evaluated the effect of conservative versus aggressive

SSI regimens on hypoglycemic and hyperglycemic events in hospitalized patients with diabetes.

METHODS: Medical records of 177 patients with diabetes (91% type 2, 9% type 1), admitted to a community-based family medicine inpatient service between July, 2000 and June, 2001, were reviewed. Regimens were classified as either aggressive (≥ 150 mg/dl) or conservative (≥ 200 mg/dl) based on the blood glucose (BG) threshold for insulin administration. The occurrence of clinically relevant hypoglycemia (BG ≤ 60 mg/dl) or hyperglycemia (BG ≥ 300 mg/dl) was determined for each group. Differences were evaluated using chi-square or Fisher Exact Test using Sigma Stat.

RESULTS: Thirty-five patients were excluded because of incomplete records. Hyperglycemia occurred in 45% of patients while hypoglycemia occurred in 16.9% of patients. Hypoglycemia was similar in the aggressive (17.9%) and conservative groups (16.3%; $p=0.987$); hyperglycemia was also similar in patients receiving the aggressive (53.6%) and conservative (39.5%) regimens ($p=0.14$). Among patients receiving a scheduled regimen (oral agent or insulin), hyperglycemia was more common with an aggressive scale (63.9%) than a conservative scale (37%; $p=0.022$).

CONCLUSION: Hypoglycemia and hyperglycemia occurred commonly in patients receiving SSI. A conservative insulin scale did not reduce the likelihood of hypoglycemia and the use of an aggressive scale did not reduce the likelihood of severe hyperglycemia.

Gastroenterology

40E. Celecoxib reduces the risk of upper GI complications in patients with osteoarthritis of the knee, hip or hand taking low-dose aspirin for cardiovascular prophylaxis: the SUCCESS-1 in osteoarthritis trial. Gurkirpal Singh, M.D., John G. Fort, M.D., G. Triadafiloutos, Al Bello, M.D., Suzanne Boots, COT; Stanford University, Palo Alto, CA; Pharmacia Corporation, Peapack, NJ; Pharmacia Corporation, Skokie, IL.

Presented at the 65th Annual Scientific Meeting of the American College of Rheumatology, San Francisco, CA, November 11-15, 2001.

41. A randomized, single-dose, two-period, crossover study to determine the effect of a liquid antacid on the pharmacokinetics of a 16 mg dose of cilansetron in healthy male and female volunteers. Roseline Pardue, Ph.D., Troy ZumBrunnen, Pharm.D., Holger Fritsch, Ph.D., Mike DiSpirito, M.Sc., John Brennan, Ph.D.; Solvay Pharmaceuticals, Inc., Marietta, GA; Solvay Pharmaceuticals GmbH, Hannover, Germany; MDS Pharma Services, P.Q, Canada.

PURPOSE: Cilansetron is a selective 5-HT₃ antagonist being developed for treatment of diarrhea predominant Irritable Bowel Syndrome. Concurrent administration of antacids with cilansetron may cause drug interaction due to physicochemical interaction, changes in gastrointestinal motility, and increases in gastric and urine pH. The effect of a liquid antacid (200 mg MgOH and 225 mg ALOH/5 ml) on the pharmacokinetics of cilansetron in healthy volunteers was evaluated in this study.

METHODS: Twelve males (32.1 \pm 6.4 years) and 12 females (27.7 \pm 6.0 years) were included in the analysis. Each subject received a single 16-mg oral dose of cilansetron alone (reference) or concurrently with the antacid (test) with a 7 day washout between treatments. Cilansetron plasma concentrations after each treatment were determined using validated GC/MS/MS methods. Pharmacokinetic parameters for cilansetron were derived using noncompartmental method. Equivalence test and criteria were used on peak plasma concentration (C_{max}) and area under the curve (AUC) to compare treatments.

RESULTS: Test treatment resulted in a 14% decrease in mean C_{max} ($p<0.05$) and an approximately 15 minute delay in mean peak time (T_{max}). However, mean AUC, elimination half-life (T_{1/2}), weight adjusted apparent oral clearance (CL/F/kg) and apparent volume of distribution (Vd/F/kg) values were similar between treatments. The 90% confidence intervals for AUC and C_{max} were 92.9-108.1% and 78.8-95.5%, respectively.

CONCLUSION: The slight effect on rate but not extent of cilansetron absorption by the antacid was judged clinically irrelevant. No dosage adjustments on cilansetron are considered necessary when used concurrently with a liquid antacid.

42. Variability in the expression of key transporters and metabolic enzymes in human intestine. David R. Foster, Pharm.D., Duxin Sun, B.S., Lynda S. Welage, Pharm.D., FCCP, Jeffery L. Barnett, M.D., Christopher P. Landowski, B.S., David Fleisher, Ph.D., Kyung-Dall Lee, Ph.D., Gordon L. Amidon Ph.D.; University of Michigan, Ann Arbor, MI.

PURPOSE: Intestinal transporters (both efflux and influx) and metabolic enzymes present in enterocytes are recognized as key determinants in oral drug absorption. Although numerous studies have demonstrated that drug absorption is often variable, the precise explanation for this variability has not been elucidated. The purpose of this investigation was to examine the inter-subject variability in gene expression of key intestinal transporters and metabolic enzymes.

METHODS: Human volunteers (n=10) underwent esophagogastroduo-

denoscopy with duodenal biopsy. Total RNA was extracted from samples, and transporter expression was determined by Affymetrix Genechip[®] analysis. The expression of more than 12000 genes was analyzed. For purposes of this analysis, the inter-subject variability in the expression of p-glycoprotein (MDR1), cytochrome P450 3A4 (CYP3A4), human oligopeptide transporter (hPEPT1), amino acid transporter (Y+ LAT1), organic cationic transporter (OCTN2), and the glucose transporter (SGLT1) was evaluated.

RESULTS: Over 5000 genes were expressed in human duodenum. Inter-subject variability in transporter/enzyme expression ranged from 11-33%, depending on the transporter/enzyme evaluated. Coefficients of variation for the transporters/enzymes were: MDR1 33.2%, CYP3A4 11%, hPEPT1 28.7%, Y+LAT1 29.8%, OCTN2 21.5%, and SGLT1 12.8%. Although the coefficient of variation for CYP3A4 was relatively small, a 4.37 fold change in expression was observed, as one subject exhibited extremely low expression compared to the other subjects.

CONCLUSIONS: Our data indicates inter-subject variability in expression of key intestinal transporters/enzymes. This may account for a significant portion of the variability that is often observed in oral drug absorption.

Geriatrics

43. Do rural dwelling elderly and elderly Hispanic people receive adequate pharmacy services?: an analysis of the Texas Tech 5000 Dataset (TT5000). Carlos H. Rojas-Fernandez, Pharm.D., Tom Xu, Ph.D.; Texas Tech University, Amarillo, TX; Texas Tech University, Lubbock, TX.

PURPOSE: Provision of pharmacy services beyond traditional dispensing of medications can improve the quality of health care provided to elderly persons. This study examined the level of pharmacy services provided to rural dwelling older people and whether differences existed for rural dwelling elderly Hispanics.

METHODS: TT5000 was a two-part survey designed to assess health status of a randomly selected sample of 5000 elderly persons living in West Texas. The second part assessed medication related issues, including provision of pharmacy services. Respondents were asked whether their pharmacies provided delivery of medications, counseling, written information, blood pressure monitoring, blood glucose monitoring, osteoporosis screening and immunization services.

RESULTS: Fewer pharmacists were available in rural and frontier areas (5.6 and 6.2/10,000 population vs 8.2/10,000 [$p<0.001$]). Respondents in rural areas reported higher availability of medication delivery and immunization services vs urban areas (53% vs 41% and 21% vs 15%, respectively, [$p<0.001$]); and lower availability of others service such as blood pressure monitoring (39% vs 49%, $p<0.001$). No differences were noted for medication counseling (72-75%), providing written information (92-92%), blood glucose monitoring (15%) and osteoporosis screening (6-8%). Further analysis revealed that elderly Hispanics are less likely to report availability of most pharmacy services.

CONCLUSIONS: Older people living in rural/frontier areas have limited access to many pharmacy services. Some important services are provided only by a minority of pharmacies. Future work needs to examine the impact of differential pharmacy services on health outcomes in these populations.

44. Pharmacists' knowledge of essential geriatric pharmacotherapy principles: a pilot study in Texas. Carlos H. Rojas-Fernandez, Pharm.D., Patricia W. Slattum, Ph.D., Pharm.D., Joseph Hanlon, Pharm.D., MS, Kellee A. Howard, MA, MS; Texas Tech University, Amarillo, TX; Virginia Commonwealth University, Richmond, VA; University of Minnesota, Minneapolis, MN.

PURPOSE: Appropriate medication use in those aged ≥ 65 presents a challenge to health care providers and drug related problems (DRPs) are highly prevalent in this population. Knowledge of essential geriatric pharmacotherapeutic principles (EGPP) may help pharmacists reduce DRPs in this population. Unfortunately, it's not known to what extent pharmacists are aware of EGPP necessary to provide care for this population. The purpose of this study was to assess pharmacists' level of knowledge of EGPP.

METHODS: A structured questionnaire was mailed to a random sample of 1000 pharmacists in TX. It included questions related to EGPP as follows: Demography, pharmacokinetics (PK), adverse drug reactions (ADRs), and potentially inappropriate drugs (PID) for older people. Questions were composed using well-known facts about EGPP and accepted criteria for PID from the literature and standard geriatrics textbooks.

RESULTS: The response rate was 12.6% (n=126). 59% were male, 6.3% were board certified, 12.7% completed a residency. Most practiced in community (42.1%) or hospital (23%) pharmacy. 89% correctly identified the most important PK question. Items related to ADRs were correctly identified by $\geq 73%$ of respondents. 35% to 82% correctly identified PIDs/drug doses. Demography items were correctly identified by 19.2% to 58% of respondents. **CONCLUSIONS:** This preliminary data suggests that pharmacists' knowledge of EGPP may be adequate for ADRs. Improvement is necessary, however, for items in PK and knowledge of PIDs for most older people. Further work with a larger sample is necessary to validate these findings.

Health Services Research/Managed Care

47E. Evaluating the impact of computerized guidelines for ordering digoxin levels. Daniel M. Hartung, Pharm.D., Margaret E. McGuinness, Pharm.D.; Oregon State University; Department of Veterans Affairs Medical Center, Portland, OR.

Presented at the 36th Annual Midyear Clinical Meeting of the American Society of Health-System Pharmacists, New Orleans, LA, December 5, 2001.

48. The impact of a clinical pharmacist intervention on the outcomes of primary care patients with depression: 6-month (preliminary) outcomes. David A. Adler, M.D., Kathleen M. Bungay, Pharm.D., Ira Wilson, M.D., Stacey Supran, M.Sc., Emily Peckham, B.S., Yu Pei, M.S., Diane Cynn, B.A., William H. Rogers, Ph.D.; The Health Institute, Boston, MA.

PURPOSE: of this abstract is to report preliminary results of a prospective RCT conducted between 1998 and 2000 in 9 eastern Massachusetts primary care settings.

METHODS: Patients presenting to their Primary Care Physicians (PCPs) offices (n=16,707) for a routine visit were screened for depression. 1182 screened positive for major depressive disorder (MDD) or dysthymia. 535 consented to participate and were randomly assigned to either a clinical pharmacist intervention (n=269) or control (n=266). Pharmacists (n=5) intervention activities were guided by a protocol based on principles of pharmacy practice, and AHCPR guidelines for the treatment of depression in primary care (minimum of 9 contacts/18 mos.). The control group received usual care from their PCP.

RESULTS: 507 evaluable patients were enrolled; 258 in the intervention, and 249 in control. There were no significant differences in sociodemographics between the two groups. Patients were 42.3 years, mean age; 71.8% female, 72.4% Caucasian, 27.9% married, 60.9% employed \geq 20 hrs/week, and 17.6% with mean household income < \$10 K. 40% of the sample met criteria for MDD; 24% met criteria for dysthymia, and 36% met criteria for both (double depression). 49.5% of patients reported current antidepressant use at baseline, 63.5% reported prior depressive episodes totaling \geq 4; 81.5% reported \geq 2 prior episodes in their lifetime. In the group overall, patients followed by pharmacists were more likely than controls to take antidepressants (p=0.032) and had slightly better outcomes, as measured by Beck Depression Inventory (BDI; p=0.07). There were large differences related to whether the patient was already taking antidepressants at the beginning of the study. Those patients who were already on antidepressants continued to take their medication regardless of whether a pharmacist followed them. For those patients followed by the pharmacist who were not already on antidepressants, 29% began to take them by 3 months. Almost all of these continued to take them at 6 months, whereas only 11% of patients in the control group were taking antidepressants at 6 months. Pharmacist intervention patients increased antidepressant use at 3 months to 60.6% (from 49.6% at baseline) vs 48.9% (from 49.3% at baseline) in the control (p=0.024); at 6 months 56% of intervention patients were taking antidepressants compared to 45% in the control (p=0.032).

CONCLUSIONS: This 6-month outcome suggests that in clinical practice, interventions to increase antidepressant use should be focussed on patients in whom antidepressants are indicated and who have not yet started taking them. The improvements in mental health (main outcome) seen in the intervention group, compared with the control were of similar magnitude to those seen in other intervention studies. However, the modest effects of the pharmacist intervention were insufficient to demonstrate improvements in outcomes for the experiment as a whole, given the power of medication treatment in and of itself to improve outcomes.

IMPLICATIONS: These results and the investment of the pharmacist's time and energy (data not shown) suggest that some patients may benefit more than others may from ongoing contact with a pharmacist. In the case of patients with affective disorders, other health care professionals (social workers, psychologists) may be better suited, and more efficient in caring for the needs of patients for whom antidepressant treatment is already in place. Further evaluations of the efficiency, impact of the intervention on subgroups and on patient adherence, as well as the cost-effectiveness of the pharmacist(s) are underway.

Hematology/Anticoagulation

49. Comparison of group versus individual appointment format on patient satisfaction and education in a VA warfarin clinic. Carole L. Bradley, Pharm.D., BCPS, Rita E. Lakamp, Pharm.D., BCPS, Tammy L. Kellebrew, Pharm.D., Myra T. Belgeri, Pharm.D.; St. Louis College of Pharmacy; John Cochran St. Louis VAMC, St. Louis, MO.

PURPOSE: Pharmacist-managed warfarin clinics result in improved patient outcomes, but formats for orientation visit education have not been compared. For initial warfarin education and clinic orientation, individual appointments available daily or group appointments available weekly were provided in a VA warfarin clinic. A survey was designed to compare 1)

patient satisfaction and 2) patient retention of warfarin knowledge and clinic policy information between the appointment formats.

METHODS: Patients were randomized to individual or group orientation appointments based on birth date. Patients completed an anonymous 10-item satisfaction survey during the orientation visit, which included the global assessment question "Rate your overall experience at this appointment: poor, fair, good, excellent." After 4-12 weeks, all patients attended an individual follow-up appointment and completed a 16-point education survey assessing warfarin and clinic policy understanding.

RESULTS: Fifty-seven patients completed the satisfaction survey (31 individual, 26 group). Thirty-nine completed the educational survey (24 individual, 15 group). Patients needing to be seen right away were given individual orientation appointments resulting in a discrepancy in numbers between the 2 arms. On the satisfaction survey, 93.5 and 88.5% of patients in the individual versus group orientation appointments, respectively, rated their overall experience good or excellent (p=NS). On the 16-point education survey, scores were 7.54 ± 2.55 in patients seen individually versus 7.13 ± 2.39 for those seen in group format (p=NS).

CONCLUSION: Regardless of initial appointment format, patient satisfaction was high. Retention of information did not differ between groups. The education survey results highlight the need for ongoing patient education.

50E. Warfarin in patients with atrial fibrillation: pattern of use in an ambulatory care clinic. Jill S. Burkiewicz, Pharm.D., Karen M. Merrill, Pharm.D. candidate; Midwestern University, Downers Grove, IL; Chicago College of Pharmacy, Chicago, IL.

Presented at the 36th Annual ASHP Midyear Clinical Meeting 2001, New Orleans, LA, December 3-6, 2001.

Herbal Medicine

51. Evaluation of utilization, knowledge and attitudes towards alternative pharmacotherapy in patients with cardiovascular diseases. Larisa Chagan, Pharm.D., Vitalina Rozenfeld, Pharm.D., BCPS, Gina Caliendo, Pharm.D., BCPS, Bernard Mehl, DPS, Judy W.M. Cheng, Pharm.D., BCPS; Mount Sinai Medical Center, New York, NY.

PURPOSE: This is a survey to 1) determine demographics on the use of alternative pharmacotherapy (AP) in cardiovascular (CV) diseases patients; 2) assess patients' knowledge and perceptions regarding the safety/efficacy of AP; 3) determine the percentage of patients who disclose AP use to health care providers, 4) determine common AP used; 5) determine potential AP-drug interactions.

METHODS: 146 patients with CV diseases (57 AP users and 89 non-users) were surveyed. The study took place in a university hospital.

RESULTS: Users had significantly higher level of education than non-users (College graduate or above: 49% vs 28% p=0.001). Users reported a significantly higher incidence of drug allergy/adverse drug reactions to prescription medications than non-users (44% vs 22%, p=0.007). Top 10 AP used were vitamin E (28 [49%]), multivitamins (26 [46%]), vitamin C (20 [35%]), coenzyme Q (9 [16%]), fish oil (8 [14%]), calcium (8 [14%]), glucosamine (6 [11%]), magnesium (5 [9%]), selenium (4 [7%]), vitamin A (4 [7%]). 54% of users' physicians knew of their AP use. Only 7.5% of patients stated their physician routinely inquired about AP use. 41% users spend >\$200 annually on AP. Compared to non-users, users believed AP to be safer (p<0.0001) and more effective (p<0.0001) than prescription drugs. Only 5 users could name side effect of the AP they used and only 2 were aware of drug/food interactions. 5 potential drug-AP interactions were identified.

CONCLUSIONS: Incidence of use of AP in patients with CV disease is high (39%). Patient level of education correlates positively to AP use. Most AP use were not supervised. Health care providers need to pay more attention to AP use in CV patients.

52. Hawthorn effects on digoxin's ECG parameters. Roberta Tankanow, Pharm.D., Helen R. Tamer, Pharm.D., Daniel S. Streetman, Pharm.D., Scott G. Smith, Janice L. Welton, Thomas Annesley, Ph.D., Keith D. Aaronson, M.D., Barry E. Bleske, Pharm.D., FCCP; University of Michigan; University of Michigan Health Care Systems, Ann Arbor, MI.

Hawthorn, an herbal supplement, may have beneficial effects in treating cardiac disease, including heart failure. It has been suggested that hawthorn may affect electrophysiological parameters; if true, this may have important implications in regard to using hawthorn in combination with other drugs for treatment of cardiac disease.

PURPOSE: To determine the effect of hawthorn to potentiate the electrophysiological effects (heart rate [HR] and PR interval) of digoxin.

METHODS: Randomized, crossover trial in 8 healthy volunteers evaluating digoxin 0.25 mg alone (D) and digoxin 0.25 mg with hawthorn 450 mg twice daily (D+H) for three weeks. ECG was performed at baseline and at digoxin steady state trough concentrations. Data are expressed as mean and standard deviation.

RESULTS: The baseline PR interval for D and DH phase was 149 ± 20 msec

and 150 ± 16 msec ($p > 0.05$). Following each phase the PR interval increased to 156 ± 24 msec and 152 ± 14 msec for D and DH, respectively. The mean change in PR interval for D and DH was 6.5 ± 11 msec vs 1.0 ± 13 msec ($p > 0.05$). Baseline HR during D and DH phase was 65 ± 6 beats/min and 64 ± 6 beats/min ($p > 0.05$). Following each phase the HR was 62 ± 4 beats/min and 65 ± 7 beats/min for D and DH, respectively. The mean change in HR for D and DH was -2.5 ± 8 beats/min and 1 ± 6 beats/min ($p > 0.05$). There was no difference in digoxin trough concentrations between the two phases.

CONCLUSION: Hawthorn did not significantly effect the electro-physiological parameters for digoxin following three weeks of concomitant therapy.

53E. A pilot study comparing kava extract and placebo in stressful social situations. Holly E. Rogers, Pharm.D., Richard Ogletree, Pharm.D.; University of Mississippi Hospital and Clinics, Jackson, MS.

Presented at the Southeastern Residency Showcase, Athens, GA, April 26, 2001.

54E. A survey of dietary supplement use in an urban teaching hospital's outpatient clinics. Darren W. Grabe, Pharm.D., Gina Garrison, Pharm.D., George Eisele, M.D.; Albany College of Pharmacy; Albany Medical Center, Albany, NY.

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HIV/AIDS

55. Utilization of a computerized reminder system to improve tracking of vaccination rates for HIV-positive patients. Marisel Segarra-Newnham, Pharm.D., BCPS; Veterans Affairs Medical Center, West Palm Beach, FL.

PURPOSE: Vaccine-preventable diseases have a large impact on the health care system. HIV-positive patients are a high risk for complications from streptococcal pneumonia and other vaccine-preventable infections. This study reports the vaccination rates in an HIV clinic after a computerized reminder system was implemented in 1997.

METHODS: A computerized reminder system for vaccinations was implemented in 1997. Before this time, vaccinations were not reliably recorded on the medical record. When patients are vaccinated, information is entered in the computer. If a patient declines vaccination, documentation is also entered and patient is entered as "compliant" with requirement of addressing issue but declining vaccination. The system alerts providers when patients are due for a Pneumovax[®] or tetanus booster, among other vaccinations. Charts for all patients currently followed in the HIV clinic ($n=211$) were reviewed to assess dates for vaccinations against Pneumococcal disease and tetanus. Vaccination rates for patients followed before 1997 ($n=71$) were compared with rates for patients enrolled in the clinic after computerized system implemented ($n=140$). The clinical pharmacist monitors vaccination rates on a quarterly basis and facilitates appointments for patients.

RESULTS: Vaccination rates for patients followed before 1997 were 100% for Pneumovax and 100% for tetanus. In addition, 76% of patients due for a Pneumovax booster have received it. In contrast, patients followed after 1997 had vaccination rates of 94% for Pneumovax with eight patients enrolled in the last three months not having documentation of vaccination. The clinical pharmacist is scheduling these patients in the next three months to receive vaccine along with the flu shot. Due to shortage, only 61% of patients enrolled after 1997 have received tetanus vaccine.

CONCLUSIONS: A computerized reminder system allows for reliable tracking of vaccination rates among patients followed in an HIV clinic. A clinical pharmacist can utilize this tool to enhance provision of preventive care for HIV-positive patients. Overall vaccination rates are well above the national norm.

56E. Assessing the magnitude and duration of didanosine-induced elevation of gastric pH in HIV-infected subjects. Peggy L. Carver, Daryl DePestel, Carol A. Kauffman, Powel Kazanjian, Sandro Cinti; University of Michigan; Veterans Administration Medical Center, Ann Arbor, MI.

Presented at the 41st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, December 16-19, 2001.

Infectious Diseases

57. A retrospective analysis of the post-therapy complications of oseltamivir, zanamivir, and rimantadine in the treatment of the influenza A virus in hospitalized and ambulatory patients. Joan P. Cannon, Pharm.D., Christine L. Sullivan, M.B.A., M.S., Eui S. Kim, R.Ph., BCPS, Constance T. Pachucki, M.D.; Edward Hines VA Hospital; Hines, IL.

PURPOSE: To determine if there is a difference in the post-therapy complications of oseltamivir, zanamivir, and rimantadine in the treatment of the influenza A virus (IAV).

METHODS: From 11/99 to 2/00, data were collected retrospectively for patients diagnosed with IAV via Directigen[™], polymerase chain reaction, or viral isolation and treated with either oseltamivir, zanamivir, or rimantadine. Data collection included demographics, comorbid conditions, vaccination status, symptoms, nature of acquisition, time from onset of symptoms to initiation of treatment, side effects from treatment, and complications post-treatment.

RESULTS: Of 98 patients with symptoms consistent with influenza virus, 38 were positive for IAV and received treatment: 16 oseltamivir, 9 zanamivir, and 13 rimantadine. Age, sex, and vaccination status were similar between treatment groups. Onset of symptoms prior to therapy were documented in 14 of the community-acquired cases with 79% treated within 48 hours of the onset of symptoms. 50%, 33%, and 36% of patients treated with oseltamivir, zanamivir, and rimantadine, respectively, received concomitant antibiotic therapy. Respiratory complications post-therapy occurred in 25%, 11%, 8%, and 22% of oseltamivir, zanamivir, rimantadine, and non-treated patients, respectively ($p=NS$).

CONCLUSIONS: Most outpatients presented within the therapeutic window of initiation of antiviral therapy. Both vaccinated and unvaccinated patients were infected and treated. Concurrent antibiotic use was common even with a specific diagnosis of influenza. There did not appear to be a significant difference in post-therapy complications between treatments. Prospective studies are in progress at our institution to determine the differences in the complications, adverse events, and cost for the various therapies.

58E. Evaluation of variability in MIC90 values for single vs multi-center trials. Roger L. White, Pharm.D., Kevin A. Enzweiler, Pharm.D., John A. Bosso, Pharm.D.; Medical University of South Carolina, Charleston, SC.

Presented at the 100th General Meeting of the American Society for Microbiology, Los Angeles, CA, May 2000.

59. In vitro activity of cefepime, piperacillin/tazobactam, meropenem, levofloxacin, and tobramycin alone and in combination against extended-spectrum beta-lactamase producing *K. pneumoniae*. David S. Burgess, Pharm.D., Andrew Nelsen, Pharm.D. candidate, Dehuti Patel, Pharm.D. candidate; University of Texas at Austin, Austin, TX; University of Texas Health Science Center at San Antonio, San Antonio, TX.

PURPOSE: Currently, carbapenems are the drug of choice for treating ESBL producing organisms. However, resistance to these drugs is likely to develop with broader utilization. Therefore, evaluation of combination therapy for the treatment of ESBL organisms is warranted. The objective of this study was to evaluate the in vitro activity of cefepime (CFP), piperacillin/tazobactam (P/T), meropenem (MERO), levofloxacin (LEVO), and tobramycin (TOBRA) alone and in combination against ESBL-producing *K. pneumoniae*.

METHODS: MICs and time-kill studies were performed against 4 clinical isolates of ESBL producing *K. pneumoniae*. ESBL production was confirmed utilizing the ESBL E-strip of ceftazidime \pm clavulanate. Time-kill studies used the following concentrations alone and in combination with LEVO (2 μ g/ml) and TOBRA (4 μ g/ml): P/T (40/5 μ g/ml), CFP (20 μ g/ml), and MERO (4 μ g/ml). Samples were taken at 0, 2, 4, 6, 8, 12, and 24 hours then serially diluted if necessary and plated on TSA plates. After incubation for 24 hours at 35°C, colony counts were determined using a laser colony counter (CASBA 4). Synergy was defined as >2 log reduction in killing at 24 hours when compared to the most active agent alone.

RESULTS: MICs (μ g/ml) were: P/T (8), CFP (1-2), MERO (0.03), LEVO (2-8), and TOBRA (0.25-16). For monotherapy, only MERO maintained bactericidal activity over the 24 hour period against all isolates. LEVO and TOBRA maintained bactericidal activity against the susceptible isolate; whereas, CFP and P/T did not maintain bactericidal activity against any isolate. For combination regimens, TOBRA plus either CFP or P/T demonstrated synergy more often than LEVO plus either CFP or P/T. However, CFP plus either TOBRA or LEVO maintained bactericidal killing over the 24-hour period more often than P/T plus either TOBRA or LEVO.

CONCLUSION: Combination therapy appears to be an alternative to carbapenems for the treatment of ESBL producing organisms and should be further evaluated.

60. Admission criteria to differentiate severe versus non-severe community-acquired pneumonia. David S. Burgess, Pharm.D., Christopher R. Frei, Pharm.D.; University of Texas at Austin, Austin, TX; University of Texas Health Science Center at San Antonio, San Antonio, TX.

PURPOSE: To analyze differences in objective criteria for severe and non-severe community-acquired pneumonia (CAP).

METHODS: We examined the records of all adult patients with CAP between 1 November 1999 and 30 April 2000. We collected information on patient demographics, comorbid diseases, ICU admission, LOS, mortality, time to clinical stability, antibiotic therapy, time to first antibiotic dose, ICD-9 and DRG codes, hospital cost and reimbursement, and payer. All patients were stratified into 5 risk classes according to the Pneumonia Severity of Illness (PSI) model. All patients admitted to the ICU were defined as having severe CAP. Statistical analysis was performed using univariate and multivariate logistic regression.

RESULTS: A total of 782 patients were evaluated with 133 (17%) having severe pneumonia. Mortality and PSI scores were significantly higher in severe than non-severe pneumonia patients 21% vs 4.8% ($p < 0.0001$) and 100 ± 39 vs 122 ± 39 ($p < 0.0001$), respectively. Univariate analysis identified 12 admission criteria that predicted severe CAP. A total of 31 (23%) ICU patients required mechanical ventilation. In multivariate analysis, only SBP < 90 ($p = 0.0004$), pH < 7.35 ($p < 0.0001$), O_2 saturation < 90 ($p < 0.0001$), and pulse > 125 ($p < 0.0001$) were predictive of severe CAP. Inclusion of 3 or more of these variables resulted in a sensitivity, specificity, positive predictive value, and negative predictive value of 83%, 84%, 52%, and 96%, respectively.

CONCLUSION: Criteria at admission differ between severe and non-severe CAP patients. For our patient population, severe CAP was best predicted by the presence of at least 3 of the following criteria: SBP < 90 , pH < 7.35 , O_2 saturation < 90 , or pulse > 125 .

61. Effect of different antimicrobial usage markers on clinically significant susceptibility vs drug use relationships. David S. Burgess, Pharm.D., Bradi L. Jones, Pharm.D.; University of Texas at Austin, Austin, TX; University of Texas Health Science Center at San Antonio, San Antonio, TX.

PURPOSE: Relationships between antimicrobial susceptibility and drug usage are becoming routinely performed. However, the marker of antibiotic usage has varied tremendously from simply using total mg or Defined Daily Dose (DDD) to normalization of these measurements (mg/patient day or DDD/1000 patient days). The purpose of this study was to determine the effect of these different markers of antibiotic usage on the number of relationships found for antimicrobial susceptibility vs drug usage.

METHODS: Antibiotic usage and susceptibility data were determined biannually from July 1998 through June 2001 for 12 units in our tertiary teaching hospital. Antibiotic usage was determined as mg, mg/patient day, DDD, and DDD/1000 patient days for 15 antibiotics. Susceptibility data was determined for *S. aureus*, *E. coli*, *Enterobacter spp.*, *K. pneumoniae*, and *P. aeruginosa*. Relationships between antimicrobial susceptibility and drug usage (mg, mg/patient day, DDD, and DDD/1000 patient days) were assessed by simple linear regression. Only relationships with susceptibility $> 70\%$ and a correlation coefficient (r) > 0.7 were considered clinically significant.

RESULTS: Clinically significant relationships between antimicrobial susceptibility vs drug usage occurred most often using total mg as the drug marker (65) followed by DDD (52), mg/patient day (50), and DDD/1000 patient days (48). Only 50% of the relationships were detected by all four methods. The normalization of drug usage (mg/patient day and DDD/1000 patient days) provided the best agreement (88%) amongst the different markers of antibiotic usage.

CONCLUSION: The marker of antibiotic usage can affect the relationships found between antimicrobial susceptibility and drug usage. DDD/1000 patient days is the most conservative measure of drug usage.

62. Levofloxacin low dose (500 mg) and high dose (750 mg) alone and in combination against *P. aeruginosa*. David S. Burgess, Pharm.D., Ronald G. Hall, II, Pharm.D.; University of Texas at Austin, Austin, TX; University of Texas Health Science Center at San Antonio, San Antonio, TX.

PURPOSE: To evaluate the in vitro activity of low and high dose levofloxacin (LEVO) in combination with ceftazidime (CTZ), cefepime (CFP), piperacillin/tazobactam (P/T), imipenem (IMI), and tobramycin (TOBRA) against *P. aeruginosa*.

METHODS: MICs were performed using NCCLS guidelines against 12 non-duplicate clinical isolates of *P. aeruginosa*. Time-kill studies were performed against each isolate with the following antibiotics and concentrations ($\mu\text{g/ml}$) alone and in combination with LEVO (2 and 4): CTZ (16), CFP (20), P/T (40/5), IMI (4), and TOBRA (4). Bacterial densities were determined at 0, 2, 4, 6, 8, 12, and 24 hours with synergy defined as > 2 log reduction in killing at 24 hours compared to the most active agent alone.

RESULTS: MICs ($\mu\text{g/ml}$) range and %S were: LEVO (0.25-8, 67%), CTZ (8-64, 42%), CFP (4-32, 58%), PT (4/4-256/4, 75%), IMI (1-32, 75%), and TOBRA (1-2, 100%). TOBRA was the most active agent alone killing and maintaining $\geq 99.9\%$ killing over a 24-hour period against all isolates. LEVO 4 $\mu\text{g/ml}$ alone reached 99.9% killing and maintain this killing over the time period more often than LEVO 2 $\mu\text{g/ml}$. No combination was antagonistic and LEVO 2 or 4 $\mu\text{g/ml}$ plus TOBRA was indifferent for all isolates. LEVO 2 $\mu\text{g/ml}$ plus a β -lactam was statistically more synergistic (65%) than LEVO 4 $\mu\text{g/ml}$ plus a β -lactam (44%, $p = 0.0405$). However, LEVO 4 $\mu\text{g/ml}$ combinations maintained a > 3 log kill over the entire 24-hour period more often than LEVO 2 $\mu\text{g/ml}$ combination (94% vs 83%).

CONCLUSION: LEVO low dose (2 $\mu\text{g/ml}$) was more synergistic than LEVO high dose (4 $\mu\text{g/ml}$) when combined with a β -lactam but LEVO high dose (4 $\mu\text{g/ml}$) combinations maintained 99.9% killing more often than LEVO low dose (2 $\mu\text{g/ml}$) combinations. In vivo studies are needed to evaluate the clinical significance of these findings.

63. Similarities and differences of *Escherichia coli* and *Klebsiella pneumoniae* susceptibility to cephalosporins and fluoroquinolones from 1987-2001: results of the Antimicrobial Resistance Management (ARM) program. John G. Gums, Pharm.D.; University of Florida, Gainesville, FL.

PURPOSE: Using data from the ARM program, this study examined national and regional susceptibility rates of *E. coli* and *K. pneumoniae* to cephalosporin and fluoroquinolone antibiotics.

METHODS: Since 1987, more than 10 million US inpatient and outpatient isolates have been collected from 101 hospitals in 5 regions (Northeast, North Central, Southeast, South Central, Southwest). Antibiograms and sensitivity reports of isolates for *E. coli* and *K. pneumoniae* were reviewed for susceptibility to cephalosporins (cefazolin, cephalothin, cefuroxime, cefoxitin, cefotetan, cefotaxime, ceftazidime, ceftriaxone, cefepime) and fluoroquinolones (ciprofloxacin, levofloxacin, ofloxacin, trovafloxacin).

RESULTS: Nationally, *E. coli* susceptibility to first-generation cephalosporins ($n = 402,596$) ranged from 70.2% to 92.2%; second generation ($n = 368,877$), 95.3% to 99.6%; third generation ($n = 568,828$), 97.3% to 99.4%; cefepime ($n = 33,184$) was 99.1%. Fluoroquinolone susceptibility ranged from 95.4% to 97.8%; $n = 562,693$. *E. coli* susceptibility was 99.4% to third-generation ceftriaxone and 95.4% for levofloxacin, a difference seen largely in Northeast (99.1%, ceftriaxone; 92.7%, levofloxacin). Nationally, *K. pneumoniae* susceptibility to third-generation cephalosporins ranged from 94.1% for ceftazidime ($n = 46,899$) to 98.2% for ceftriaxone ($n = 99,345$); a range seen in every region except Northeast. *K. pneumoniae* susceptibility to first-generation cefazolin ($n = 116,035$) and second-generation cefuroxime ($n = 58,081$) was equal (92.5%), an anomaly attributed to North Central differences (90.7%, cefazolin; 88.9%, cefuroxime). In Southwest, differences were seen between ciprofloxacin (91.1%) and ceftriaxone (98.7%) for *E. coli* and between levofloxacin (91.6%) and ceftriaxone (98.0%) for *K. pneumoniae*.

CONCLUSION: National and regional differences in *E. coli* and *K. pneumoniae* susceptibility were detected to cephalosporin and fluoroquinolone antibiotics; these differences were associated with an anticipated class/subclass effect.

64. Rapid response of methicillin-resistant *Staphylococcus aureus* infections to quinupristin/dalfopristin plus vancomycin in patients failing vancomycin. Pamela A. Moise, Pharm.D., Alan Forrest, Pharm.D., Joseph A. Paladino, Pharm.D., Jerome J. Schentag, Pharm.D.; CPL Associates, LLC; University at Buffalo, Buffalo, NY.

PURPOSE: The combination of quinupristin/dalfopristin (QD) plus vancomycin (Vm) has demonstrated in vitro synergy against methicillin-resistant *S. aureus* (MRSA). In addition, the combination eradicates bacteria in animal models more rapidly than either compound alone. We wish to test whether this also applies to patients.

METHODS: Hospitalized patients that did not responding clinically and microbiologically, despite susceptible MICs, after at least five days of traditionally dosed Vm (VmTD, Vm trough 5-15 mg/L) were enrolled in an open label non-randomized multi-center trial. Patients enrolled received either QD + VmTD, or high dose Vm (VmHD, trough > 15 mg/L). The treatment arm and treatment durations were determined by the investigators. The times to bacterial eradication of the different treatment arms were compared.

RESULTS: Between June 2001 and November 2001, 49 patients failing Vm were enrolled. The median age is 73 (range 46-90) years. The infections include (%): lower respiratory (55.1), bacteremia (30.6), wound (12.2), and endocarditis (2.0). Eight patients received QD + VmTD, 17 received VmHD, and 24 received VmTD. The median time to bacterial eradication was 3.5 days for QD + VmTD, 6 days for VmHD and in excess of 11 days for VmTD ($p < 0.005$). For Vm treated patients, we have also derived a PD relationship between outcome and drug concentrations and MIC.

CONCLUSIONS: In patients failing Vm, the combination of QD + VmTD appears synergistic based on time to bacterial eradication. In Vm treated patients, it is important to optimize drug concentrations in relation to MIC.

65. Evaluating the inpatient use of oral linezolid. Ngoc-Quyen L. Nguyen, Pharm.D., Jennifer Cupo, Pharm.D., George S. Jaresko, Pharm.D., Victoria Zarotsky, Pharm.D., Paul D. Holtom, M.D.; University of Southern California, Los Angeles, CA.

PURPOSE: To describe characteristics of and assess safety in hospitalized patients treated with oral linezolid.

METHODS: A chart review of the first 30 hospitalized patients treated with oral linezolid. Demographic features, admitting diagnosis, rationale for linezolid use, duration of therapy, hospital course, microbiological and laboratory values were retrieved.

RESULTS: During hospitalization, eighteen patients were treated with intravenous plus oral linezolid; twelve patients received only oral therapy. Infections treated with linezolid were: osteomyelitis (8), urinary tract (8), complicated skin structure (7), bacteremia (5), pneumonia (4), prosthetic-infected devices (3), COPD (1). The average inpatient days (median; range) on linezolid were 17 ± 20.8 (9.5; 1-95). Twelve patients were discharged on oral linezolid with the average outpatient treatment days of 15.3 ± 9.4 (12; 7-35). Documentation of infection (# of patients) was obtained from 29 subjects: vancomycin-resistant enterococcus (VRE; 14); MRSA (7); coagulase-negative *Staphylococcus* (CNS) spp. (7); *Streptococcus* spp. (6); oxacillin-resistant *S. epidermidis* (5); *Corynebacterium* spp. (4); oxacillin-sensitive *S. aureus* (2); *S. aureus* (2); oxacillin-sensitive *S. epidermidis* (1).

Three cases of VRE were non-susceptible to quinupristin/dalfopristin. Among 28 evaluable patients, three cases of thrombocytopenia were identified. The duration of linezolid therapy for patients with and without thrombocytopenia was 33 ± 30.8 days and 16.3 ± 19.8 days, respectively. None required discontinuation of therapy due to thrombocytopenia. All patients received heparin products and two received histamine-2 antagonist concomitantly with linezolid. The platelet count of one subject returned to normal, one patient was lost to follow-up, and one lung transplant patient had multiple risk factors for thrombocytopenia.

CONCLUSION: Linezolid is used for approved and non-FDA approved indications. Thrombocytopenia, may occur in patients with risk factors, including length of therapy. Results of risk factor analysis will be presented.

Nephrology

66E. Effect of itraconazole on P-glycoprotein-mediated transport of cimetidine in MDRI-MDCK cells. Chetan S. Karyekar, M.D., Natalie D. Eddington, Ph.D., Tushar Garimella, MS, Paul O. Gubbins, Pharm.D., Thomas C. Dowling, Pharm.D., Ph.D.; University of Maryland, Baltimore, MD; University of Arkansas for Medical Sciences, Little Rock, AR.

Presented at the ASN/ISN World Congress of Nephrology, San Francisco, CA, October 14, 2001.

67E. Ondansetron versus diphenhydramine versus placebo for hemodialysis-associated itching. R.A. Subach, R.S. Radabaugh, D.K. Williams, M.A. Marx; Western University of Health Sciences, Pomona, CA; University of Arkansas for Medical Sciences, Little Rock, AR.

Published in *J Am Soc Nephrol* 2001;12:348A.

68E. Effect of dialyzer reprocessing on the clearance of low and intermediate molecular weight solutes. Paul M. Palevsky, M.D., Reginald F. Frye, Pharm.D., Ph.D., Gary R. Matzke, Pharm.D.; VA Pittsburgh HCS; University of Pittsburgh, Pittsburgh, PA

Published in *J Am Soc Nephrol* 2001;12:273A.

69. Nephrology Practice and Research Network surveillance study: anemia management in dialysis patients. Joanna Q. Hudson, Pharm.D., Melanie S. Joy, Pharm.D., Mary K. Stamatakis, Pharm.D., Ted Walton, Pharm.D., Gina Miller, Pharm.D., Cindy Smith, Pharm.D.; University of Tennessee, Memphis, TN; University of North Carolina, Chapel Hill, NC; West Virginia University, Morgantown, WV; Grady Health System, Atlanta, GA; Dialysis Center of Lincoln, Lincoln, NE; Indian Health Service, Gallup, NM.

PURPOSE: Anemia affects the majority of patients with endstage renal disease (ESRD). Recommendations by the NKF Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) [*Am J Kidney Dis* 2001;37:S182] provide a basis for management. The objectives of this study were to evaluate 1) laboratory indicators of anemia management and 2) patterns of use of medications (MEDs) for treatment of anemia in a multicenter population of patients with endstage renal disease (ESRD).

METHODS: Prescribed MEDs, medical history, demographics, and laboratory data were determined via chart review and patient interviews for hemodialysis (HD) and peritoneal dialysis (PD) patients in the Nephrology Drug Surveillance Network (NDSN) database. Data were compared to NKF-K/DOQI recommendations for target Hgb/Hct and iron status (transferrin saturation and ferritin). Data from patients with suboptimal hemoglobins (<10 g/dl) were evaluated compared to patients with Hgb ≥ 10 g/dl to identify factors that may contribute to development of anemia.

RESULTS: Records for 299 patients (277 HD) were reviewed from 9 dialysis centers. Demographics - ethnicity: 62% African-American, 25% Caucasian; gender: 54% male; mean age: 57.7 ± 15.0 years; primary cause of ESRD: HTN 36%, diabetes mellitus 35%. The mean anemia parameters for all patients with laboratory data (n=294) were Hgb 11.3 ± 1.9 g/dl, Hct $35.5 \pm 5.7\%$, transferrin saturation $28.4 \pm 12.6\%$, ferritin 541 ± 404 ng/ml.

Parameter	Hgb ≥ 10 g/dl (n=246, 84%)	Hgb <10 g/dl (n=48, 16%)	NKF-K/DOQI Guidelines
Hgb (g/dl)	$11.9 \pm 1.4^{***}$	8.5 ± 1.2	10-12
Hct (%)	$37.2 \pm 4.3^{***}$	26.9 ± 4.2	33-36
Transferrin saturation (%)	28.6 ± 12.3^{NS}	27.2 ± 14.3	20-50
Ferritin (ng/ml)	$507.4 \pm 298.0^{**}$	720.6 ± 712.6	100-800
Erythropoietin alfa (% pts)	85.0	83.3	—
Route of administration	IV (n=164) SC (n=44)	IV (n=34) SC (n=6)	SC Preferred
Dose (units/wk)	IV: $13,695 \pm 9,833^*$ SC: $9,761 \pm 768^*$	IV: $19,571 \pm 14,629$ SC: $19,583 \pm 5,771$	—
Iron Supplementation (% pts)	59.8	75.0	—
Iron route of administration	IV (n=125) PO (n=22)	IV (n=26) PO (n=10)	IV Preferred
Kt/V	$1.59 \pm 0.40^*$	1.45 ± 0.52	1.2
IPTH (pg/ml)	403.0 ± 476.5^{NS}	370.8 ± 423.0	—
Years of dialysis	4.20 ± 4.75^{NS}	3.83 ± 4.61	—

*p<0.05, **p<0.001, ***p<0.001, NS=not statistically significant

Suboptimal Hgbs (< 10 g/dl) were reported for 16% of patients and were not associated with iron deficiency or dialysis adequacy (Kt/V). Patients in this

subgroup were prescribed significantly higher IV and SC erythropoietin alfa doses and a larger percent of patients were receiving iron supplementation when compared with the patients with target Hgbs.

CONCLUSIONS: Overall anemia management was consistent with guidelines established by NKF-K/DOQI for the majority of patients surveyed. Despite the recommendation for SC erythropoietin administration, most patients continue to receive erythropoietin intravenously. Identification of causes of resistance and implementation of strategies for more efficient use of erythropoietin are warranted in ESRD patients with suboptimal Hgbs.

70E. Induction of apoptosis by intracellular acidification. Alan H. Lau, Pharm.D., Yi Yong Qiu, B.S., Jose A. Arruda, M.D.; University of Illinois at Chicago, Chicago, IL.

Published in *J Am Soc Nephrol* 2001;12:615A.

71. Nephrology PRN surveillance study: treatment of diabetes mellitus in dialysis patients. Ted Walton, Pharm.D., BCPS, Melanie S. Joy, Pharm.D., Mary K. Stamatakis, Pharm.D., Joanna Q. Hudson, Pharm.D., Gina Miller, Pharm.D., Cindy Smith, Pharm.D.; Grady Health System, Atlanta, GA; University of North Carolina, Chapel Hill, NC; West Virginia University, Morgantown, WV; University of Tennessee, Memphis, TN; Dialysis Center of Lincoln, Lincoln, NE; Indian Health Service, Gallup, NM.

PURPOSE: Diabetes mellitus (DM) is the most common cause of endstage renal disease (ESRD) in the United States. DM is also a risk factor for higher morbidity and mortality rates in this patient population. The objective of this study was to evaluate medication use, patient demographics, medical history, and laboratory parameters of dialysis patients in the Nephrology Drug Surveillance Network (NDSN) database.

METHODS: Pharmacists collected demographic data, medical and medication histories, and laboratory data via chart review and patient interviews at 9 dialysis centers.

RESULTS: DM was listed as the primary cause of ESRD in 104 of 299 patients (35%). This is consistent with the 41% reported by the USRDS. Demographic data for patients with DM were: age 62.6 ± 22 years, 54% male, 58% African-American, 22% Caucasian and 19% Asian. The dialysis modality most commonly used in the DM group was hemodialysis (91%) followed by continuous ambulatory peritoneal dialysis (7%). The vascular access sites that were reported in DM patients were arterio-venous fistulas (36%), followed by AV-grafts (29%) and catheters (22%). Dialysis adequacy (measured by urea reduction ratio (URR) was reduced in the DM group (URR of 67.5 ± 9.9) compared to all other patients (71.7 ± 4.3). Measures of glycemic control showed that dialysis patients with DM were reasonably well controlled with an average random blood sugar of 195 ± 112 mg/dl and an average HgA_{1c} of $7.58 \pm 1.82\%$. The most commonly utilized medication regimen for DM was long-acting human insulin (72%) at an average daily dose of 36 units. Thirty percent of these patients received split dosage regimens. Regarding oral sulfonylureas, eight patients received glyburide (8.125 ± 6.4 mg/day, range 2.5-15 mg/day) despite being relatively contraindicated in renal disease. Nine patients received the shorter-acting sulfonylurea agent glipizide (average 13.25 ± 14.7 mg/day). Two patients received combination sulfonylurea/insulin therapy. HgA_{1c} was more controlled in sulfonylurea-treated patients ($6.96 \pm 1.2\%$) than in patient who received insulin therapy ($8.5 \pm 1.1\%$). Thirty-nine percent of DM patients were receiving anti-platelet therapy.

CONCLUSIONS: This surveillance study describes several disease state markers and pharmacotherapy regimens used to evaluate and treat DM. DM medication regimen selection may affect degree of disease control and provide areas for clinical pharmacy intervention.

72. Treatment of hyperphosphatemia and secondary hyperparathyroidism in patients undergoing dialysis: results from the nephrology drug surveillance network. Mary K. Stamatakis, Pharm.D., Joanna Hudson, Pharm.D., BCPS, Melanie S. Joy, Pharm.D., BCPS, Ted Walton, Pharm.D., BCPS, Gina Miller, Pharm.D., Cindy Smith, Pharm.D.; West Virginia University, Morgantown, WV; University of Tennessee, Memphis, TN; University of North Carolina, Chapel Hill, NC; Grady Health System, Atlanta, GA; Dialysis Center of Lincoln, Lincoln, NE; Indian Health Service, Gallup, NM.

PURPOSE: Hyperphosphatemia and secondary hyperparathyroidism commonly occur in patients with chronic renal failure, necessitating treatment with phosphate binders and vitamin D analogues, respectively. The purpose of this study was to characterize phosphate binder and vitamin D medication use and laboratory endpoints in dialysis patients in the Nephrology Drug Surveillance Network (NDSN) database.

METHODS: Pharmacists collected demographic and laboratory data, and medical and medication histories via chart review and patient interview at 9 dialysis centers.

RESULTS: Data from a 251 dialysis patient subset receiving treatment for hyperphosphatemia and/or secondary hyperparathyroidism were assessed. Demographics were: 97.6% HD/2.4% CAPD, age 58.2 ± 14.7 years, and gender 53% male. The mean phosphorus (P) concentration was 5.9 ± 2.1 mg/dl, calcium (Ca) concentration 9.1 ± 1.0 mg/dl, intact PTH concentration 407.0 ± 460.4 pg/ml, Ca x P product 53.6 ± 18.5 mg²/dl², and aluminum

concentration 15.8 ± 18.1 ng/ml. Evaluation of phosphate binder usage indicates that 82.9% of patients received a Ca-containing phosphate binder (53.0% Ca carbonate, 29.9% Ca acetate), while 12% received sevelamer and 5.1% received an aluminum-containing binder. Eight percent were on more than one phosphate binder. Despite treatment with phosphate binders, 46.6% and 16.7% of patients had a serum P ≥ 6 mg/dl and 8 mg/dl, respectively. Of the 148 patients receiving vitamin D therapy for the treatment of secondary hyperparathyroidism, 67% received IV calcitriol, 29.5% received IV paricalcitol, and 3.4% received oral calcitriol. The percentage of patients from this cohort with iPTH concentrations greater than 200 and 300 pg/ml was 62.6 and 46.5%, respectively. The percentage of patients with a serum Ca concentration > 10.5 mg/dl and 11 mg/dl was 10.4% and 3.6%, respectively. CONCLUSIONS: Despite recommendations for more aggressive control of phosphorus and PTH concentrations to prevent or limit bone and cardiovascular complications, patients continue to remain above the accepted target ranges.

73. Description of the Nephrology PRN drug surveillance network program. *Melanie S. Joy, Pharm.D., Joanna Q. Hudson, Pharm.D., Mary K. Stamatakis, Pharm.D., Ted Walton, Pharm.D., Gina Miller, Pharm.D., Cindy Smith, Pharm.D.;* University of North Carolina, Chapel Hill, NC; University of Tennessee, Memphis, TN; West Virginia University, Morgantown, WV; Grady Health System, Atlanta, GA; Dialysis Center of Lincoln, Lincoln, NE; Indian Health Service, Gallup, NM.

PURPOSE: Renal disease comprises a variety of distinct diseases ranging from complications of other processes (e.g. diabetes, hypertension) to immune mediated glomerulonephritis. Renal diseases often affect other organ systems resulting in the use of multiple medications to manage primary and secondary complications. Consequently, these patients are at risk for several drug-related complications. The Nephrology Drug Surveillance Network (NDSN) was formed by the research committee of the nephrology practice and research network and was open to all of its members. The premise of this network was to evaluate defined nephrologic diseases (and/or their complications) and their respective medication usage. The purpose of the first project was to describe pharmacologic treatment approaches across a dialysis patient cohort.

METHODS: Six distinct geographical sites at 9 dialysis centers participated in this project. Pharmacists collected demographic and laboratory data, and medical and medication histories via chart review and patient interviews. Investigators at each site recorded their blinded patient data on a data collection form and sent these to the data management site. The information contained on the forms was then entered into an Access® database and was verified by a second individual.

RESULTS: Data from a total of 299 patients were collected. Patient demographic results were: age 57.7 ± 15 years, 54% male, ethnicity AA (62%)/Caucasian (25%)/Hispanic (2.3%)/other (10.7%), 95% HD, BMI 25.3 ± 6 , predialysis SBP/DBP $156.0 \pm 37 / 81.6 \pm 17$ mm Hg, and postdialysis SBP/DBP $140.4 \pm 28 / 73.8 \pm 16$ mm Hg. Causes of ESRD were hypertension 36%, diabetes 35%, chronic GN 7%, unknown 6%, and other 16%. Patients were taking an average of 9.4 medications (range 2 to 21). Several topics from this project's dataset including cardiovascular disease, renal osteodystrophy, anemia and diabetes mellitus management were further analyzed for assessment of pharmacologic treatment approaches and are described elsewhere.

CONCLUSIONS: The medication management of the renal disease population has not been adequately assessed and described outside of controlled clinical trials. The NDSN provides a research opportunity for pharmacists to become involved in evaluating drug therapies in patients with renal diseases.

74. Nephrology PRN surveillance study: cardiovascular disease and treatment in dialysis patients. *Melanie S. Joy, Pharm.D., Joanna Q. Hudson, Pharm.D., Ted Walton, Pharm.D., Mary K. Stamatakis, Pharm.D., Gina Miller, Pharm.D., Cindy Smith, Pharm.D.;* University of North Carolina, Chapel Hill, NC; University of Tennessee, Memphis, TN; Grady Health System, Atlanta, GA; West Virginia University, Morgantown, WV; Dialysis Center of Lincoln, Lincoln, NE; Indian Health Service, Gallup, NM.

PURPOSE: Cardiovascular disease (CVD) is 4-10x more frequent in dialysis patients versus normal patient controls. The purpose was to evaluate blinded data from dialysis patients from the Nephrology Drug Surveillance Network database in order to appropriately describe treatment approaches in the CVD diagnosis subset.

METHODS: Pharmacists collected demographic and laboratory data, and medical and medication histories via chart review and patient interview at 9 dialysis centers.

RESULTS: CVD was noted in 76% of 299 patients. Demographic data were: age 58.9 ± 15 years, BMI 25.2 ± 6 , 52% male, 58% African-American, predialysis BP $158.9 \pm 40 / 81.8 \pm 16$ mm Hg, postdialysis BP $143.3 \pm 28 / 75.6 \pm 16$ mm Hg, 77% HD and predominant causes of ESRD (31% diabetes and 30% hypertension). Hypertension was present in 222 patients, with 38% maintained on single agents. Calcium channel blockers (CCBs) were the most frequently prescribed single agents followed by β -blockers (BBs) and ACE

inhibitors (ACEIs). Three or more medications were required in 28% of patients. The usage frequency of antihypertensive classes were: CCBs (60%) > BBs (41%) > α -blockers (33%) > ACEIs (31%) > vasodilators (17%) > diuretics (10%) > AT receptor blockers (5%). Systolic and diastolic BP < 140 and < 90 mm Hg after dialysis were achieved in 45% and 77% of hypertensive patients, respectively. Of the 25% that had concomitant hypertension and diabetes mellitus, 36% were treated with BBs. Twenty-two patients were treated for hyperlipidemia, while 10 patients with the diagnosis were not receiving pharmacotherapy. HMG CoA reductase inhibitors were the predominantly prescribed hyperlipidemia therapy. The mean lipid concentrations in the dataset were: cholesterol 157.9 ± 45 , triglycerides 171.5 ± 137 , HDL 42.5 ± 42 , and LDL 84.4 ± 36 mg/dl. Out of 94 patients with CHF, LVH, cardiomyopathy or edema, 83 were treated with furosemide or digoxin. Ischemic coronary disease (ICD) was present in 93 patients: 53% female, age 61.1 ± 15 years, 53% African-American, and hemoglobin 12.4 ± 13 g/dl. Aspirin and nitroglycerin were prescribed in 75% and 39% patients, respectively, for an indication of ICD. Patients prescribed nitroglycerin had lower mean hemoglobins (11.4 ± 3 g/dl). CCBs were prescribed for ICD in 29% of patients.

CONCLUSIONS: This research described pharmacotherapy approaches for CVD in a cohort of dialysis patients. Evaluation of prescribed medications for CVD may uncover less than optimal usage patterns and provide opportunities for improved interventions and outcomes.

75. Prophylaxis versus treatment of dysfunctional hemodialysis catheters with hrombolytic therapy. *Daniel E. Hilleman, Pharm.D., Kathleen A. Packard, Pharm.D., Richard L. Wurdeman, Pharm.D.;* Creighton University, Omaha, NE.

PURPOSE: To compare the use of reteplase (RPA) administered prophylactically or as treatment of dysfunctional hemodialysis (HD) catheters.

METHODS: 57 patients with ESRD undergoing HD with dual-lumen, cuffed, tunneled HD catheters comprised the study group. In the treatment group, RPA was given at a dose of 0.5 U in each lumen of a dysfunctional catheter and allowed to dwell until the next HD session. In the prophylaxis group, RPA was given at a dose of 0.1 U in each lumen of the catheter once a week and allowed to dwell until the next HD session. Catheter patency and the frequency of catheter replacement were compared between the treatment groups over a one year follow-up. Differences in patency duration were compared using the Mann-Whitney U test while differences in the need to replace catheters was compared using the Fisher's exact test.

RESULTS: In the treatment group, 45 instances of catheter dysfunction occurred in 18 patients over 12 months. RPA restored catheter function in 38 cases (84%) allowing dialysis to be completed. Catheter replacement was required in 7 (39%) patients. Mean duration of catheter patency was 46 days. In the prophylactic group, 8 instances of HD catheter dysfunction occurred in 39 patients. Catheter function was restored in 6 of 8 (75%) cases with RPA treatment with 2 (5%) catheters requiring replacement. Mean duration of catheter patency in this group was 103 days. Patency duration and the need to replace catheters were significantly different between the two groups ($p < 0.01$). Cost of treatment (cost of RPA plus cost of catheter replacement) was \$1280 per patient per year in the treatment group compared to \$1290 per patient per year in the prophylaxis group ($p > 0.05$).

CONCLUSION: Prophylactic administration of RPA reduces episodes of catheter dysfunction, increases the duration of catheter patency, and reduces the need for catheter replacement compared with RPA treatment of dysfunctional catheters with no increase in cost.

Neurology

76. Crossover comparison of Aggrenox® with its generic components. *Daniel E. Hilleman, Pharm.D., Kathleen A. Packard, Pharm.D., Thomas L. Lenz, Pharm.D.;* Creighton University Cardiac Center, Omaha, NE.

PURPOSE: Aggrenox® is a fixed-dose combination of immediate-release aspirin (ASA) 25 mg and extended-release (ER) dipyridamole (DIP) 200 mg given twice daily for the secondary prevention of stroke. The object of the present study was evaluation of the short-term side effect profile of patients switched from Aggrenox to generic ASA and immediate-release (IR) DIP.

METHODS: 33 patients (16 men/17 women; mean age 68 ± 12 years) with prior TIA/stroke had been receiving Aggrenox BID for a mean of 3.7 ± 4.0 months. All patients were switched to generic ASA 81 mg QD (n=25) or generic ASA 325 mg QD (n=8) plus IR-DIP 100 mg QID (all patients). Patients were queried concerning side effects prior to the switch and at weekly intervals for one month after the switch. Differences in the frequency of side effects between the treatment periods was assessed by the chi square statistic.

RESULTS: The incidence of side effects is summarized in the table.

Side Effect	Aggrenox	ASA QD/DIP 100 mg QID
Headache	18% (n=6)	45% (n=15)*
Dizziness	15% (n=5)	42% (n=14)*
Abd Pain	15% (n=5)	36% (n=12)*
Dyspepsia	18% (n=6)	39% (n=13)*
Nausea	6% (n=2)	18% (n=6)*

Vomiting	6% (n=2)	15% (n=5)*
Diarrhea	3% (n=1)	9% (n=3)
Angina	0% (n=0)	3% (n=1)
Total # of patients reporting one or more side effects	13 (39%)	24 (73%)*
Number of patients discontinuing therapy	—	14 (42%)

*p<0.05

CONCLUSION: Generic substitution of the individual components of Aggrenox is associated with an unacceptably high rate of side effects. Generic substitution of ASA and IR-DIP for Aggrenox is not recommended.

77E. Secondary stroke prevention gap. Susan C. Fagan, Pharm.D., C. Ron Cantrell, B.S., Bradley C. Martin, Pharm.D., Ph.D., David C. Hess, M.D.; Medical College of Georgia, Augusta, GA.

Presented at the First CDC National Prevention Conference, Atlanta, GA, August 22, 2001.

78. The safety and efficacy of intravenous valproate in the treatment of seizures in pediatric patients. B. Patrick Coots, Pharm.D., Kathryn A. O'Hara, R.N., Maria M. Ibrahim, Pharm.D., Jay T. Graham, Pharm.D., Lawrence D. Morton, M.D., William R. Garnett, Pharm.D.; Virginia Commonwealth University, Richmond, VA.

PURPOSE: The purpose of this study was to review the safety, efficacy, and use of intravenous valproate in pediatric patients in a university hospital.

METHODS: Pharmacy records were reviewed to identify pediatric patients who received IV VPA from 1/1998 through 3/2001. Dosage by weight, underlying medical condition, demographics, obtained serum levels, vitals, potential adverse effects, and current medications were recorded. Also, in a pilot study, ten patients received IV VPA via rapid infusion. Patients were monitored throughout the infusion, 30 minutes post-infusion, and 24 hours post-infusion for AEs.

RESULTS: 34 patients with a total of 50 admissions were identified who received IV VPA by standard infusion. The patients received 497 doses of VPA as loading and maintenance doses. On 28 admissions IV VPA was used to acutely treat intermittent seizure activity. It was noted to be effective in all but one case. No AEs were attributed to, or warranted discontinuation of IV VPA. In the rapid infusion study, ten patients from 2.5 to 16.25 years of age received 38 total doses of IV VPA, given in doses ranging from 7.5 mg/kg/dose to 42 mg/kg/dose with a mean of 23.4 mg/kg/dose, infused at a rate of 1.5 mg/kg/min to 11 mg/kg/min with a mean of 6 mg/kg/min. Vitals remained stable throughout the study. No site complications were noted throughout the study.

CONCLUSIONS: IV VPA is well tolerated in pediatric patients across a wide range of dosages and infusion rates. IV VPA is efficacious in treating seizures.

Oncology

79. Randomized, active-controlled, phase 1/2, dose-finding study of darbepoetin alfa administered weekly or every 2 weeks in patients with solid tumors. Dora Liang, Pharm.D., John Glaspy, M.D., Joan O'Byrne, MS, Susan Armstrong; University of California, Los Angeles, CA; Amgen Inc, Thousand Oaks, CA.

PURPOSE: Darbepoetin alfa (Aranesp®) has a longer serum half-life than recombinant human erythropoietin (rHuEPO), allowing less frequent administration. This 2-part study assessed the safety and dose-response relationship of darbepoetin alfa administered every 1 (QW) or 2 weeks (Q2W).

METHODS: Anemic patients (hemoglobin \leq 11.0 g/dl) with solid tumors receiving chemotherapy participated. In Part A, patients were randomized to rHuEPO (150 IU 3 times weekly [TIW]) or darbepoetin alfa (0.5, 1.0, 1.5, 2.25, 4.5, 6.0, 8.0 μ g/kg/ QW). In Part B, randomization was to rHuEPO (40,000 U/wk) or darbepoetin alfa (3.0, 5.0, 7.0, or 9.0 μ g/kg/Q2W). The Kaplan-Meier proportion of patients with a response (hemoglobin \geq 12.0 g/dl or \geq 2.0 g/dl increase from baseline) and the time to a \geq 2 g/dl increase (among other parameters) were calculated.

RESULTS: Higher doses of darbepoetin alfa generally resulted in higher response rates and achieved faster increases in hemoglobin than lower doses and than rHuEPO (e.g., the median time \geq 2.0 g/dl increase from baseline was 7 weeks for darbepoetin alfa 4.5 μ g/kg QW and 10 weeks for darbepoetin alfa 2.25 μ g/kg QW and rHuEPO 150 IU TIW). Similar cumulative weekly doses of darbepoetin alfa administered QW and Q2W resulted in similar response rates (e.g., response rates (95% CI) for 2.25 μ g/kg QW and 5.0 μ g/kg Q2W were 66% (53, 79) and 84% (67, 100).

CONCLUSION: The data suggest that when used QW or Q2W the rapidity of response increases at doses of darbepoetin alfa increase. Darbepoetin alfa Q2W appeared to be as effective as darbepoetin alfa QW.

Pharmacoeconomics

80. Outcome and cost analysis of predominantly African-American kidney transplant patients switched from cyclosporine to tacrolimus. Tracie J. Sannicandro, Pharm.D., Lynn A. Uber, BS, Pharm.D., Fuad Afzal, M.D., Evyonne M. Thurman, R.N., MSN, Prabhakar Baliga, M.D., Milos Budisavljevic, M.D.; Medical University of South Carolina, Charleston, SC.

PURPOSE: Cyclosporine and tacrolimus have many effects in common, however, some studies have shown racial differences in graft survival and side effect profiles. We prospectively evaluated the outcomes and costs associated with renal function, diabetes, hyperlipidemia, and hypertension (HTN) in a predominant African-American population switched from cyclosporine to tacrolimus.

METHODS: We evaluated all patients who switched from cyclosporine to tacrolimus over a 2-year period. Outcome variables analyzed were (percent change from baseline) at 1, 3, 6, and 12 months after switching therapy; creatinine, SBP, DBP, lipids, glucose, and doses and costs of the medications.

RESULTS: A total of 24 patients were evaluable, of which 83% were African-American. The percent change in creatinine from baseline at 1, 3, 6, and 12 months were; (-18.6, -29.2, -30.0, and -29.4), respectively. Both SBP and DBP improved; SBP (-2.4, -5.4, -7.2, -7.5) and DBP (0.2, -7.7, -1.2, -2.9). Lipids also improved; HDL (10.4, 0.8, 19.8, 22.1) and LDL (-7.9, -3.6, 3.1, -3.4). Glucose improved at 1 and 12 months; (-3.3, 18.8, 7.1,

-18.2). An increase in medications was observed for the following; 25% HTN, 4% hyperlipidemia, 8.3% diabetes. A medication decrease; 12.5% HTN, 4% hyperlipidemia. There was an average 20% increase in the total cost of medications after the switch, which was attributed to the higher cost of tacrolimus.

CONCLUSIONS: Tacrolimus appears to be a safe and effective alternative immunosuppressant even in the African-American population. The improvement in renal function observed with tacrolimus may outweigh the increase in cost of this therapy.

81. Pharmacoeconomic analysis of lipid formulations of amphotericin B for the treatment of febrile neutropenia. Daniel M. Hartung, Pharm.D., Daniel R. Touchette, Pharm.D., MA, Ali J. Olyaei, Pharm.D.; Oregon Health and Science University; Oregon State University, Portland, OR.

PURPOSE: Amphotericin-induced nephrotoxicity is associated with considerable morbidity, mortality, and cost. Several lipid formulations have been developed in attempts to attenuate this toxicity. There is mounting evidence suggesting toxicities differ among these newer agents. The purpose of this analysis was to assess the cost-effectiveness of conventional amphotericin (Camph), amphotericin B lipid complex (ABLC), and liposomal amphotericin (Lamph) for empiric treatment of patients with neutropenic fever.

METHODS: A simple economic decision model was developed from the healthcare system perspective. The probability of treatment-induced nephrotoxicity and its cost were obtained from controlled clinical trials. Drug costs were estimated using average wholesale price. One way and multivariate sensitivity analysis was employed to evaluate variability in the model.

RESULTS: In clinical trials versus Camph, ABLC and Lamph reduced the risk for nephrotoxicity by 40% and 45%, respectively. However, toxicity estimates of ABLC are conflicting and highly variable. In the reference case, average treatment costs with Camph, ABLC, and Lamph were \$12,221, \$20,951, and \$15,824, respectively. The incremental cost per nephrotoxic event avoided using Lamph was \$24,017. Lamph became cost savings when the expected probability of nephrotoxicity from Camph exceeded 44%. Assuming ABLC reduced the risk of nephrotoxicity by 40% compared to Camph, the cost per nephrotoxic event avoided was \$33,071. Average treatment costs for ABLC were insensitive to changes in the rate and costs of nephrotoxicity.

CONCLUSION: Lamph is likely cost-effective and approaches cost savings in patients at high risk for nephrotoxicity. Even at extremes in its variability, ABLC is less cost-effective than Lamph.

82E. Symptom relief and work productivity: moxifloxacin compared to levofloxacin and amoxicillin clavulanate in the treatment of acute bacterial sinusitis. J. Behm, G. Corcoran, C. Pause, D. Church; Genesis Medical Associates, Inc., Pittsburgh, PA; Bayer Corporation, West Haven, CT.

Presented at the 14th Annual Meeting and Showcase of the Academy of Managed Care Pharmacy, Salt Lake City, UT, April 3-6, 2002.

83. Factors affecting growth in prescription drug costs: a PBM perspective. Teresa Nie, MBA, Michele Rath, BS, Hitesh Patel, R.Ph., MM, Kenneth E. Johnson, Pharm.D.; Caremark Rx Inc., Northbrook, IL.

PURPOSE: To identify and measure key factors affecting the growth in PBM-managed pharmacy costs.

METHODS: Literature was reviewed to identify those factors that are most commonly cited as contributing to increases in pharmacy costs. Data from Caremark's pharmacy benefit database was then analyzed to estimate the absolute and relative impact of each of these factors on pharmacy costs in 2000. The Caremark database includes over 1,250 employers and approximately 22 million covered lives. All analyses were conducted on a per-member basis.

RESULTS: Factors commonly identified as contributing to the growth in pharmacy costs include: 1) Drug price inflation (i.e., changes in average wholesale drug prices and PBM-negotiated discounts); 2) introduction of new drugs in 2000; 3) changes in the mix of drugs used (i.e. generics, brands with generic alternatives, and brands without generic alternatives); and 4) changes in the drug utilization (i.e., changes in number of persons on prescription medications). Results of analysis are:

Factor	Absolute Impact	Relative Impact
All	16.80%	100%
Price inflation	3.20%	19%
New drugs	0.70%	4%
Drug mix	7.10%	42%
Utilization	5.80%	35%

CONCLUSIONS: Changes in drug mix of new and existing drugs was the main driver behind the increase in pharmacy costs during 2000, followed by changes in utilization and price inflation. New drugs made the smallest contribution to the overall growth in pharmacy costs. The analysis will be repeated for 2001 when data are available.

84. Quality of life assessment in patients with uncontrolled type 2 diabetes. Madeline Betancourt, Pharm.D., Richard R. Slaughter, M.S., Sandra N. Nowak, Pharm.D., David Bach, Pharm.D., MPH, Linda A. Jaber, Pharm.D.; Wayne State University, Detroit, MI.

BACKGROUND: Diabetes mellitus is a chronic metabolic disease with wide implications for patient well-being. Mixed results have been obtained from QOL studies.

OBJECTIVE: To determine the impact on QOL resulting from the addition of metformin therapy to obese, insulin-dependent patients with uncontrolled type 2 diabetes.

METHODS: Sixteen subjects were evaluated in a prospective, open-label, cross-over study comparing insulin monotherapy to insulin-metformin combination. Patients were administered two QOL instruments, SF-36 and Diabetes Form 2.1 before and at the end of the intervention period. (Clinical data in press. J Clin Pharmacol, 2002)

RESULTS: Overall, positive responses were observed with insulin requirements and glycated hemoglobin significantly decreasing from baseline. The most common adverse events reported were diarrhea and hypoglycemia; none warranted treatment discontinuation. SF-36 results showed no statistical difference between the eight domains tested. Diabetes Form 2.1 showed a worsening in 6 of 7 domains (pre-post values, respectively); cardiovascular (93%-5%), leg discomfort (69%-18%), urinary frequency (64%-31%), vision difficulty (97%-2%), general symptoms (82%-22%), and hypoglycemic symptoms (79%-24%).

CONCLUSION: Despite decreasing insulin requirements and improving glycemic control, QOL indicators worsened. Discordant results may be due to confounding variables rather than a treatment effect. These confounding variables include: introduction of recall bias may have affected the study's internal validity, study participation may have triggered a more keen awareness of disease characteristics being tested, and study requirement of increased clinic visits may have negatively impacted disease perception. We recommend that future QOL studies should consider standardizing familiarity with disease characteristics and with the instruments used before assessing patients' perceptions.

85. Assessing the health status of patients receiving epidural steroid injections for chronic back pain. Marianna Cafarelli, Pharm.D., Robert Silverman, M.D.; The Valley Hospital, Ridgewood, NJ.

PURPOSE: Epidural Steroid Injections (ESI) are often performed as regional analgesia for patients with chronic back pain, yet limited data exist about the health status (HS) of these patients. We sought to determine if ESI improves the HS of patients with chronic back pain.

METHODS: Patients ≥ 18 years old with back pain lasting ≥ 6 months were included. Prior to the procedure, patients self-administered the Short Form 36-Item Health Survey (SF-36), a pain visual analogue scale (VAS), and listed past and current pain medications. Each participant received up to 3 epidurals of 80 mg of Depo-Medrol® within a 6-month period with a minimum of 2 weeks between ESI. The SF-36 was administered at subsequent treatment visits or was mailed to those not returning to clinic.

RESULTS: 47 patients were enrolled in the study (64% women, 36% men), mean age 64 years. 22 follow-up SF-36s were obtained, with a mean follow up of 26 (± 7) days.

SF-36 Scale	Baseline (Std. Error)	Follow-up (Std. Error)	p values
Physical Function	41.36 (5.84)	47.27 (6.11)	0.4889
Role-Physical	21.59 (6.84)	34.09 (8.14)	0.2467
Bodily Pain	34.29 (3.64)	50.27 (3.11)	0.0018
General Health	58.81 (4.77)	64.00 (3.95)	0.4081
Vitality	49.54 (4.19)	57.50 (3.95)	0.1754
Social Functioning	60.43 (5.56)	71.27 (4.94)	0.1530
Role-Emotional	57.59 (9.61)	69.63 (8.48)	0.3529
Mental Health	66.72 (4.43)	72.72 (4.12)	0.3277

Statistically significant (p=0.02) improvement in VAS also occurred.

CONCLUSION: ESI significantly improved patients' SF-36 Bodily Pain scores and VAS. A follow up study is needed to determine if these improvements are maintained.

Pharmacoepidemiology

86. Is socioeconomic status associated with beta-blocker use after myocardial infarction? Amanda G. Kennedy, Pharm.D., Richard G. Pinckney, M.D., Benjamin Littenberg, M.D.; University of Vermont, Burlington, VT.

PURPOSE: It is unknown why patients fail to receive β-blockers after myocardial infarction (MI). We wished to evaluate if socioeconomic status (SES) is associated with β-blocker use after MI.

METHODS: Adults age 40 and over in the third National Health and Nutrition Examination Survey (NHANES III, 1988-1994), with history of MI, and without CHF, COPD, or asthma were eligible. Education and annual household income were used as markers of SES. Age, angina, body-mass index (BMI), cholesterol, diabetes, family history of MI, hypertension, insurance status, race, sex, and smoking were included in the univariate analysis. Covariates with p<0.2 were included in the multivariate logistic regression model.

RESULTS: 417 adults were eligible. β-blockers were used in 26% of our sample. The rates of β-blocker use after MI by income were: \$50,000 or greater (40%), \$30,000-\$49,999 (29%), \$10,000-\$29,999 (25%), < \$10,000 (20%). In the univariate logistic model, income was associated with β-blocker use after MI (OR 1.37, p=0.01), but education was not (OR 1.01, p=0.94). In the multivariate model controlling for age, BMI, smoking, and race, income was associated with β-blocker use (OR 1.42, p=0.01), but education was not (OR 1.01, p=0.92).

CONCLUSIONS: Income as a marker of SES was associated with β-blocker use after MI. In spite of proven efficacy and low cost, β-blockers are underutilized, especially by the poor.

Pharmacogenomics

87. Stability of polycation-based non-viral gene delivery system in the presence of blood components. Brent J.L. Nightingale, Tatiana Bronich, Ph.D., Catherine Gebhart, Ph.D., Serguei Vinogradov, Ph.D., Alexander Kabanov, Ph.D.; University of Nebraska Medical Center, Omaha, NE.

PURPOSE: Polyplexes, complexes of DNA and polycations, are a relatively new class of non-viral delivery systems, which form spontaneously as a result of electrostatic interactions between polycation and DNA. The stability of these polyplexes in simple buffer has been well studied, however, questions exist regarding stability in the presence of biological components. Heparin is one such component that may be capable of destroying polyplexes in vivo. The goal of this project was to evaluate the stability of a multi-component polyplex system, P123:P123-g-PEI, in the presence of increasing concentrations of heparin in order to evaluate its stability both in the presence and absence of one of the components, non-modified Pluronic® P123.

METHODS: The P123-g-PEI copolymer was synthesized at the University of Nebraska by conjugation of PEI (2K) with Pluronic P123. Polyplexes were prepared at a nitrogen to phosphate ratio of 10:1. The samples were allowed to stabilize for 1 hour and were then incubated in various concentrations of heparin for 1 hr. Samples were electrophoresed through a 0.8% agarose gel, stained with ethidium bromide and then DNA was visualized by UV illumination.

RESULTS: Polyplexes formed without non-modified Pluronic P123 were completely disrupted between 7-8 heparin equivalents. When polyplexes were formed with non-modified P123 (0.03%), complete dissociation of the DNA/polycation complexes occurred between 8-9 heparin equivalents.

CONCLUSION: The inclusion of non-modified Pluronic P123 in the polyplex does not diminish stability of the polyplex in the presence of heparin. Therefore P123:P123-g-PEI polyplexes, which display improved transfection in vitro compared to P123-g-PEI polyplexes, will also likely display improved resistance to Heparin destruction in vivo. The results of these studies will be combined with studies of other polyplex systems in order to further improve the in vivo effectiveness of polyplex based gene delivery systems.

88E. Polymorphisms of CYP2D6 as a risk factor for weight gain with olanzapine. Vicki L. Ellingrod, Pharm.D., BCPP, Del Miller, Pharm.D., M.D., Susan K. Schultz, M.D., Stephan Arndt, Ph.D., Heidi Wehring, Pharm.D.; University of Iowa, Iowa City, IA.

Published in Schizophr Res 2001;49:283-4.

89. 5HT2A receptor promoter polymorphism -1438G/A and negative symptom response to olanzapine in schizophrenia. Vicki L. Ellingrod, Pharm.D., BCPP, Paul J. Perry, Ph.D., BCPP, Kristy Bever-Stille, Pharm.D., BCPP, Brian J. Lund, Pharm.D., Frank Fleming, BSN, Timothy L. Holman, MA, Del Miller, Pharm.D., M.D.; University of Iowa, Iowa City, IA.

BACKGROUND: The 5HT_{2A} receptor 102T/C polymorphism may be related to olanzapine negative symptom response. Since, this polymorphism does not result in any amino acid changes within the 5HT_{2A} receptor, any associations with olanzapine response may be due to the 5HT_{2A} receptor promoter polymorphism -1438G/A, since this polymorphism may be in complete linkage disequilibrium with the 102T/C polymorphism.

PURPOSE: To determine the relationship between the -1438G/A polymorphism and olanzapine negative symptom response.

METHODS: DNA from 41 subjects with schizophrenia (DSM-IV) was analyzed for the -1438G/A polymorphism of the 5HT_{2A} receptor promoter region and 5 other polymorphisms of the 5HT_{2A} receptor. Weekly assessments included the Scale for Assessment of Negative Symptoms (SANS). Olanzapine dosage ranged from 7.5-20 mg/day for 2 to 6 weeks.

RESULTS: A general linear regression used percent change in SANS score as the dependent variable. Independent variables included 5HT_{2A} receptor polymorphisms and interactions. The -1438 G/A polymorphism was significantly associated with percent change in SANS score ($p=0.05$). The mean SANS score reduction in subjects with an A/A genotype was 45% compared to 19%, in the other groups.

CONCLUSION: Thus, the previous association between negative symptom response to olanzapine and the 102T/C polymorphism may actually be due to the -1438G/A polymorphism of the promoter region. The -1438 A/A genotype may be related to olanzapine negative symptom response, which may be clinically important.

Pharmacokinetics/Pharmacodynamics/ Pharmacometrics/Drug Metabolism

90. Influence of vardenafil on blood pressure and pharmacokinetics in hypertensive patients on nifedipine therapy. *Gabriele Rohde, Ph.D., P.J. Jordan; Bayer AG, Wuppertal, Germany; MDFARMOVS-PAREXEL Clinical Research Organisation, Brandhof, South Africa.*

PURPOSE: Men with erectile dysfunction (ED) often have hypertension as a comorbidity. This study examined the influence of vardenafil, a selective PDE5 inhibitor being evaluated for treating ED, on BP and heart rate and nifedipine pharmacokinetics in hypertensive males receiving nifedipine.

METHODS: In this double-blind, two-fold crossover study, 22 men with essential hypertension (27-65 years) who received 30 or 60 mg/day nifedipine (Adalat-XL) were randomized to single dose vardenafil 20 mg or placebo, repeated after ≥ 7 days. Supine and standing BP were measured for up to four hours after dosing. The a priori definition of no BP effect of vardenafil (over that seen without nifedipine, in the order of 5-6 mm Hg) was the 90% CE for maximal Δ BP from baseline (varidenafil-placebo) to not surpass 12 mm Hg. Nifedipine plasma levels were determined in the 24-hour period after vardenafil or placebo.

RESULTS: Vardenafil 20 mg caused maximal decreases in Δ diastolic BP of 5.2 (CI 7.7 to 2.7) mm Hg (supine) and 2.7 (CI 5.4 to 0.1) mm Hg (standing); the maximal decreases in Δ systolic BP were 5.9 (CI 8.8 to 3.0) mm Hg (supine) and 5.1 (CI 8.0 to 2.2) mm Hg (standing). Confidence intervals for Δ BP did not surpass 12 mm Hg, thus indicating that vardenafil co-administration with nifedipine did not alter BP synergistically. The maximal compensatory HR was +3.7 bpm in both positions. Nifedipine pharmacokinetics were unchanged with vardenafil to placebo geometric mean ratios of 93.7% for AUC₀₋₂₄ and C_{max} (90% CI, 78% to 112%). No serious adverse events were reported. Adverse events were predominantly mild and had similar incidences between treatment groups.

CONCLUSION: In hypertensive males, single-dose vardenafil 20 mg produced no clinically significant alteration of the hemodynamic effects or bioavailability of nifedipine.

91. The interaction of alcohol with vardenafil, a potent and highly selective phosphodiesterase type 5 inhibitor. *Richard-Josef Bauer, M.D., Gabriele Rohde, M.D., George Wensing, M.D.; Bayer AG, Wuppertal, Germany.*

PURPOSE: Vardenafil, a potent and selective PDE5 inhibitor under investigation for treatment of erectile dysfunction, is often likely to be taken in conjunction with alcohol. The purpose was to determine the pharmacokinetics and safety of vardenafil when taken concomitantly with ethanol.

METHODS: In this randomized, double-blind, placebo-controlled, 3-fold crossover study, 12 healthy male subjects, ages 18 to 45, received a single oral dose of 20 mg vardenafil or placebo concomitantly with alcohol (0.5 g/kg with 200 ml of orange juice) or an ethanol placebo. Hemodynamic and pharmacokinetic interactions were evaluated and safety parameters monitored.

RESULTS: Ethanol had no influence on systemic exposure of vardenafil (see table). C_{max} was slightly increased, although not significantly, with alcohol consumption. In addition, ethanol did not influence the terminal elimination t_{1/2} and T_{max} of vardenafil.

	Vardenafil w/o ethanol	Vardenafil + ethanol	Ratio ^b of treatments* 100% (90% confidence interval)
AUC ^a $\mu\text{g}^*\text{h/l}$	45.5 (2.0)	45.3 (1.9)	99.7% (85.0%-116.9%)
C _{max} ^a $\mu\text{g/l}$	11.7 (2.3)	12.6 (2.2)	107.8% (80.0%-145.3%)

^ageometric mean (geometric SD), ^bvardenafil + ethanol divided by vardenafil alone

Vardenafil (var) and ethanol (eth) administered concomitantly were generally well tolerated. The most frequently reported adverse events were vasodilatation and rhinitis. Difference of maximum diastolic BP changes between treatment groups were -3.8 mm Hg for ((var +eth) minus (eth)) and -4.1 mm Hg for ((var + eth) minus (var)). Maximal changes in HR of 23 bpm with (var + eth) and 20 bpm with (eth) were considered primarily due to the effect of ethanol.

CONCLUSION: The pharmacokinetics and hemodynamic profile of vardenafil were not affected if vardenafil was taken together with 0.5 g/kg ethanol.

92. Effect of renal impairment on the single-dose pharmacokinetics of vardenafil 20 mg, a selective PDE5 inhibitor, for the treatment of erectile dysfunction. *Theodor Klotz, M.D., Richard-Joseph Bauer, M.D., Gabriele Rohde, Ph.D.; University of Cologne, Cologne, Germany; Bayer AG, Wuppertal, Germany.*

PURPOSE: Renal impairment occurs in a number of conditions associated with erectile dysfunction (ED), including age, diabetes, hypertension, and cardiovascular disease. Vardenafil, a selective PDE5 inhibitor is under development for the treatment of ED. Although primarily excreted via the feces, it was important to evaluate the effects of renal impairment on the pharmacokinetics of vardenafil.

METHODS: In this non-randomized, single-dose study, vardenafil 20 mg was administered to 32 male subjects (30-60 years) stratified by renal function (normal renal function, or mild, moderate, or severe renal impairment (8 patients/group). Pharmacokinetics and tolerability were evaluated. Differences in pharmacokinetics were determined by ANOVA.

RESULTS: Vardenafil pharmacokinetics were mildly increased (< 2-fold) in subjects with moderate and severe renal impairment relative to healthy subjects. Although renal clearance was reduced in the more severe cases of renal impairment, < 1% of administered drug appeared in the urine, consistent with biotransformation and subsequent biliary/fecal excretion being the dominant route of elimination for vardenafil.

	Normal	Mild	Moderate	Severe
Cl _{Cr} , ml/min	> 80	> 50-80	> 30-50	< 30
AUC ₀₋₂₄ , $\mu\text{g}\cdot\text{hr/L}^a$	96.3 (60.0)	87.9 (47.9)	106.7 (34.6)	101.4 (42.1)
C _{max} , $\mu\text{g/L}^a$	31.8 (25.4)	24.2 (9.4)	35.3 (17.4)	18.4 (7.2)
T _{1/2} , hr ^b	4.7 (1.2)	5.3 (1.9)	5.8 (1.7)	56.1 (2.2)
T _{max} , hr ^b	0.8 (0.3-1.5)	0.8 (0.8-1.5)	0.6 (0.5-3.0)	1.4 (0.5-5.0)
Renal clearance, L/h ^a	2.3 (0.8)	1.3 (0.6)	1.0 (0.2)	0.8 (0.4)
Ae _{ur(0-48)} , % ^c	1.0 (0.7)	0.5 (0.3)	0.6 (0.2)	0.4 (0.3)

^aarithmetic mean (SD), ^bmedian (range), ^camount excreted in urine, percent of administered dose mean (SD)

Vardenafil was well-tolerated. A mild headache was reported by 2 patients, one with normal and one with severe renal impairment.

CONCLUSIONS: In this study, vardenafil pharmacokinetics were largely unaffected by renal impairment, suggesting that dose alterations are not necessary in these renally impaired patients not on dialysis.

93E. Coadministration of tenofovir disoproxil fumarate and didanosine: pharmacokinetic drug-drug interaction and safety evaluations. *John F. Flaherty, Jr., Pharm.D., Brian P. Kearney, Pharm.D., John J. Wolf, MS, Steve Barriere, Pharm.D., Shan-Shan Chen, MPH, John R. Sayre, RN, Dion F. Coakley, Pharm.D.; Gilead Sciences, Foster City, CA.*

Presented at the 8th European Conference on Clinical Aspects and Treatment of HIV Infection, Athens, Greece, October 27-31, 2001.

94E. Lack of clinically relevant drug-drug interactions between tenofovir disoproxil fumarate and lamivudine, efavirenz, indinavir, and lopinavir/ritonavir in healthy subjects. *Brian P. Kearney, Pharm.D., John F. Flaherty, Jr., Pharm.D., Stan C. Gill, Ph.D., John R. Sayre, RN, John J. Wolf, MS, Dion F. Coakley, Pharm.D.; Gilead Sciences, Foster City, CA.*

Presented at the 8th European Conference on Clinical Aspects and Treatment of HIV Infection, Athens, Greece, October 27-31, 2001.

95E. The pharmacokinetics of darbepoetin alfa and changes in endogenous erythropoietin in patients with nonmyeloid malignancies receiving or not receiving chemotherapy. *Anne Heatherington, Ph.D., Johannes Schuller, M.D., Dusan Kotasek, John Glaspy, M.D., Robert Smith, M.D., Robert Rovetti, Gregory Rossi, Ph.D.; Amgen Inc, Thousand Oaks, CA; University of California at Los Angeles, Los Angeles, CA; Ashford Cancer Centre, Ashford, SA, Australia; Krankenstalt Rudolfstiftung, Vienna, Austria; South Carolina Oncology Associates, Columbia, SC.*

Presented at the 43rd Annual Meeting of the American Society of Hematology, Orlando, FL, December 7-11, 2001.

96E. The pharmacokinetics of darbepoetin alfa administered subcutaneously in patients with non-myeloid malignancies receiving multicycle chemotherapy. Anne Heatherington, Ph.D., Johannes Schuller, M.D., Andrew J. Mercer, M.D., Robert J. Rovetti, Alan B. Colowick, M.D.; Amgen Inc, Thousand Oaks, CA; Krankenstalt Rudolstiftung, Vienna, Austria.

Presented at the 43rd Annual Meeting of the American Society of Hematology, Orlando, FL, December 7-11, 2001.

98E. Influence of gonadal hormones and steroid kinetics on post-transplant osteoporosis. K.M. Tornatore, Pharm.D., R.J. Fountaine, Pharm.D., K.A. Gilliland, Pharm.D., J. Hom, M.D., K.A. Reed, R.N., R.C. Venuto, M.D.; University of Buffalo; Erie County Medical Center, Buffalo, NY.

Published in J Am Soc Nephrol 2001;12:949A (abstract A4960).

99E. The pharmacokinetics and safety of oral transmucosal fentanyl citrate administered to healthy volunteers as two 400 mcg ACTIQ[®] doses or as a single 800 mcg ACTIQ dosage unit. Talmage Egan, M.D., Steven E. Kern, Ph.D., Kiumars Q. Vadie, Ph.D., R.Ph., FCP; University of Utah, Salt Lake City, UT; Cephalon, Inc., West Chester, PA.

Presented at the 20th Annual Scientific Meeting of the American Pain Society, Phoenix, AZ, April 20, 2001.

Pharmacy Practice

100. Attitudes of ACPE constituents regarding environmental factors likely to affect pharmacy in the near future. Dawn G. Zarembski, Pharm.D., BCPS, Peter H. Vlasses, Pharm.D., BCPS; American Council on Pharmaceutical Education, Chicago, IL.

PURPOSE: In April 2000, the American Council on Pharmaceutical Education (ACPE) developed a web-based survey as part of a strategic planning initiative. One purpose of the survey was to obtain information regarding environmental factors that ACPE constituents believe will impact the pharmacy profession in the near future.

METHODS: An independent consulting firm was utilized to conduct the survey. Constituents, including 357 CE administrators, 81 deans, 18 national organizations' executive directors and 50 miscellaneous individuals were invited to complete the survey. Feedback regarding future trends in the profession was obtained from a series of questions that requested participants to assess the importance using a Likert-scale from Very Strongly Agree (1) to Very Strongly Disagree (7).

RESULTS: Over a three-week period, 838 responses from a broad array of responders were received including 43% of Deans and 68% of CE Providers accredited by ACPE. Regarding the potential impact of the listed variables on the pharmacy profession in the near future the findings were:

Variable	Agree (1-3)	Neutral (4)	Disagree (5-7)
Internet	96%	2%	2%
Technicians	91%	6%	3%
Regulatory changes	91%	7%	2%
Virtual learning	87%	9%	4%
Robots	86%	9%	5%
National health insurance	82%	11%	7%

Responders agreed with ACPE providing consultation on distance education (81%) and that ACPE should convene a conference to discuss the need for educational standards for pharmacy technicians (82%).

CONCLUSIONS: Environmental factors involving technology, regulatory changes and technician support were highly rated for their potential to impact the pharmacy profession in the near future by ACPE constituents.

101E. Validation of instrument for characterizing pharmacists' interventions. Boon Peng Lim, B.Pharm.(Hons), Shyamala Narayanaswamy, B.Sc.(Pharm), M.Sc.(Clin Pharm), Hui-Xin Lou, B.Sc.(Pharm), M.Sc.(Clin Pharm); Singapore General Hospital, Republic of Singapore.

Published in Pharmacotherapy 2001;21(10):1291.

Psychiatry

102. Efficacy of ziprasidone for agitation, aggression and self-injurious behavior and effect on body weight. Brian J. Fitzgerald, Pharm.D., Anthony J. Okos, M.D., Seth A. Cohen, M.D.; Fircrest Residential Habilitation Center; University of Washington, Seattle, WA.

PURPOSE: To determine the efficacy of ziprasidone for agitation, aggression and self-injurious behavior and its effect on body weight.

METHODS: All 26 adult developmentally disabled patients at our institution who were started on ziprasidone were included in this retrospective study.

Behavior data primarily consisted of counts for agitation, aggression and self-injury and baseline counts were collected for 12 weeks. Data were also collected during 8 weeks of active ziprasidone treatment after antipsychotic medication, usually risperidone, was switched to ziprasidone and its daily dose was increased in an open fashion to 120-160 mg. Monthly weight data were collected and the baseline value was compared with the most recent month during ziprasidone treatment. Behavior data for 6 patients were incomplete and so were excluded. Paired *t*-test was performed.

RESULTS: The mean average behavior count of the treatment group (n=20) before ziprasidone (22.10) was not statistically different (p<0.327) from the mean after ziprasidone (29.12). Behavioral counts for most patients (55%) improved or stayed the same. There was a marked reduction of mean body weight (n=26) from 170.8 pounds to 161.7 (p<0.0002). Most patients (85%) either lost weight or maintained the same after ziprasidone.

CONCLUSIONS: Ziprasidone is a very effective treatment for agitation, aggression and self-injurious behavior in this population. As an additional benefit, ziprasidone proved to markedly reduce body weight by an average of 9 pounds.

103. Elevation of carbamazepine-10, 11-epoxide by quetiapine: a novel drug-drug interaction. Brian J. Fitzgerald, Pharm.D., Anthony J. Okos, M.D.; Fircrest RHC; University of Washington, Seattle, WA.

PURPOSE: To describe the first two case reports that quetiapine elevates carbamazepine-10,11-epoxide blood level.

METHODS: A 52 year-old female with ataxia and agitation and a 56 year-old asymptomatic male were found to have markedly elevated carbamazepine-10,11-epoxide levels. Retrospective chart reviews were performed to study carbamazepine and carbamazepine-10,11-epoxide levels in relation to initiation of quetiapine and maintenance dosing of 300 mg twice daily. No other medication changes occurred. Carbamazepine-10,11-epoxide to carbamazepine ratio was calculated before and after quetiapine treatment. Documentation of neurotoxicity was collected.

RESULTS: In the first patient, the ratio increased from 0.23 (normal value 0.12) to 0.82. In the second patient, the ratio increased from 0.31 to 1.04. This corresponds to approximately a 3.5-fold elevation in each patient. Carbamazepine-10,11-epoxide levels returned to their baseline values after discontinuation of quetiapine, confirming this interaction. The first patient had ataxia and agitation while on quetiapine that resolved upon its discontinuation.

CONCLUSIONS: Quetiapine can markedly increase carbamazepine-10,11-epoxide level, resulting in neurotoxicity. It is recommended that carbamazepine-10,11-epoxide concentration be monitored if these drugs are used concurrently. Oxcarbazepine is preferred over carbamazepine when quetiapine is given concurrently because it does not lead to the epoxide active metabolite.

104E. Lack of metabolic effects of short-term divalproex sodium treatment Mahtab Jafari, Pharm.D., Alan Swann, M.D., Patricia Wozniak, Ph.D., Kenneth Sommerville, M.D., Katherine Tracy, M.D., Ph.D., Michelle Collins, Ph.D.; Abbot Laboratories, Abbott Park, IL; University of Texas, Houston, TX.

Presented at the 40th Annual Meeting of the American College of Neuropharmacology, Waikoloa, HI, December 12, 2001.

105. Evaluation of falls in non-geriatric adult psychiatric inpatients. Amy M. Vandenberg, Pharm.D., Cherry W. Jackson, Pharm.D., BCPP; Nova Southeastern University, Ft. Lauderdale, FL; Medical University of South Carolina, Charleston, SC.

PURPOSE: This study reviewed falls in adult psychiatric inpatients under the age of 65 over a 16-month period in order to determine common factors in patients who fall, identify high-risk populations and develop guidelines for treatment to reduce the incidence of falls. Risk factors that have been established in geriatric populations were included in the assessment.

METHODS: Medical records and incident reports were reviewed for all inpatients age 18 to 65 at the Medical University of South Carolina Institute of Psychiatry who had an incident report of a fall between August 1, 1998 and December 31, 1999. Patients' medical history, age, all medications administered within 24 hours of fall, hospital unit, vital signs, and course of fall were documented.

RESULTS: A total of 74 falls were evaluated. Disease states known to increase fall risk in geriatric patients were rare in this population, except for depression (43%), cardiovascular disease (22%) and incontinence (17%). Age was distributed evenly with a peak between 41 and 50 years of age. The most commonly used medications were benzodiazepines (72%), anticonvulsants (69%) and antihypertensives (40%). Patients received an average of 8 medications in the 24 hours preceding the fall.

CONCLUSION: Medications and medical conditions that are associated with increased fall risk in geriatric populations were also associated with falls in this adult inpatient population. Adult psychiatric inpatients may benefit from evaluation of fall risk on admission. High-risk patients would be those on multiple medications including benzodiazepines, anticonvulsants and antihypertensives.

Rheumatology

106. Lack of diagnosis and treatment of osteoporosis in men and women following hip fracture. *Sheryl L. Follin, Pharm.D., BCPS, Jennifer N. Black, B.S., Michael T. McDermott, M.D.; University of Colorado Health Sciences Center; Denver, CO.*

PURPOSE: To evaluate the diagnosis and treatment of osteoporosis in men and women after hip fracture.

METHODS: Inpatient records of 118 patients admitted to the University of Colorado Hospital with a low-trauma hip fracture from 1993-1998 were reviewed. Outpatient records for the first year after the hip fracture were also reviewed for 88 patients. Statistical analyses were performed using the chi-square distribution.

RESULTS: The average age of the patients was 70 years. Forty-three were men and 75 were women. Twenty-eight percent had a previous history of fracture and <20% were receiving osteoporosis therapy (calcium, vitamin D, or antiresorptive therapy). On discharge, an osteoporosis diagnosis was documented in only 14% of charts. Patients were infrequently discharged on osteoporosis therapies (calcium, 16%; vitamin D, 14%; ERT/HR, 10%; alendronate, 6%; calcitonin, 5%). Twenty-nine men and 59 women had ≥ one follow-up visit after their fracture. During follow-up, 13% of patients re-fractured. Documentation of an osteoporosis diagnosis (26%), performance of bone densitometry (8%) and use of calcium (17%), vitamin D (14%) and antiresorptive therapy (20%) was lacking. The men in this study were younger compared to the women (average age=64.3 years vs 73.2 years) and were less likely to have had a previous fracture (14% vs 36%, $p<0.05$). They were also less likely to receive a documented diagnosis of osteoporosis (7% vs 36%, $p<0.05$) or osteoporosis therapy (2% vs 37%, $p<0.05$) during the one-year follow-up.

CONCLUSION: In patients with hip fractures, especially men, documentation of the diagnosis and treatment of osteoporosis is lacking.

107. Comparison of electronic versus survey assessment of a patient's risk for NSAID-induced GI hospitalization. *Michele Spence, Ph.D., T. Craig Cheetham, Pharm.D., M.S., Stephanie Teleki, MPH; Kaiser Permanente Drug Information Service, Downey, CA; University of California at Los Angeles, Los Angeles, CA.*

PURPOSE: Known factors place patients at increased risk for developing an NSAID induced GI bleed. This study compares the ability of administrative databases to capture risk factors versus information obtained from a survey instrument (SCORE[®]).

METHODS: The SCORE assesses risk of a GI bleed based on six factors: age, health status, type of arthritis, prednisone use, previous NSAID GI hospitalization, and previous GI side-effects to NSAIDs. Patients receive points for the various risk factors, which are translated into Risk Levels (1 lowest to 4 highest). Randomly selected patients who received a prescription for a COX-2 or traditional NSAID were mailed a survey that included the SCORE. The same patients were also scored electronically using administrative databases with available measures that approximate the SCORE.

RESULTS: 1387 patients returned a usable survey. The correlation between the survey and electronic points was high ($r=0.89$, $p<0.001$). The correlation was somewhat lower when points were translated into risk levels ($r=0.78$, $p<0.001$). Individually, age was the most highly correlated variable ($r=0.99$) while GI side effects had the lowest correlation ($r=0.14$). Both versions were found to be predictive of GI hospitalizations.

CONCLUSION: Administrative databases provide a reliable method to identify NSAID patients at risk for a GI bleed. This method is less expensive than surveys and can provide a rapid way to identify high-risk patients who are most likely to benefit from treatment with a COX-2 inhibitor.

108. Lack of clinically relevant interaction between etanercept and warfarin. *Joan M. Korth-Bradley, Pharm.D., Ph.D., Virginia Parks, BS, Mary E. Buckwalter, BA, Alain Patat, M.D., Deborah Metzger, M.D.; Wyeth Ayerst Research, Collegeville, PA; Paris and Forenap Pharma, Rouffach, France.*

PURPOSE: To compare the PK of R-, S-warfarin and etanercept after administration of warfarin and etanercept alone as well as together and to compare INR after warfarin alone and when given with etanercept.

METHODS: In a 3-way cross-over, nonrandomized twelve healthy male volunteers received single oral 25-mg dose of warfarin after an overnight fast (period 1), followed by twice weekly 25-mg subcutaneous doses of etanercept for 7 doses (period 2). The last dose of etanercept was administered concurrently with a second dose of warfarin (period 3). Serial blood samples for plasma warfarin concentration measurement and INR assessment were collected before and then 12, 24, 36, 48, 60, 72, 120 and 144 hours post dose. Serial blood samples for serum etanercept concentration measurement were collected before and 12, 24, 36, 48, and 60 hours after the 6th and 7th doses as well as 72, 96, 120, 144, 192, and 264 hours after the 7th dose. Warfarin R- and S- enantiomer concentrations were measured by HPLC/UV procedure with LOQ of 0.15 µg/ml. Etanercept concentrations were measured with ELISA methodology with LOQ of 0.3 ng/ml based on a 1:5 minimum

dilution. PK parameters were calculated by noncompartmental methods. Paired t-test procedures were used to compare PK parameters and the INR ratio. Bioequivalence criteria were also applied the C_{max} and AUC for maximum concentration/effect values as well as the area under the concentration/effect time curves.

RESULTS: All ratio 90% confidence intervals (CI) for C_{max} and AUC (PK) and INR fell within conventional bioequivalence 90% CI of 0.8 to 1.25. Although the AUC for effect for INR was consistently decreased when etanercept was administered with warfarin, the effect was modest and should not necessitate dosage adjustment.

	Ratio of C/E_{max} (90% CI)	Ratio of AUC/E (90% CI)
R-warfarin	0.95 (0.88-1.01)	0.98 (0.90-1.07)
S-warfarin	0.96 (0.89-1.02)	1.03 (0.88-1.17)
etanercept	0.94 (0.80-1.08)	1.06 (0.89-1.23)
INR	0.86 (0.82-0.89)	0.90 (0.88-0.92)

CONCLUSIONS: Coadministration of etanercept and warfarin would not be expected to change the pharmacokinetics of either medication, or the therapeutic response to warfarin and no dosage adjustment is required when both drugs are combined.

Transplantation/Immunology

109. The safety and efficacy of atorvastatin in the treatment of hyperlipidemia in kidney transplant recipients on cyclosporine and sirolimus. *Lynn A. Uher, Pharm.D., Shajuana D. McMillan, Pharm.D., Milos Budisavljevic, M.D., Prabhakar Baliga, M.D., P.R. Rajagopalan, M.D.; Medical University of South Carolina, Charleston, SC.*

PURPOSE: Cyclosporine has been shown to inhibit the metabolism of HMG CoA reductase inhibitors via the CYP 450 3A4 enzyme system thus increasing statin levels and increasing side effects. Sirolimus is also a substrate for CYP 450 3A4 therefore adding to the potential for toxicity. The purpose of this study was to evaluate the safety and efficacy of atorvastatin in the treatment of hyperlipidemia associated with cyclosporine and sirolimus.

METHODS: All patients on Neoral, sirolimus and atorvastatin for ≥ 3 months were evaluated. Lipid profiles were analyzed at 3, 6, and 12 months post transplant. Atorvastatin was initiated and titrated to reach LDL goals according to the National Cholesterol Education Program (NCEP II) guidelines in non-diabetics, and the American Diabetes Association (ADA) guidelines in diabetics.

RESULTS: A total of 25 patients were evaluable. Nine patients received high dose sirolimus (15 mg loading dose, 5 mg maintenance) and 16 patients received low dose sirolimus (6 mg loading dose, 2 mg maintenance.) Percent of patients at 3, 6, and 12 months requiring atorvastatin therapy were 52%, 88%, and 90%, respectively. Percent of patients reaching goal LDL cholesterol were 59%, 73% and 75% at 3, 6, and 12 months. The average dose of atorvastatin required was 15 mg ± 8.3 with the most common dose of 10 mg. Analysis of liver function tests and creatinine kinase show no significant differences at any time point compared to baseline.

CONCLUSION: This study suggests that atorvastatin can be used safely and effectively in the treatment of hyperlipidemia in patients on cyclosporine and sirolimus.

110. A retrospective comparison of the incidence of rejection between antithymocyte globulin preparations (Atgam[®] and thymoglobulin) when used for induction therapy in renal transplantation. *Daniele K. Gelone, Pharm.D., Jennifer Rais, Pharm.D. candidate, Kathleen D. Lake, Pharm.D., BCPS, FCCP; University of Michigan, Ann Arbor, MI.*

PURPOSE: The aim of this retrospective study was to evaluate the effectiveness of thymoglobulin- and Atgam-based induction protocols used in high-risk renal allograft recipients.

METHODS: A retrospective chart review of 293 adult renal transplant patients was conducted documenting all pertinent patient demographics and outcome data. We identified 44 Atgam recipients and 31 thymoglobulin recipients for this review. Patients received either thymoglobulin at 1.5 mg/kg intravenously or Atgam 15 mg/kg intravenously, administered immediately post-transplant, then daily for at least five days. Induction therapy was initiated per protocol to immunologically high risk patients; African Americans, re-transplants (< 1 year) and PRA > 30% (current or historical). Standard initial immunosuppression for both groups consisted of cyclosporine, modified (Neoral[®]), mycophenolate mofetil (Cellcept[®]) and prednisone.

RESULTS: Patient demographics including gender, race, donor organ type, re-transplants and elevated PRA were similar between both groups. ($p=NS$) 12.9% of thymoglobulin-treated patients experienced an acute rejection episode compared with 36.4% of Atgam-treated patients ($p=0.033$). Patient survival and graft loss were similar between the groups.

CONCLUSIONS: Compared with Atgam-treated patients, induction therapy with thymoglobulin resulted in significantly less frequent acute rejection episodes ($p=0.033$) when used in high-risk renal allograft recipients.

Urology

111E. Efficacy and safety of vardenafil, a selective phosphodiesterase 5 inhibitor, in men with erectile dysfunction on antihypertensive therapy. Hartmut Porst, M.D., Harin Padma-Nathan, Ian Eardley, M.D., Marc Thibonnier; The Male Clinic, Beverly Hills, CA; St. James University Hospital, Leeds, United Kingdom; Bayer Corporation, West Haven, CT.

Presented at the 17th Congress of the European Association of Urology, Birmingham, United Kingdom, February 23-26, 2002.

Women's Health

112. Home-pregnancy test kits: proper usage. Yolande B. Saab, Pharm.D., Nawfal Y. Nawfal, Pharm.D.; Lebanese American University; LaVita Pharmacy, Byblos, Lebanon.

PURPOSE: Early knowledge of pregnancy is vital so that women can avoid harmful drugs and/or activities during the early and serious stages. Home pregnancy-test kits can be convenient for women to check whether they are pregnant. The objective of this study is to investigate and evaluate the proper usage of home pregnancy-test kits.

METHODS: A survey was conducted on 238 women entering a community pharmacy in the summer of 2001 to purchase a home pregnancy-test (HPT) kit. Studied parameters mainly included socio-demographic and economic status of users, their testing procedure awareness and compliance, and their ability to interpret test results. HPT kits brand name selection criteria and pharmacist involvement in counseling were also appraised.

RESULTS: Results indicated that nearly 85% of respondents were between 25 and 36 years of age. Among the users, 21% falsely interpreted the test results. The main explanation was due to the fact that some HPT kits were not accompanied with instructions on the proper usage of the kit. In addition, a few users feel embarrassed to discuss the concern with the pharmacist, who, however, was found to counsel 59% of respondents. HPT kits brand selection was essentially based on either advertisements or the cost.

CONCLUSION: Since some HPT kits don't include any instructions on the proper usage of the kit, and are sold in several countries including Lebanon, the pharmacist's role in counseling is very crucial. Factors that can cause false results should be emphasized as well before marketing them to the general public.

CLINICAL PHARMACY FORUM

These abstracts describe the delivery, development, justification, or documentation of innovative clinical pharmacy services; they may be descriptive only and need not contain an evaluative component.

113. Time evaluation of the medication use cycle. John G. Fowler, Pharm.D., Kirsii M. Hearon, Pharm.D., Sara B. Jutte, Pharm.D., Ken W. Kenyon, Pharm.D., Ashley A. Krygiel, Pharm.D., Petra Schultz, Pharm.D., Anne P. Spencer, Pharm.D.; Medical University of South Carolina, Charleston, SC.

PURPOSE: The purpose of this evaluation was to characterize the medication use cycle at our institution for intravenous antibiotics. Improved patient outcomes have been associated with the timely administration of antibiotics.

METHODS: First dose intravenous antibiotic orders were identified and data were collected from September 4, 2001 through October 30, 2001 in two patient care areas; a general medicine (GM) floor and an intensive care unit (ICU). These data included the following times on a 24-hour clock: order written, order transcribed onto the medication administration record, pharmacist received order, pharmacist entered order in computer system, antibiotic delivered and antibiotic administered. The time elapsed between various time points was calculated. The primary outcome was the mean time elapsed between, 1) order written and antibiotic administered to reflect the entire medication use cycle. In addition, the following outcomes representing pieces of the entire cycle were evaluated. The mean time elapsed between, 2) order written to received by pharmacist, 3) order received by pharmacist to antibiotic delivered, and 4) antibiotic delivery to administration. Mean, median and standard deviations were reported for all elapsed times.

RESULTS: Three hundred and twenty-six intravenous antibiotic orders were analyzed. For the GM floor, the outcomes were (mean): 266 min, 98 min, 105 min, 104 min, respectively. For the ICU, the primary outcomes were (mean): 215 min, 63 min, 46 min, 122 min, respectively.

CONCLUSION: The length of time from antibiotic order to administration was greater than desired. These data will be shared with appropriate groups at our institution to explore quality improvement processes.

114. Development and implementation of calcium replacement policies and procedures and dosing guidelines in adults and pediatrics. Julie Barnes, Pharm.D., BCPS, Melissa Sanacore, Pharm.D., Chad M. Reynolds, Pharm.D., Joseph E. Mazur, Pharm.D., BCPS; Medical University of South Carolina, Charleston, SC.

PURPOSE: The Institute for Safe Medication Practices (ISMP) recommends that hospitals standardize protocols for the safe and efficacious use of electrolyte solutions, including calcium, in order to address proper dose expression and limits, labeling methods, infusion rates, and monitoring parameters. No published standards exist addressing calcium replacement. We sought to develop policies to ensure patient safety with calcium supplementation, and to develop guidelines for the treatment of hypocalcemia.

METHODS: A multidisciplinary Electrolyte Task Force, comprising pharmacists, physicians, and nurses, was convened to review the current literature. The Task Force designed policies and procedures, plus dosing guidelines for the appropriate use of calcium in adults and pediatrics.

RESULTS: Policies were implemented restricting the use of calcium chloride to the intensive care units and in emergency situations. Calcium gluconate emerged as the preferred intravenous replacement in all other situations. Maximal infusion rates and concentrations for calcium gluconate and chloride were addressed in the policy. A policy for proper prescribing procedures emerged which outlined treatment guidelines for calcium supplementation based on patient symptoms and laboratory values. Oral supplementation was stressed throughout the dosing guidelines where applicable. Multiple hospital committees approved the recommendations.

CONCLUSIONS: This process improvement initiative should provide for enhanced calcium replacement use. Access to the dosing guidelines and policies will be via the Medical University of South Carolina Intranet. The Electrolyte Task Force is now developing policies/guidelines for magnesium, phosphorous, and potassium. Intended future outcome measures include: monitoring physician adherence, adverse effect reporting, and nursing/pharmacy feedback via surveys.

115. Prevention of medication misadventures: a myth or reality? A team effort by physician, nursing and pharmacy in implementing a non-punitive adverse event reporting system. Roy Guharoy, Pharm.D., Jeanna Maraffa, Pharm.D., Nancy Page, M.S., Karen Hirschman, B.S., David Lehmann, M.D., Se Choi, B.S.; University Hospital, SUNY-Upstate Medical University, Syracuse, NY.

PURPOSE: Medication misadventures are a significant cause of morbidity and mortality. The objective of this report is to describe a multidisciplinary process to improve the adverse event reporting system.

METHOD: A retrospective review of documented medication misadventures reported only 150 events over a one-year period. A multidisciplinary group was formed and explored various options to address the issue. Keeping the challenges of creating a "true" non-punitive medication occurrence reporting culture in mind, the team devised a new adverse event reporting form. The new system was implemented in November 2000. All events are analyzed by a multidisciplinary team to identify system related problems.

RESULT: There were 2244 events reported over past twelve months. 28% of the events had the capacity to cause error, medication did not reach the patients in 42% of cases, error occurred in 27% of events but did not cause the patient any harm, 6% of the events required patient monitoring without causing any patient harm, 0.09% cases had adverse impact on patient outcome. As a result of the reported events, we have created an awareness of the significance of the issue and made various process changes to avoid potential adverse events.

CONCLUSION: We have made some progress and we have a long way to go. We conclude that a true non-punitive adverse event reporting system can bring significant changes to improve quality of care of our patients.

116. Development and implementation of a comprehensive epoprostenol therapy management program. Joseph E. Mazur, Pharm.D., BCPS, G. Mark Baillie, Pharm.D., MHA, Walter E. Uber, Pharm.D., Helen Holland, R.N., Charlie Strange, M.D.; Medical University of South Carolina, Charleston, SC.

PURPOSE: Flolan® (epoprostenol sodium) is a direct-acting pulmonary vasodilator indicated for the long-term treatment of pulmonary arterial hypertension. Flolan therapy requires intravenous administration. Vigilant monitoring is necessary to maintain a balance between therapeutic efficacy and potential life-threatening adverse reactions. Brief interruptions in therapy may produce untoward reactions or death. We sought to establish multidisciplinary clinical protocols and guidelines for the safe and efficacious management of adult patients with pulmonary hypertension.

METHODS: Three core critical care clinical pharmacy specialists were organized to first identify Flolan patient populations and their respective providers. The nursing units capable of safely managing Flolan therapy were identified with the aid of key nurse managers. Consensus-building strategies were employed to foster a multidisciplinary approach to Flolan therapy among physician specialty groups (pulmonary/critical care, cardiology, and hepatology).

RESULTS: Two distinct Flolan-usage patient populations were identified: those admitted for acute dose ranging studies and patients admitted from home on a stable dose. The clinical guidelines developed encompassed patient assessment, sequence of interventions, dosing guidelines, reportable conditions and events, clinician documentation, patient education, and discharge planning. Preprinted physician order sets were developed and approved through multiple hospital committees. A series of inservices on

appropriate management of Flolan therapy were conducted for nurses, pharmacists, and physicians. The clinical guidelines and preprinted physician order sets were posted on a hospital intranet website for easy access by health professionals.

CONCLUSION: This comprehensive epoprostenol (Flolan) therapy management program serves as an example of a systematic approach to safe and efficacious medication management and process improvement.

117. Success of a pharmacist-managed lipid clinic: a year in review. Janet L. Ritter, Pharm.D.; Midwestern University, Downer's Grove, IL.

PURPOSE: A pharmacist-managed lipid clinic (LC) was established in 11/00 to assist the physicians with ongoing lipid management at Suburban Heights Medical Center in Chicago Heights, IL.

METHODS: Patients establish care with LC after their physician completes a referral form. New visits are scheduled for one hour and follow-up visits for 1/2 hour with the cardiology receptionists. Extensive education is provided. The LC is staffed weekly with 1 clinical pharmacist, 1 ambulatory care pharmacy resident, and several Pharm.D. students from Midwestern University, Chicago College of Pharmacy. The Cholestech LDX[®] analyzes a complete lipid profile plus glucose. Lipid medications are initiated or modified by the clinical pharmacist per an accepted Scope of Practice, with all plans reviewed and co-signed by the cardiology physician.

RESULTS: Over 200 patients are actively enrolled in LC. Patient satisfaction is high because of individual attention, extensive counseling, motivation provided, and point of care service. The breakdown of therapeutic agents utilized in LC is as follows: 73% statins; 13% fibrates; 3% niacin; 1% bile acid sequestrants; 16% no drug therapy; 6% combination therapy. Diabetes is present in 24% of patients, and 42% are secondary prevention; over half have achieved their LDL-cholesterol goal. National averages are 37% and 18% for primary and secondary prevention, respectively. Additional results will be presented.

CONCLUSIONS: The LC is successful in managing hyperlipidemia by achieving outstanding LDL reduction and goal attainment. Our multidisciplinary approach provides for integration and education among several health care practitioners, which serves to strengthen awareness of clinical pharmacy.

118. The effect of a pharmacist-implemented sedation/analgesia protocol in the intensive care unit. Thuy Anh Nguyen, B.Pharm, M.Sc., Sophie Lecompte, B.Pharm, M.Sc., David Williamson, B.Pharm, M.Sc., Anne Fillion, B.Pharm, M.Sc., Lucie Blais, Ph.D.; Hôpital du Sacré-Coeur de Montréal; Faculté de pharmacie, Université de Montréal, Montreal, PQ, Canada.

PURPOSE: To measure the effect of a pharmacist-implemented sedation/analgesia protocol on critically ill and mechanically ventilated patients.

METHODS: A total of 238 patients were included in the study. One hundred thirty-six patients hospitalized between November 1, 1998 and May 31, 1999 constituted the before-protocol group. One hundred and six patients hospitalized between November 1, 2000 and May 31, 2001 formed the after-protocol group.

RESULTS: New sedation/analgesia protocol promoted lorazepam and morphine use in preference to midazolam and fentanyl as suggested by the Society of Critical Care Medicine. This protocol also recommended daily interruption of sedative infusions and nurse adjustment of sedation according to Ramsay score. Protocol adherence was 52.8%. A non-significant decrease of the duration of mechanical ventilation, the length of stay in the intensive care unit and the total sedation/analgesia drug costs was observed. However, when the before-protocol group was compared to the subgroup of patients receiving the whole protocol (n=25), a decrease of 68 hours in the length of stay in the intensive care was obtained (p=0.023). The pharmacist made 54 interventions in favor of the protocol.

CONCLUSION: The protocol was not applied enough to demonstrate a significant effect of its use. However, when it was prescribed integrally, the length of stay in the intensive care unit was reduced. Finally, this protocol contributes to standardize the practice to offer the best treatment and to improve the quality of care.

119. Implementation of a drug information service in a community hospital system. Denise E. Daly, Pharm.D.; St. Joseph's/Candler, Savannah, GA.

Providing drug information is an important and integral part of every pharmacists' daily responsibilities. To enhance this responsibility we developed a more formalized approach to drug information requests received by our pharmacists. The first phase of implementation required determining and quantifying the types of questions asked, the resources needed to provide answers and the source of the questions. Two drug information survey forms were developed to minimize the disparity and maximize the consistency of documentation among the various pharmacists. All drug information questions, whether complex or simple, were tracked over a one month period. Phase two consisted of building a computer program into our current system so that questions, answers and resources used could be documented easily and efficiently. We also required that the program was capable of search and retrieval so that the documenting pharmacist could determine if a

particular question had been asked and answered in the past. Phase three consisted of educating the pharmacy staff on the program and going live with the computer documentation. Phase four will consist of implementing a peer review process to assure the accuracy and completeness of the documented answers so that the integrity of the database of information being built can be maintained. As a community hospital system with no formal drug information service available or a method of knowing what information was being disseminated by our pharmacists, we believe the implementation of this program with peer oversight will enhance the current pharmacy services we provide to our institution.

120. Development of a statewide competency-based pharmacotherapy curriculum for family medicine residents in South Carolina. Kelly Jones, Pharm.D., Adrienne Ables, Pharm.D., Betsy Blake, Pharm.D., Melissa Blair, Deborah Carson, Sandra Counts, Lori Dickerson, Steve Eggleston, Spencer Morris, Pharm.D., Kelly Ragucci, Eric Schneider, Sharm Steadman, Wayne Weart, Andrea Wessell, Pharm.D.; McLeod Family Medicine, Florence, SC.

PURPOSE: Pharmacists in family medicine have developed a competency-based pharmacotherapy curriculum to be delivered to medical residents in each of the seven residency programs in South Carolina. It is important to prioritize the pharmacotherapy knowledge and develop core competencies that are practical and evidence-based. By connecting the Programs using a web-based curriculum, educational material can be standardized, and data can be systematically evaluated for further education and development. The purpose of this presentation is to describe this statewide initiative.

METHODS: Pharmacists have developed a curriculum based on common medical conditions encountered by family physicians. Modules will coincide with the residents' corresponding second and third year rotations. Each curricular module will include core attitudes in pharmacotherapy training, mandatory and suggested reading, and a determination of mastery of the material. During designated rotations, residents will review the rotation competencies and reading material, and complete an on-line examination. The curriculum will enhance the usual pharmacotherapy teaching activities. Material will be maintained on an Internet site linked to the home page of each of the residency programs, and the educational evaluation and feedback components will be developed using WebCT.

RESULTS: The curriculum is being evaluated by the residency program directors. Pilot testing is planned for spring 2002, with full implementation scheduled for July 2002. Development, delivery and evaluation methods will be presented.

CONCLUSIONS: A statewide pharmacotherapy curriculum for family medicine residents has been developed in South Carolina. Data obtained will be used to further education and curricular development within the Programs.

121. Implementation of the Residency Learning System Model to the San Antonio combined military pharmacy practice residency. Krissa J. C. Crawford, R.Ph., Steven S. Carlisle, Pharm.D., BCPS, Libby S. Schindler, Pharm.D.; Wilford Hall Medical Center, San Antonio, TX.

PURPOSE: This resident project was designed to transform the San Antonio Combined Military Pharmacy Practice Residency into a program governed by the Residency Learning System (RLS) Model. This change allows us to provide a more readily individualizable residency program and to more fully meet the standards mandated by our accrediting organization.

METHODS: A residency re-design committee was created. Committee members included the residency director, associate residency director, all preceptors, and the resident in charge of this project. This group met to determine the transition timeline, and the goals, objectives and activities that would be included in the newly re-designed program. An aggressive timeline was implemented and frequent follow-up meetings were scheduled. Additional expert input was obtained through a site-visit by a member of the initial RLS creation team.

RESULTS: Goals, objectives, and activities specific to all offered rotations were selected to create a more flexible and focused program ensuring each resident has the unique experiences needed to become a well-rounded clinician. Moreover, military specific goals and objectives were created to fulfill the unique requirements of this military pharmacy practice residency.

CONCLUSIONS: The changes implemented in this program have resulted in significant improvements in preceptor interaction, resident involvement in the tailoring of their residency, improved documentation and accountability, and greater adherence to residency accreditation standards. We feel that other institutions struggling with this change may benefit from a similarly structured transition program.

122. A pharmacy practitioner training model incorporated into a multidisciplinary geriatric assessment clinic. George A. DeMaagd, Pharm.D., BCPS, Jeanette Myers, M.D., Ann Zemlick, RN, David Orchanian, M.P.A., OTR, BCG, Linda LaBlanc, Ph.D.; Ferris State University, Big Rapids, MI; Western Michigan University, Kalamazoo, MI.

PURPOSE: We describe a pharmacy practice-training model that utilizes the multidisciplinary assessment of geriatric patients to educate pharmacy students in the care of the elderly. Students assess patients through their

participation in screening and assessments during home and clinic visits. Through the utilization and evaluation of this information, recommendations are provided during a multidisciplinary team meeting. Recommendations are incorporated into a comprehensive report that provides education to the patients and their families, in addition to pharmacotherapy recommendations for their primary care physicians.

METHODS: Students are assigned patients and perform initial home visits with faculty team leaders. During the home visits students conduct physical assessments including, Get up and Go gait evaluations, blood pressure screening and visual tracking screens. In addition, they administer the Mini Mental State Exam (MMSE) and obtain a medical and medication history from the patient or their family. During the clinic visit students obtain patients weight and check vital signs, conduct a review of systems questionnaire, review present medications and conduct a medication history. Thirdly, they accompany the physician during the physical exam, assist with documentation and provide assistance when necessary.

RESULTS: Pharmacy student involvement in this pharmacy training clerkship model allows them to experience the value of assessing and evaluating patients and the importance of this interface in making important and appropriate therapeutic decisions. Tools to evaluate the impact of assessments on patient and physician satisfaction are being utilized. Tools to evaluate other patient outcomes including, patient falls and hospital admissions are being developed.

CONCLUSIONS: This pharmacy training model provides an opportunity for students to develop introductory physical assessment skills and utilize them in making appropriate pharmaceutical care recommendations in a multidisciplinary geriatric assessment environment.

123. Unique ambulatory care experience through partnership with a human services provider. *Raylene M. Rospond, Pharm.D., Christine Myers, B.S.; Drake University, Des Moines, IA.*

PURPOSE: A strategic goal of Drake University College of Pharmacy is to foster professional excellence and social responsibility (PE&SR) in Pharm.D. graduates. Through partnership with Community Support Advocates (CSA), a human services provider, a unique ambulatory care experience was developed to enhance PE&SR through increasing student exposure to the mentally disabled, their healthcare barriers and to improve the medication management of the clients.

METHODS: A 4-week rotation with CSA began in May 2000. CSA provides comprehensive services (job skill development, residential services, supportive community living assistance, health care management) to 110 clients suffering from mental retardation, developmental disability or mental illness for a capitated fee. Services provided are evaluated in 14 outcome areas by an independent consultant. Pharm.D. candidates provide medication histories, identification and resolution of drug therapy problems, coordination of healthcare, client/team education, and documentation of time and interventions.

RESULTS: Eight students have completed the experience to date. Student awareness of the population and their healthcare barriers was increased as measured by activity logs, preceptor and team meetings, and student evaluations. CSA team members gained enhanced awareness of pharmacy profession and medication knowledge. CSA evaluation scores in somatic care outcomes increased from 2-3 (0-3 scale) directly attributable to student intervention documentation per independent evaluator.

CONCLUSION: Partnership with a human services provider can provide Pharm.D. candidates with exposure to the mentally disabled and their healthcare barriers. CSA and the clients directly benefit from enhanced level of pharmaceutical care provided by pharmacy faculty and students.

124. Identification of potentially inappropriate medication use in a program of all inclusive care for the elderly. *Tanya C. Knight, Pharm.D., Michael R. Jacobs, Pharm.D., Albert I. Wertheimer, Ph.D., M.B.A.; Temple University School of Pharmacy, Philadelphia, PA.*

PURPOSE: This study documented medication therapy received by frail, elderly patients at a Program of All Inclusive Care for the Elderly in order to 1) identify the presence of potentially inappropriate medication use using explicit criteria, to 2) analyze the consequences of such use, and to 3) determine the acceptance of pharmacist intervention recommendations by the physician.

METHODS: Medical records of 83 patients enrolled in the Living Independently For Elders program were reviewed between October 3 and November 2, 2001. A current medication list was used to identify medications that were included in the Beer's criteria as inappropriate for use in the elderly. Medications that were identified were investigated using the medical chart to search for health related outcomes. The physician was notified of the concern and a recommendation was offered as appropriate.

RESULTS: Thirty-four potentially inappropriate medication instances were identified in 30 patients. Two instances were classified as high severity according to the Beer's criteria (6%). Twenty-six (76%) were drug-age concerns, whereas 8 (24%) were drug-disease interactions. Oxybutynin was implicated in 12 (35%) instances and Darvocet® in 6 (18%) instances. Twenty-seven (79%) instances occurred without documentation of adverse

outcome, and 4 (12%) led to a decrease in medication dose secondary to adverse outcome.

CONCLUSION: The use of potentially inappropriate medications continues to be observed in a geriatric practice despite the popularity of the Beer's criteria in the geriatric literature. However, in many instances, patients can tolerate these medications without adverse events and continuation with monitoring may be feasible.

125E. Group visits: an innovative role for pharmacists in a multi-disciplinary team. *Oralia V. Bazaldua, Pharm.D., BCPS, James Alexander, M.D., Richard Drewa, R.N., Joshua Freeman, M.D., David Schneider, M.D.; University of Texas Health Science Center at San Antonio, San Antonio, TX.*

Presented at the 34th Annual Spring Conference of the Society of Teachers in Family Medicine (STFM), Denver, CO, April 2001.

126. Serving the underserved: providing clinical pharmacy services to patients in a community health center. *Laura Shane-McWhorter, Pharm.D., BCPS, FASCP, CDE, BC-ADM; University of Utah, Salt Lake City, UT.*

PURPOSE: Community health centers (CHCs) provide services for underserved patients including many who are at the federal poverty level and are ethnically diverse. These centers rarely provide clinical pharmacy services. Through an alliance between the University of Utah College of Pharmacy and the CHCs, a clinical pharmacy demonstration project was started in June, 2000. The goals of the project were for a faculty clinician to provide individualized disease state management, primarily in diabetes, assist providers in selecting and monitoring medications, and assist patients in obtaining and understanding medications procured through pharmaceutical industry medication assistance programs.

METHODS: The service was created by an alliance between the CHCs and the University of Utah and obtaining support of providers in the clinic. Scheduled patient education appointments were initiated where providers refer patients to the pharmacist. Providers also ask the pharmacist to conduct patient chart reviews to make pharmacotherapy recommendations. Patients are referred for counseling when picking up manufacturer-provided medications. A Microsoft Access database was created to track clinical interventions.

RESULTS: The clinical pharmacy service has been established. Thus far, approximately 110 diabetes patients have been seen for patient education appointments. Mean HbA_{1c} in these patients has declined from a baseline of 9.4% to 7.7%. Providers often consult with the pharmacist for pharmacotherapy consults. A total of 1500 clinical pharmacy interventions have been entered into the Microsoft Access database.

CONCLUSION: A clinical pharmacy service model for the management of underserved patients in a CHC has been accomplished with the alliance of a College of Pharmacy and CHCs. Similar services may be initiated and maintained in other underserved patient settings.

127. What's new in anticoagulation practice? Innovative strategies for inpatient and outpatient management. *Wendy A. Leong, Pharm.D., BCPS, Terence G. Sparling, M.D.; Burnaby Research, BC, Canada; University of British Columbia, Vancouver, BC, Canada.*

Thromboembolism (TE) affects large patient populations (e.g., cardiology, neurology and geriatrics) who often require warfarin. This project demonstrates excellent opportunities for clinical pharmacists to expand their role in anticoagulation practice.

This is an overview of 3 interrelated strategies: 1) Strategy 1: an inpatient warfarin dosing service implemented in 1994; 2) Strategy 2: an outpatient DVT treatment program implemented in 1995; and 3) Strategy 3: an outpatient warfarin dosing service implemented in November 2001.

Three retrospective evaluations were conducted for Strategies 1 and 2. Strategy 3 was a prospective project, with program evaluation scheduled for 2002. An interdisciplinary team was involved in all 3 strategies.

Strategy 1 was re-evaluated in 1999 with a 50-chart review showing: average age 50 years; 32 females; average hospitalization 13.4 days; warfarin for DVT prophylaxis (40%), atrial fibrillation (28%), DVT/PE (14%); average time to therapeutic INR 2.9 days; no INR results over 6.0; and 1 GI bleed.

A 1995/1996 evaluation of Strategy 2 demonstrated a safe alternative to hospitalizations for selected DVT and PE patients. LMWH and warfarin dosing were managed by clinical pharmacists. No hemorrhage or recurrent TE was reported.

Strategy 3 was implemented at 2 pilot sites of a major chain drug store. The new program, based on consensus guidelines, included physician referral, certified anticoagulation pharmacists, warfarin co-prescribing, point-of-care INR testing (POCT), certified POCT assistants, etc.

These 3 strategies offer more convenience and choices for patients and physicians; and more opportunities for clinical pharmacists in anticoagulation management.

128. Development of a core herbal product list and a pharmacist education program within a university-based outpatient pharmacy. *Jessica L. Kill, Pharm.D., Joseph J. Saseen, Pharm.D., BCPS; University of Colorado Health Sciences Center, Denver, CO.*

PURPOSE: The objectives of this ongoing project are: 1) to identify a select number of herbal products with documented safety and efficacy for use in a university-based outpatient pharmacy and select one reliable manufacturer to supply these agents, 2) to educate university-based outpatient pharmacists on these core herbal products, 3) to encourage pharmacists to routinely ask about herbal product use and document use in the outpatient medication profile.

METHODS: Ten herbal products were chosen for the core list of products. Individual agents were selected based on available safety and efficacy data. One manufacturer with the ability to continually provide purity and standardization data was selected to supply these agents. Fifty pharmacists/pharmacy interns will be evaluated using a pre-test that assesses baseline knowledge of herbal supplements. This test will focus on potential use, adverse effects, contraindications, drug interactions, and patient counseling. A 1-hour continuing education program was developed addressing the use, dosage, drug interactions, adverse reactions, safety, and efficacy of the core herbal products. It will be presented in December 2001. This will be followed up by a similar post-test after completion of the program. An on-line natural product information reference will be selected to enable pharmacists to prospectively screen patients for drug interactions and appropriateness of supplement use. Use of herbal supplements will be documented in the outpatient prescription record.

RESULTS: Evidence for selection of the core list, results from the pre- and post-testing, and methods of documentation will be presented.

129. An innovative oncology integrative medicine information service. Maria B. Yaramus, Pharm.D.; University of Pittsburgh Cancer Institute, Pittsburgh, PA.

PURPOSE: Complementary Medicine (CM) data in health promotion, disease prevention and treatment is often equivocal, and the manner of synthesizing, disseminating and incorporating this information into self-care choices is controversial. Students, professionals and patients lack information on CM safety, research, standards, efficacy, regulation, and legislation. An Integrative Medicine Information Service (IMIS) was designed to improve Complementary (Integrative) Medicine education, clinical programming and research within a National Cancer Institute designated Comprehensive Cancer Center.

METHODS: IMIS is an information service based on an electronic database for professional /patient consultation and outcomes analysis. It utilizes clinical algorithms for professional consultation and intervention, and incorporates botanical drug product research information to provide interdisciplinary communication/partnership strategies

RESULTS: The IMIS service and database 1) analyzes CM utilization trends, motivators and goals for use, interactions, cancer history, contra-indications and out-of-pocket expense. 2) responds to requests for information utilizing evidence-based medicine resources. 3) captures and documents "red-flag" interventions. 4) identifies promising candidates for chemopreventive/treatment investigation and assists with protocol design in accordance with FDA Center for Drug Evaluation and Research methods and 4) provides individualized and innovative CM communication, education and training via interactive internet technology to multidisciplinary students and oncology professionals.

CONCLUSION: The systematic educational interventions to multidisciplinary oncology professionals, patients, consumers and CM practitioners provided by IMIS has modified CM knowledge, attitudes, referral patterns, behaviors and health outcomes. These interventions will continue to facilitate the integration of scientifically validated data into conventional care and stimulate novel research.

130. Guidelines for community-acquired pneumonia: compliance with, cost and efficacy of ceftriaxone alone as initial therapy. Ko H. T. Humphrey, B.Sc., L.S. Tham, Paul A. Tambyah, MBBS; Dip ABIM Int Med; Dip ABIM Infectious Diseases; National University Hospital, Singapore.

PURPOSE: Community-acquired pneumonia (CAP) is a major cause of morbidity and mortality. Recommendations were developed for CAP patients admitted to the National University Hospital (NUH) based on microbiological sensitivity and published guidelines.

METHODS: Patients with CAP from Nov 2000-Apr 2001 were identified through admission records and prospectively followed to determine clinical outcome and antibiotic therapy.

RESULTS: 74 patients with CAP were admitted into the study. 37 (50%), were initially started with ceftriaxone alone (CA) as recommended in the NUH guidelines while the rest were initially treated with other combination (OC) antibiotics. Patients in the CA and OC groups were similar in terms of age (66.38 ± 17.88 vs 68.65 ± 14.58 years), gender (female:male, 17:20 vs 23:14) and acute physiology and chronic health evaluation (APACHE II) scores (10.3 ± 4 vs 9.8 ± 6). The length of stay (9.9 ± 9.7 vs 8.3 ± 6.1) and clinical outcome (resolved 92% vs 89%) were comparable in both groups. However, there were marked differences in the hospital acquisition costs in both initial antibiotics (S\$3.7 \pm 0.7 vs S\$22.4 \pm 34.6) and total antibiotic costs (\$79.8 \pm 150 vs \$139.7 \pm 215). Predominant pathogens included *S. pneumoniae*, *H. influenzae* and *M. pneumoniae*.

CONCLUSION: A guideline for CAP based on initial empirical therapy with ceftriaxone alone had a compliance rate of 50%. Compliance with the guideline resulted in cost savings to the hospital with patient outcomes comparable with individual physician's own empiric choices.

131. Multifaceted intervention to promote judicious use of antibiotics in primary care clinics. Jonathan M. Zand, Pharm.D., MBA, Venessa S. Price, Pharm.D., Marianne Y. Lee, Pharm.D.; Harvard Vanguard Medical Associates, Boston, MA.

PURPOSE: This paper describes an intervention led by clinical pharmacists to promote judicious use of antibiotics and reports possible impact on prescribing behavior.

METHODS: Four one hour lectures with continuing medical education (CME) credits were developed and presented to clinicians by clinical pharmacists on judicious antimicrobial therapy for sinusitis, bronchitis, community acquired pneumonia, and "saying no" to antibiotics. Participants evaluated CME program quality. Summaries of evidence-based guidelines were presented during lectures and individually to clinicians. Guidelines were prepared by clinical pharmacists, reviewed by specialists, and endorsed by a committee of clinicians. A pocket card summarizing recommendations was distributed. Patient education materials were linked in automated medical record to enhance access. Clinical pharmacists provided decision support. Number of prescriptions of predefined first line narrow spectrum antibiotics and second line broad spectrum antibiotics were tabulated prior to and during intervention. Ratio of first line and second line antibiotics for each prescriber were measured and shared with clinicians.

RESULTS: Over 90% of target clinicians participated in CME lectures, individual detailing, or both. Evaluations of CME lectures were consistently high. Total volume of antibiotic prescriptions in Q3 2001 was 29% less than Q3 2000 prior to intervention. Ratio of first line antibiotics to second line antibiotics was unchanged.

CONCLUSION: A comprehensive pharmacist led intervention to promote judicious use of antibiotics was well received by clinicians. We report preliminary evidence that such interventions may be effective for reducing unnecessary antibiotic prescriptions. Reducing second line antibiotics as a proportion of all antibiotics poses a greater challenge.

132. Retrospective cohort study: development of therapeutic guidelines to deliver pharmaceutical care: management of acute uncomplicated pyelonephritis in adult patients. Ru-Ming Fan, Pharm.D., MPH; Brookdale University Hospital and Medical Center, Brooklyn, NY.

PURPOSE: The purpose of the study is to develop evidence-based pharmaceutical care/therapeutic guidelines for patients with pyelonephritis, identify the appropriate and cost-effective antibiotic regimens, and measure the association of risk factors with prolongation of IV antimicrobial therapy.

METHOD: A retrospective cohort study was conducted at The Brookdale University Hospital and Medical Center from April 1, 1999 to March 31, 2000. A total of 161 cases, patients older than 18 with clinical evidence of uncomplicated pyelonephritis were reviewed. Variables of interest included demographics, antibiotics category, length of IV antibiotics therapy, comorbidity, and clinical laboratory data, etc. Multivariate logistic regression model was used to demonstrate correlation, if any, of these variables.

RESULT: The results demonstrated that the patients diagnosed with comorbid illness, such as immunosuppression, diabetes, and/or cardiovascular diseases had statistically significant association with prolonged length of IV antibiotic therapy (OR=2.65, $X^2=11.52$, 95% CI=2.3-26.8, $p<0.05$) as well as age, respectively (OR=1.54, $X^2=4.27$, 95% CI=1.9-20.3, $p<0.05$). The selection of IV antibiotic category demonstrated a difference in terms of the duration of IV therapy. Penicillin, co-trimoxazole, and ciprofloxacin showed that there is a statistically significant difference in comparison to cephalosporins (OR=1.75, $X^2=5.12$, 95% CI=2.3-26.8, $p<0.05$). Patients were admitted to the hospital with leukocytosis and/or fever did not have statistically significant impact on the duration of the IV therapy.

CONCLUSION: Development and implementation of the pharmaceutical plan/therapeutic guidelines for the management of patients with uncomplicated pyelonephritis to decrease the length of hospital stay and more economical selection of antimicrobials could potentially save substantial funds without compromising the quality of care. From the results of the study, guidelines for the selection of antibiotics for pyelonephritis can also be developed.

133. Implementation of a hepatitis C treatment clinic. Helen S. Yee, Pharm.D., Stephen J. Rossi, Pharm.D., Teresa L. Wright, M.D.; Department of Veterans Affairs Medical Center, San Francisco, CA.

PURPOSE: There is an increased prevalence of hepatitis C virus (HCV)-infection among veterans compared to the general population in the United States. Chronic HCV is the leading cause of cirrhosis, hepatocellular carcinoma, and endstage liver disease requiring liver transplantation. Given the 1) complex nature of HCV; 2) need for frequent monitoring while on treatment; 3) importance of ensuring compliance with treatment; and 4) need to manage treatment-related adverse effects, pharmacists can make a significant impact in optimizing treatment and improving the outcomes of HCV-infected patients.

METHODS: To treat the unexpected number of chronic HCV-infected patients, the clinical pharmacist collaborated with an interdisciplinary team to establish a Hepatitis C Treatment Clinic. A protocol for HCV treatment was developed for the clinic. Primary functions of the clinical pharmacist include: 1) patient evaluation for HCV treatment candidacy; 2) treatment and medication adjustment; 3) evaluating treatment efficacy; 4) evaluating and managing treatment-related adverse effects; 5) medication counseling; and 6) counseling on HCV prevention guidelines.

RESULTS: The Hepatitis C Treatment Clinic was successfully implemented and is managed by the clinical pharmacist to provide interdisciplinary care for HCV-infected patients. Patient outcomes including compliance with treatment, treatment response, and adverse effects of treatment will be evaluated. Treatment response will be based upon changes in liver enzymes, viral load, and liver biopsy.

CONCLUSION: The clinical pharmacist can be a key role in educating, optimizing treatment, and improving the outcomes of HCV-infected patients.

134. The development of a pocket guideline, including speciation information, concerning fungi in a medical intensive care unit to improve appropriate use of antifungal drugs. *Geoffrey C. Wall, Pharm.D., BCPS, Meghan Wilson, Pharm.D. candidate, Lisa Veach, M.D., Gary Clark, Pharm.D.;* Drake University; Integra Health Infectious Disease; Iowa Methodist Medical Center, Des Moines, IA.

PURPOSE: A dramatic increase in the inappropriate use of antifungal agents, particularly fluconazole, was observed at a tertiary-care teaching hospital's medical intensive care unit (MICU). To educate house staff and other Physicians, we collected information concerning various fungal organisms, analyzed this data and developed a pocket guideline that was distributed to prescribers.

METHODS: Using archived microbiology information, we reviewed all positive fungal cultures from the MICU for a one-year period. We then stratified these results by site, paying special attention to positive urine, blood, and abdominal fluid cultures. As there are no standard breakpoints for determining susceptibilities of fungal agents, we used published national susceptibility data and local patient subpopulations to estimate general resistance patterns. This information was included with published guidelines for the treatment of systemic fungal infections, printed as a pocket card, and distributed to all Physicians in the MICU.

RESULTS: *Candida albicans* was the most commonly isolated fungal organism in the MICU (Blood [B] 28/57 isolates [49%], Urine[U] 216/379 [57%] Abdomen [A] 40/56 [71%]), followed by *Candida glabrata* (B 14/57 [25%], U 96/379 [25%], A 16/56 [29%]), and *Candida tropicalis* (B 2/57 [4%], U 32/379 [8%], A 0/56 [0%]). Other fungal organisms, including *Candida krusei*, and *Cryptococcus* species were rare. A survey conducted by the pharmacy indicated that both resident and attending physicians felt that this information was well written and clinically relevant.

CONCLUSIONS: The development of a pocket card containing location, species, and treatment guidelines for fungi is a unique way to educate prescribers in an MICU. A future evaluation will determine if this effort results in more appropriate use of antifungals in our MICU.

135. Survey of vancomycin dosing programs nationwide. *Megan Rose, Pharm.D., Mary Beth Bobek, Pharm.D.;* New Hanover Health Network, Wilmington, NC.

OBJECTIVE: Survey institutions regarding the specifics of their vancomycin dosing programs

METHODS: Pharmacists who specialize in critical care and infectious disease were identified by ACCP and ASHP residency guides and were sent a vancomycin dosing program questionnaire via e-mail. They were questioned regarding hospital demographics, specifics of the initiation of dosing protocols and nomograms for vancomycin, exclusion criteria for their protocols, adjustments in dosing, vancomycin serum concentrations, and the level of involvement by pharmacists.

RESULTS: Seventeen surveys (28.3%) were returned. The average size of the responding institutions was 500 beds. Only 3 respondents did not have a vancomycin dosing program. Forty-seven percent of responders (n=8) have a fixed dosing protocol for vancomycin. The majority of protocols were used only "on request" (62.5%, n=5), and the dosing was based upon a combination of serum creatinine or creatinine clearance (70.6%, n=12). Of the total responding population, 88.2% (n=15), pharmacists were responsible for dosing of vancomycin and for making dose adjustments needed to attain therapeutic levels. A majority, 88.2% (n=15), stated that only trough levels were drawn. A majority of those levels were drawn at the third dose (70.5%, n=12). Fifty-three percent (n=9) of responders draw levels only in specific populations such as renal patients, pediatric patients, and those patients receiving nephrotoxic medications.

CONCLUSIONS: Approximately half the institutions surveyed have formal vancomycin dosing protocols with dosing based upon serum creatinine. More than half draw only trough levels and only draw these levels in specific patient populations. Pharmacists play an active role in dosing and monitoring vancomycin regimens, and based on this information we plan to implement one at our institution.

136. Implementation of an assessment method for the recognition of depression in cancer patients. *Hung V. Chau, Pharm.D. candidate, Danlun Lim, Pharm.D. candidate, Jean Chen, Pharm.D., Siu-Fun Wong, Pharm.D., Kari Franson, Pharm.D.;* Western University of Health Sciences, Pomona, CA; University of California at San Francisco, San Francisco, CA; Centre for Human Drug Research, Leiden, Netherlands.

PURPOSE: To compare the presence of unrecognized and untreated depression in our population of cancer patients with historical data, and develop and evaluate an easy-to-use checklist for clinicians to detect depression in this population.

METHODS: A retrospective chart review was conducted at the UCIMC to determine the recognition and treatment of depression in metastatic breast cancer patients. This was compared to historical data. The Hamilton Depression Scale was then revised for length, comprehensiveness, and ease of use in the oncology setting. Oncology subspecialty physicians were surveyed to validate the acceptance of this evaluation tool.

RESULTS: Retrospectively, 20 of the 22 patients evaluated had reported at least 1 symptom of depression. Twelve patients had at least 3 depressive symptoms, yet only 4 patients had documented diagnosis. None of the patients were receiving antidepressants. After development of the revised checklist, all 12 of the physicians responding to the survey believed that our revised Hamilton depression checklist would make them more aware of their patients' emotional state and aid them in diagnosing depression in their patients.

CONCLUSIONS: Comparison of the retrospective chart review and historical data showed a positive correlation that depression has been and continues to be under-recognized and under-treated. The results from the review demonstrate a need for a better method for detecting depression in cancer patients. Physicians surveyed reported that they are satisfied with the revised Hamilton depression checklist that was developed to aid their assessment of depression in the oncology clinic. The physicians approved this evaluation tool for clinical implementation.

137. Cost impact of pharmacists' interventions in a VA medical center inpatient pharmacy. *Poonam Patel, Pharm.D, Lisa Arai, Pharm.D., Richard S. Schaefer, Pharm.D., Monica Schaefer, Pharm.D., Nicole Dolder, Pharm.D.;* VA San Diego Healthcare System, San Diego, CA.

PURPOSE: The purpose of this study was to evaluate outcomes data from pharmacists' interventions to aid in the justification of inpatient pharmacists' positions at the VASDHS Inpatient Pharmacy Section.

METHODS: A handheld personal digital assistant (PDA) was distributed to each inpatient pharmacist and the Pendragon® software was used to create a data collection sheet for pharmacists' interventions. After obtaining appropriate training and performing beta-site testing, the staff was instructed on using their PDAs to document daily interventions during two separate weeks. Data such as total number of interventions per full-time employee equivalents (FTEE), time spent per intervention per FTEE, and cost avoidance per FTEE were collected.

RESULTS: Approximately 423 interventions were made by clinical pharmacists over the two week period. The three major types of interventions documented included: cost effective alternatives, preventable adverse drug events (drug dosing), and prevention of adverse drug reaction/allergy. Based on previous studies (*Bates, et al*) the cost of a preventable adverse drug reaction/allergy is estimated at \$4685. During the two-week test period, approximately 5 adverse drug reaction/allergy interventions were made and an estimated 130 per year. At \$4685 each, the cost reduction for the year would be approximately \$609,050 (\$56,200/FTEE). Thus, it appears that approximately 1% of the interventions made by the clinical pharmacists would potentially pay for the salary of the pharmacist and provide pharmacy management the data needed to request additional staffing or at the least to maintain the current levels of staffing. Further calculations of cost effective alternatives and preventable adverse drug events will be presented at the meeting.

138. Clinical utility of a handheld device for documentation of interventions by infectious disease pharmacists. *Dorie Wilkey Hoody, Pharm.D., Alexandra Hilt, Pharm.D.;* University of Colorado Hospital, Denver, CO.

PURPOSE: Pharmacists at University of Colorado Hospital are responsible for ensuring that antimicrobial agents are appropriately utilized with regards to spectrum of activity, dose/frequency, toxicity, and formulary requirements. Documentation with outcomes data are key components for proving effectiveness of these interventions. This study utilizes a handheld electronic device for recording clinical interventions of an infectious disease pharmacist to 1) project yearly cost savings of the pharmacist, 2) address inquiries by Pharmacy and Therapeutics Committee regarding utilization of non-formulary antimicrobials, 3) identify areas of educational need to facilitate appropriate antimicrobial utilization by physicians and other practitioners, and 4) assess overall utility of handheld devices for intervention tracking. Favorable outcomes will support its use by pharmacists providing specialty services.

METHODS: A Microsoft Access® program was specifically designed for

interventional analysis of infectious disease pharmacists. Key fields of this database include patient information for evaluation of antimicrobial therapy such as allergies, renal function, infection site, significant microbiology, and other profile antimicrobials. This program has been installed onto a handheld device and is utilized for immediate recording of interventions during daily rounds with the infectious disease consult service and patient profile review. These records are exported into the original Microsoft Access program database for future analysis.

RESULTS: The program has been implemented and data is currently being collected. Results from the first six months will be analyzed and presented at the meeting.

139. Characterization and outcomes assessment of multisite, primary care, pharmacotherapy clinics. *Ginger A. Woodford, Pharm.D., Daniel R. Touchette, Pharm.D., MA, Jacquelyn S. Hunt, Pharm.D., BCPS; Providence Medical Group; Oregon State University, Portland, OR.*

PURPOSE: The clinical pharmacy program at Providence Medical Group (PMG) has expanded over four years to include 4 pharmacy practitioners in 9 clinic sites. Physicians may refer patients at three levels of pharmacy intervention (education, consult, or collaborative). This study characterizes clinical pharmacist activities and assesses outcomes from Pharmacotherapy Clinics in a multisite, non-academic, primary care medical group.

METHODS: A retrospective review was performed on a random sample of patients referred to Pharmacotherapy Clinics (June-December 2000). Data extracted include level of service, referral reason, scope of issues addressed, therapeutic interventions and follow-up status. Surrogate markers were evaluated for patients referred for hypertension, diabetes and/or hyperlipidemia.

RESULTS: Ninety-four patients were evaluated. In 80% of referrals, physicians requested collaborative management. Reasons for referral were diabetes (42%), hypertension (23%), and hyperlipidemia (9%), with the remaining 26% spread among > 15 other problems. More often than not, additional health issues were identified and/or addressed. Most common interventions included initiation, discontinuation, switch or titration of drug therapy. Significant improvement was seen in glycosylated hemoglobin (9.31% vs 7.5%; $p=0.0001$), blood pressure (systolic 146 mm Hg vs 138 mm Hg, $p=0.003$; diastolic 80 mm Hg vs 76 mm Hg, $p=0.01$), and low-density lipoprotein (83.6 mg/dl vs 80.1 mg/dl; $p=0.05$).

CONCLUSIONS: Collaborative management is the most common level of service requested by physicians referring to PMG Pharmacotherapy Clinics. Suboptimal efficacy, tolerance and cost of medicines are primary reasons for drug regimen adjustments. Collaborative care with clinical pharmacists results in significant improvements in control of diabetes, hypertension and hyperlipidemia.

140. Pharmacy medication history interview service. *Karissa Welter, Pharm.D., Elise McInnis, Pharm.D.; Northeast Medical Center, Concord, NC.*

PURPOSE: Pharmacists (RPh) are trained to focus on medication (Med) related issues. As a result, the Medication History Interview Service (MHIS) hopes to gain more accurate and complete information pertaining to patients' medication histories. Our goal is to improve patient care and decrease health care costs through verifying patient home medication and allergies, improving poly-pharmacy and compliance issues by avoiding potential adverse drug events (ADE) and adverse drug reactions (ADR), increasing ADR reporting, as well as facilitating medication use throughout hospitalization.

METHODS: The MHIS was established in a community medical center. 1 RPh daily from 11 a.m. to 7 p.m. staffs the MHIS. The MHIS RPh is notified of new admissions via Meditech printout. MHIS RPh interviews patients about home medications, compliance, adverse effects (AE), allergies, tobacco/alcohol use and vaccination history. After interview complete, MHIS RPh writes a progress note detailing information with appropriate recommendations. If necessary, the MHIS RPh will discuss pertinent information w/physician (MD) and nurse (RN). The MHIS RPh follows all recommendations up the next day. In preparation of MHIS, a 6-month staff development lecture series was established. RPhs attend mandatory weekly lectures reviewing different disease states and improving communication skills. In addition, RPh must complete "hands on training" prior to being deemed competent for MHIS. Data collection will include: number (#) of patients interviewed by MHIS, # recommendations followed by MDs, # ADR reported, and # ADE reported.

RESULTS: Pending review after 5 months of service.

141. An analysis of retention and turnover rates among academic pharmacy departments over five years. *Orly Carter, Pharm.D., Surakit Nathisuwan, Pharm.D., Patricia Jeppson, Pharm.D., Mark A. Munger, Pharm.D., FCCP; University of Utah Health Sciences Center, Salt Lake City, UT.*

PURPOSE: Pharmacy faculty manpower has been debated within the academic pharmacy community over the last several decades. Previous investigators have studied job satisfaction among faculty members, but have not evaluated faculty retention and turnover among various pharmacy departments. The aim of this study was therefore, to evaluate retention and

turnover rates in the Departments of Pharmacy Practice (PP) Pharmacology/ Toxicology, Pharmaceutics, and Medicinal Chemistry (BS) over the last five years.

METHODS: Individual faculty members in 80 colleges of pharmacy in the United States were tracked between the years 1996-2001 using the American College of Pharmacy Education (ACPE) published rosters. A faculty member was defined as a full time pharmacy faculty member with an academic rank of instructor, or assistant, associate, or full professor. Differences were analyzed by chi square with significance set at p value of < 0.05 .

RESULTS: A greater frequency of PP faculty resigned (1079/10139 [10.6%]) compared to BS (440/7437 [5.9%], $p<0.0001$). This finding was significantly constant over the 5-year period. A higher percent of females resigned in PP (14.8%) than males (8.0%, $p<0.0001$) despite a 1.6 fold male/female faculty ratio. Likewise, regardless of a 4.2 fold male/female ratio in the BS group, females resigned at 7.3% rate versus 5.6% males ($p<0.02$)

CONCLUSION: Over a 5-year period, PP constantly exhibits a higher turnover rate compared to BS. Females showed a significantly higher turnover rate than males across all pharmacy academic departments. New retention approaches, especially for female faculty members, should be explored.

142. Conformity of prescribing practices with National Cholesterol Education Program guidelines at a Saudi Arabian cardiac hospital. *Abdulhamid AlBisher, M.S., Tawfeeq Najar, M.S., Dr. Khalid AlNemer, Pharm.D.; Prince Sultan Cardiac Center, Riyadh, Saudi Arabia.*

PURPOSE: This study evaluated prescribing practices for lipid-lowering agents at our institution to determine extent of compliance with National Cholesterol Education Program (NCEP) guidelines and compared outcomes for patients treated according to NCEP guidelines with those who were not.

METHODS: This retrospective study examined 306 randomly selected medical records of adult inpatients (170 male/136 female) that were prescribed lipid-lowering agents to determine adherence to NCEP guidelines. Patients with congenital hypercholesterolemia and patients < 21 years of age were excluded. Post-treatment cholesterol and triglyceride levels and rehospitalization rates were compared for patients treated according to NCEP guidelines with those who were not.

RESULTS: Fifty-two percent of patients were treated according to NCEP guidelines and 48% did not conform to NCEP guidelines. At six months, all patients had significant decreases in mean total cholesterol and mean LDL ($p<0.001$). Patients treated according to NCEP guidelines had greater decreases in total cholesterol and LDL-cholesterol compared with those who were not. No statistical difference was found in incidence of rehospitalization or changes in triglyceride or HDL levels. Patients with hypertension, total cholesterol levels > 6.1 mMol/L, and LDL levels > 4 mMol/L were more likely to be treated according to NCEP guidelines ($p<0.05$).

CONCLUSION: Despite increasing evidence supporting use of NCEP guidelines in the management of hypercholesterolemia, nearly half of lipid-lowering agents prescribed at our center were not in conformity with NCEP guidelines. Improving awareness and clinical application of these guidelines are needed to improve patient outcomes and quality of care.

143. Applying clinical practice guidelines to promote appropriate enoxaparin prescribing in a cardiac center. *Meshal AlMutairi, Pharm.D., R.Ph., Abdulhamid AlBisher, M.S., Khalid AlNemer, Pharm.D., Kris Malmquist, R.Ph., BCNSP; Prince Sultan Cardiac Center, Riyadh, Saudi Arabia.*

PURPOSE: Guidelines were developed to promote rational enoxaparin prescribing. Goals of this study were to evaluate our center's enoxaparin prescribing practices and compliance with prescribing guidelines.

METHODS: Guidelines on appropriate patient selection, indications, dosage and duration of therapy were developed by pharmacists and cardiologists. A prospective evaluation of patients receiving enoxaparin was conducted to determine patient demographic data, indications, dosage, duration, relevant contraindications, compliance with guidelines and drug costs.

RESULTS: 221 patients were evaluated (71.1% male/28.9% female). Average age: 62.4 ± 12.1 years; average weight: 69.8 ± 12.03 kg. Average prescribed dose was 56.1 ± 8.4 mg. Indications were unstable angina/non Q-wave myocardial infarction (60.5%), as substitute for heparin (20.5%), and anticoagulation, with warfarin, until target INR achieved (7.9%). Duration was 48 hours or less in 25.8% and 3-8 days in 67.3% of patients. Compliance with guidelines was observed in 51.6% of patients. Most frequent reasons for noncompliance were: failure to appropriately monitor enoxaparin therapy or substitute unfractionated heparin in patients with severe renal failure, or prescribing enoxaparin for unapproved indications. Enoxaparin consumption was reduced by 38% compared to before implementation of guidelines. Enoxaparin costs decreased by \$2374/month.

CONCLUSION: Applying enoxaparin guidelines at our institution resulted in substantial drug cost savings. Additional savings are anticipated by increasing compliance with guidelines through further staff education and involvement of clinical pharmacists. A significant limitation of our study is that drug acquisition costs only were monitored and reported. Other costs of therapy deserve further study to determine their economic impact on overall savings.

144. Development, marketing, implementation and reimbursement for a pharmacist-managed smoking cessation program. Alan Zillich, Pharm.D., Melody Ryan, Pharm.D., BCPS, CGP, Aimee Adams, Pharm.D., Bryan Yeager, Pharm.D., BCPS; University of Kentucky, Lexington, KY.

PURPOSE: Pharmacists have developed programs for managing several chronic disease states, but there are few programs for smoking cessation. The objective of this paper is to describe the development, marketing, implementation and reimbursement for a pharmacist-managed smoking cessation program.

METHODS: A partnership was formed between the department of pharmacy and the medical center human resources department to provide smoking cessation to current employees. Permission and support to use a previously-developed, but non-functioning smoking cessation program was obtained. This program utilized weekly, one-hour, group classes over 12 weeks and incorporated nicotine replacement therapy with extensive behavioral modification counseling. Four pharmacists were trained as program facilitators. Program times, dates, and locations were planned. A joint marketing team was formed using human resources, pharmacy, health promotions, and wellness departments. Using a limited budget, program advertising was accomplished through multiple media. Initial courses were offered at no charge. After 2 courses, a nominal fee was assessed to each participant. Program effectiveness was studied. Reimbursement through a local third-party organization will be sought by presenting the program's effectiveness on smoking cessation rates.

RESULTS: The smoking cessation program was offered beginning July 2000. Eighty-five people attended the introductory class among 4 sessions. Six-month chemically verified abstinence rates of 26% were achieved (data presented previously). Sessions are continuously offered every 3 months. Participant reimbursement for the program is being discussed with a local insurance group.

CONCLUSION: The pharmacist-based smoking cessation program was successfully developed, marketed and implemented. Reimbursement strategies are ongoing.

145. Does a medication renewal service improve blood pressure control? Alan Zillich, Pharm.D., Barry L. Carter, Pharm.D., BCPS, FCCP, Michael Ernst, Pharm.D., BCPS, Michael W. Kelly, Pharm.D., M.S.; University of Iowa, Iowa City, IA.

PURPOSE: To evaluate a pharmacist-managed prescription renewal service on blood pressure control.

METHODS: Age, gender, diagnosis of heart failure and/or diabetes and frequency of clinic visits were recorded for all patients seen at the Family Medicine Clinic with an ICD-9 code for hypertension during the year 2000. Telephoned renewal requests for the year 2000 were recorded in a log containing patient name, age, medication requested, strength, and directions. Each log was reviewed to identify patients requesting a renewal for an antihypertensive. Patients who used the renewal service were compared with those who did not. Blood pressure control rates were calculated for each group as the number of patients who met blood pressure goals from recent national guidelines. ANOVA and stepwise logistic regression was performed to examine the use of the renewal service on blood pressure control between the two groups. Co-variables such as age, gender, clinic visits were included in the model.

RESULTS: Of the 940 patients seen for hypertension, 336 used the renewal service at least once while 604 did not. There were no statistical differences between the two groups with respect to blood pressure control ($p=0.86$; CI 0.7-1.3). Blood pressure control did not improve more among those patients who used the renewal service more frequently ($p=0.48$; CI 0.9-1.2).

CONCLUSION: This medication renewal service had no effect on blood pressure control. The results suggest that continuation of this time consuming service does not improve outcomes related to medication renewal access.

146. Pharmacy-based management of medication-related weight-gain in psychiatry. Mark E. Schneiderhan, Pharm.D., Melissa Holt, M.S., Mary T. Keehn, MHPE, PT, Melissa Voller, RD, LD, Melissa Chu, Pharm.D. candidate, Suzanne Chau, Pharm.D. candidate, Maggie Lee, Pharm.D. candidate; Eli Lilly and Company, Indianapolis, IN; Pfizer Inc. New York, NY.

An estimated 40-80% of patients taking some psychotropic medications may experience weight gain, which can exceed their ideal body weight by 20% or greater. Often, patients who experience weight gain with medications are at higher risk of noncompliance and relapse of their illness. There is limited information on the treatment of medication-related weight gain in psychiatric patients. The purpose of this pharmacy-based program is to provide psychiatric patients with education and experience in the areas of health, exercise, and nutrition to prevent and manage weight-gain associated with medications. The program is reimbursed through Medicaid insurance. A history of medication-related weight gain is the main criteria for admission into the group. A psychiatric pharmacist collaborates with a psychology intern, dietician, and physical therapist in a one-hour weekly session over a minimum of 16 weeks. Patients are required to record weekly

food intake/exercise logs. Activities range from group discussions to walking sessions. The *LEARN Program for Weight Management 2000* by Kelly D Brownell, Ph.D. is a textbook used throughout the program. One of the topics will include setting realistic goals for eating and exercise. Eating behavior questionnaires are assessed periodically during the program. Body weights (kg) are assessed weekly and body composition is determined approximately every 4 weeks using bio-impedance. Waist measurements (cm) are obtained approximately every 4 weeks. This pharmacy-based program may not only address the medication-related problem of excessive weight gain, but also improve the patient's self-esteem, medication compliance and reduce risk factors for cardiovascular diseases and diabetes.

147. Clinical outcomes of a pharmacist-managed tobacco cessation program. Julianne E. Himstreet, Pharm.D., Daniel Neal, Pharm.D., Kenny Har, Pharm.D.; Eugene Veterans Administration Community Based Outpatient Clinic, Eugene, OR; Veterans Administration Roseburg Health Care System, Roseburg, OR.

PURPOSE: This report documented the clinical outcomes of a pharmacist managed tobacco cessation program at three Veterans Administration outpatient clinics.

METHODS: Data for tobacco cessation rates were collected from 192 participants enrolled in tobacco cessation courses facilitated by clinical pharmacists from November 1, 2000 to November 1, 2001. Participants in the tobacco cessation course attended 6 classes based on the American Lung Association Freedom from Smoking program. Upon completion of the course, the participants chose to use either the nicotine patch (21 mg/day for 4 weeks, 14 mg/day for 2 weeks, 7 mg/day for 2 weeks), bupropion SR (150 mg twice a day for 9 weeks) or to quit without medication. Follow up classes occurred every 2 weeks for a total of 8 weeks after the tobacco quit day. Tobacco cessation rates were collected at 8 weeks, 3 months, 6 months and 12 months after quitting tobacco products.

RESULTS: Nicotine patches were prescribed for 128 participants, bupropion for 50 participants and 14 participants attempted to quit without medications. After 8 weeks, 60 participants (47%) using the nicotine patch, 29 participants (58%) using bupropion, and 7 participants (50%) using no medications had quit tobacco products. Cessation rates 3 months after quit day were 38% (48/128) for the group using nicotine patches, 50% (25/50) for the group using bupropion, and 43% for those not using medications.

CONCLUSIONS: Preliminary results from this program show successful tobacco cessation rates using nicotine patches, bupropion or no medications when these modalities were combined with classes addressing behavior modification. Tobacco cessation programs provide enormous opportunities for pharmacists to improve the health of patients and assist patients in achieving the goal of a tobacco-free lifestyle.

148. Value of pharmacist osteoporosis screening in a community pharmacy practice. Karen L. Daniel, Aisy Fabelo, Pharm.D.; Nova Southeastern University, Ft. Lauderdale, FL.

PURPOSE: To determine the value of clinical pharmacy services in the screening, prevention, and treatment of osteoporosis in a community pharmacy practice setting.

METHODS: Patients who presented to the Nova Southeastern University Clinic Pharmacy for a heel ultrasound bone mineral density (BMD) from October 2000 to October 2001 were included. All patients received an explanation of BMD results and education on the prevention and/or treatment of osteoporosis. Osteoporosis pharmacotherapy was recommended to the referring physician when appropriate. At the end of the study period, patients were surveyed by mail to assess knowledge of osteoporosis and osteoporosis prevention strategies, current osteoporosis pharmacotherapy, and perceived value of interaction with the clinical pharmacist.

RESULTS: One hundred nine patients were screened for osteoporosis. All were females, and the mean age was 58.2 years. The mean BMD and T-score were 0.508 g/cm² and -0.7, respectively. Forty-four patients (40.4%) had T-scores scores that indicated osteopenia or osteoporosis. Initiation and/or an increase in calcium supplementation was recommended for sixty-eight patients (62.4%), and osteoporosis pharmacotherapy was suggested for fourteen patients. Survey data collection to assess educational and intervention outcomes is currently in progress.

CONCLUSIONS: Results are preliminary. Final conclusions are pending. This study should help demonstrate the beneficial role of clinical pharmacy in osteoporosis screening, prevention, and treatment.

149. Impact of a clinical pharmacist organizing and managing a diabetes clinic at Siouxland Community Health Center. Steven T. Boyd, Pharm.D., David M. Scott, Ph.D., R.Ph., Samuel C. Augustine, Pharm.D., FSHP, Bruno J. Himmler, M.D., Michelle L. Stephan, R.N.; University of Nebraska Medical Center, Omaha, NE; Siouxland Community Health Center, Sioux City, IA.

PURPOSE: The implementation of ambulatory disease state management (DSM) services by a clinical pharmacist working with the Siouxland Community Health Center (SCHC) team will reduce HbA_{1c} levels of patients with diabetes mellitus type 1 or 2. Associated conditions to be studied are hypertension, obesity, and cholesterol.

METHODS: Eligible patients must be members of the SCHC, nineteen years of age or older, and have a diagnosis of DM type 1 or 2. The American Diabetes Association recognizes HbA_{1c} less than 7.0% as optimal for a patient with diabetes. Patients who consent will be randomly subdivided at baseline into four groups by HbA_{1c}. (Treatment-1 > 7.0%, Control-1 > 7.0%) and (Treatment-2 < 7.0%, Control-2 < 7.0%). Treatment-1,2 will receive four pharmacist encounters consisting of diabetes education, nutrition, exercise (YMCA), and a group session (registered nurse and dietician). A free blood glucose monitor and strips will be given to all consented study participants for nine months. After nine months, patients within Control-1 may crossover to a third treatment group (Treatment-3) and receive clinical pharmacy services for the remainder of the study.

RESULTS/CONCLUSIONS: Investigators hypothesize the implementation of DSM services by the clinical pharmacist will reduce HbA_{1c} from baseline to nine months greater in the Treatment-1,2 versus Control-1,2. Patients crossing over from Control-1 to Treatment-3 are postulated to have an additional drop in HbA_{1c} due to clinical pharmacy encounters. Implementation of DSM services in the ambulatory Siouxland Community Health Center should improve HbA_{1c} outcome in the management in patients with diabetes.

STUDENT, RESIDENT, FELLOW RESEARCH IN PROGRESS

These papers describe original research by students, residents, and fellows in therapeutics, pharmacokinetics, pharmacodynamics, pharmacoepidemiology, and pharmacoepidemiology in which the research effort is still on-going. The abstract title and authors are published in *Pharmacotherapy*; the full abstract will be published in the meeting program book.

150. Assessment of adherence to American Heart Association/American College of Cardiology consensus guideline recommendations in patients with acute coronary syndromes discharged from a cardiology service. *Anna M. Wodlinger, Pharm.D., John A. Pieper, Pharm.D., FCCP, BCPS, Debbie Montague, MS, BCPS; University of North Carolina, Chapel Hill, NC.*

151. Reduction of acute radiocontrast-induced nephropathy with N-acetylcysteine prior to coronary angiography. *Anna M. Wodlinger, Pharm.D., John A. Pieper, Pharm.D., FCCP, BCPS, Debbie Montague, MS, BCPS; University of North Carolina Hospitals and School of Pharmacy, Chapel Hill, NC.*

152. Assessment of bleeding with glycoprotein IIb/IIIa inhibitors and predictors of bleeding risk. *Kari L. Mount, Pharm.D., Kerry K. Pickworth, Pharm.D., Sondra J. Sierawski, R.Ph.; Ohio State University Medical Center, Columbus, OH.*

153. Evaluation of the impact of a clinical pathway on acute myocardial infarction quality indicators. *Megan Brewer, Pharm.D., Jeb Burchenal, M.D., Marianne McCollum, Ph.D., Kathleen A. Stringer, Pharm.D.; University of Colorado Hospital; University of Colorado Health Sciences Center, Denver, CO.*

154. The chronobiologic effects of atorvastatin: morning versus evening administration in hyperlipidemic adults. *Roda Plakogiannis, BS, Pharm.D., Joseph Reilly, BS, Pharm.D., Henry Cohen, MS, Pharm.D., BCPP, David Taft, Ph.D., Edmund J. Bini, M.D.; Arnold & Marie Schwartz College of Pharmacy, LIU, NY; Harbor Healthcare System, New York, NY.*

155. Development and implementation of a standardized diabetes educational program to improve the quality of care for patients with diabetes mellitus. *Kristen E. Rogers, Pharm.D. candidate, Debra J. Barnette, Pharm.D., Patricia A. Rozek; University of North Carolina, Chapel Hill, NC; University of Cincinnati, Cincinnati, OH.*

156. An assessment of a physician education intervention and patient assessment tool to improve adherence to recommended aspirin therapy for patients with diabetes mellitus. *Andrew G. Wright, Pharm.D. candidate, Debra J. Barnette, Pharm.D., Patricia A. Rozek, Kristen E. Rogers; University of North Carolina, Chapel Hill, NC; University of Cincinnati, Cincinnati, OH.*

157. Demonstrating the effect of attachments onto electronic medical records in improving adherence to vaccination recommendations for patients with type 2 diabetes mellitus. *Kristen E. Rogers, Pharm.D. candidate, Debra J. Barnette, Pharm.D., Patricia A. Rozek; University of North Carolina, Chapel Hill, NC; University of Cincinnati, Cincinnati, OH.*

158. Screening and treatment for dyslipidemia in HIV-infected patients: a multicenter retrospective study. *Eli J. Korner, Pharm.D., Richard Bankowitz, M.D., MBA, Julie Cerese, R.N., MSN, Laura Weber, MS, Mark A. Keroack, M.D., MPH; Clinical Practice Advancement Center; University HealthSystem Consortium, Oak Brook, IL.*

159. The clinical and economic analysis of caspofungin for aspergillus infections. *Brian A. Potoski, Pharm.D., Debra A. Goff, Pharm.D., Sondra J. Sierawski, R.Ph., Sam L. Penza, M.D.; Ohio State University, Columbus, OH.*

160. Outcomes from an *Acinetobacter baumannii* outbreak in a large community hospital. *Sandy J. Close, Pharm.D., Selina Lee, BCPS, Steven J. Martin, Pharm.D.; University of Toledo, Toledo, OH.*

161. Non-adherence with multiple sclerosis therapies. *Kimberly K. Daugherty, Pharm.D., Melody Ryan, Pharm.D.; University of Kentucky, Lexington, KY.*

162. A high-performance liquid chromatography assay validation of manumycin A, natural antibiotic produced by *Streptomyces parvulus*, in mouse plasma. *Joanne Gonzales, Sai-Ching Jim Yeung, M.D., Ph.D., Judith A. Smith, Pharm.D., BCOP; University of Houston; M.D. Anderson Cancer Center, Houston, TX.*

163. An analysis of aspirin use in diabetic adults. *Laura Morgan, Pharm.D., Oralia V. Bazaldua, Pharm.D., BCPS; University of Texas Health Science Center at San Antonio, Department of Family and Community Medicine, San Antonio, TX.*

164. Determination of the in vitro N-demethylation of erythromycin by CYP3A4 and CYP3A5. *Alison C. Lyke, Pharm.D., Roy L. Hawke, Pharm.D., Ph.D., Morris J. Clarke, Ph.D., Celeste M. Lindley, Pharm.D.; University of North Carolina at Chapel Hill, Chapel Hill, NC.*

165. Evaluation of bupropion hydroxylation as a probe of cytochrome P450 2B6 activity in cultured human hepatocytes. *Kevin Haynes, Pharm.D., Stephanie R. Faucette, Pharm.D., Celeste M. Lindley, Pharm.D., Edward L. LeCluyse, Ph.D., Roy L. Hawke, Pharm.D., Ph.D.; University of North Carolina at Chapel Hill, Chapel Hill, NC.*

166. Contribution of CYP3A4 and CYP2C8 to the in vitro metabolism of paclitaxel and its metabolites. *Kevin J. Laliberte, Pharm.D., Morris J. Clarke, Ph.D., E. Claire Dees, M.D., Celeste Lindley, Pharm.D.; University of North Carolina at Chapel Hill, Chapel Hill, NC.*

167. The correlation between functional health literacy and the ability to understand pharmacy-related terminology in an indigent population. *Yolanda M. Hardy, Pharm.D., Laura E. Hall, Pharm.D., Ruth Emptage, Pharm.D.; Ohio State University, Columbus, OH.*

168. Kidney clinic: a group medical model for community outreach, patient wellness, and compliance. *Lt. Robin A. Bartlett, Pharm.D., Christopher C. Lamer, Pharm.D., Capt. David R. Taylor, R.Ph., R.N., PA-C, Gloria M. Arnold, R.Ph.; Cherokee Indian Hospital, Cherokee, NC.*

169. Implementation and evaluation of a pharmacist-managed asthma care clinic in a family practice setting. *Barbara L. Novak, Pharm.D., Rex W. Force, Pharm.D., BCPS, David M. Hachey, Pharm.D.; Idaho State University Family Practice, Pocatello, ID.*

RESEARCH INSTITUTE

The following papers, based on Fellowships and Research Awards provided by the ACCP Research Institute, will be presented. Full titles and authors are listed, although a complete abstract may not be available for all papers at the time of this printing.

170E. GlaxoSmithKline Pharmacotherapy Research Award: Correlation between NF- κ B and changes in chlorzoxazone disposition following an acute phase response in humans. *Peter J. Van Ess, Pharm.D., Christina M. Charriez, Pharm.D., Rajna T. Tosheva, Ph.D., Steven I. Shedlofsky, M.D., Robert A. Blouin, Pharm.D.; University of Kentucky; VA Medical Center, Lexington, KY.*

Published in *Pharmacotherapy* 2001;21(10):1308.

171. Pharmacia Applied Health Outcomes Research Award: Patient willingness to pay for lipid management services provided by pharmacists: an application of the contingent valuation method. *Karen Blumenschein, Pharm.D., Alan Zillich, Pharm.D., Patricia Freeman, Ph.D., Magnus Johannesson, Ph.D.; University of Kentucky, Lexington, KY; American Pharmacy Services Corporation, Frankfort, KY; Stockholm School of Economics, Stockholm, Sweden.*

This field experiment compared hypothetical and real purchase decisions for a pharmacist provided lipid disease-management program among 114 subjects treated with lipid lowering drugs. The objectives of the investigation were to examine whether dichotomous choice contingent valuation questions lead to hypothetical bias for the good, and to assess whether "definitely sure" hypothetical yes responses correspond to real purchase decisions. Subjects were randomly divided into two groups. One group received a dichotomous choice contingent valuation question and a certainty question ("probably sure" or "definitely sure") followed by a real purchase decision. The second group received only the real purchase decision question. Two different prices were used: \$15 and \$60. In the hypothetical group, 33% of subjects said that they would purchase the good at the stated price; 26% were "definitely sure" that they would purchase the good and 29% actually purchased the good. In

the control group, 25% of subjects purchased the good (no significant differences). These results, i.e. no hypothetical bias, contrast with previous findings within the health sector and suggest that the degree of hypothetical bias may vary between health care goods and survey populations.

Furthermore, the results suggest that the hypothetical bias may depend on the degree of certainty for the hypothetical yes responses. Finally, this study confirms previous findings which suggest that "definitely sure" hypothetical yes responses can be used as a proxy for real purchase decisions.

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