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ORiGInAL RESEARCH

These papers describe original research in therapeutics, pharmacokinetics, pharmacodynamics, pharmacoeconomics, pharmacopoeiology, and pharmacogenomics.

ADR/Drug Interactions


PURPOSE: Adverse drug-related events (ADREs) are defined as unfavorable medical events related to the use of medications. Several studies have estimated the incidence of drug-related hospitalization (DRH); however, few data are available for the DRH rate and characterization in Canada. The objectives of this study were to determine the frequency, severity, preventability and classification of ADREs resulting in hospitalization in a large tertiary care Canadian hospital, and to evaluate patient, prescriber, drug, and system factors associated with these events.

METHODS: Consecutive adult admissions to a tertiary care internal medicine service were prospectively enrolled during a 12-week period in 2003. Hospitalization was defined as drug-related if it was directly related to one of the eight predefined classes defined by Hepler and Strand. Severity and preventability were also classified. Multivariate regression analysis was used to evaluate patient, prescriber, drug, and system factors associated with DRH. RESULTS: During the study period 365 patients were enrolled. DRH was found to be 24.1% (95% CI 20.6-27.8%) of which 72.1% (95% CI 63.7-79.4%) were deemed preventable. Severity was classified as mild, moderate, severe, and fatal in 81.1% (95% CI 74.1-87.6%), 13.3% (95% CI 7.8-21.4%), 3.1% (95% CI 0.4-10.3%), and 2.4% (95% CI 0.0-10.2%), respectively. Adverse drug reactions 35.3% (95% CI 27.3-43.9%), wrong/suboptimal drug 17.6% (95% CI 10.5-27.9%), and drug-error 7.4% (95% CI 3.6-13.1%) were the most common classes of DRH. No independent risk factors for DRH were identified. CONCLUSION: Approximately one-quarter of patients in our study were admitted for a drug-related cause and more than 70% were deemed preventable. Drug-related hospitalization is a significant problem that merits further research and intervention.

2. Interaction between bupropion and warfarin: a report of four cases. Katie M. Spidel, Pharm.D., Stephanie R. Maciejewski, Pharm.D., Daniel E. Hillman, Pharm.D., The Cardiac Center of Creighton University, Omaha, NE.

BACKGROUND: Warfarin (W) is predominantly metabolized by CYP3A4 and 2C9. Bupropion (B) is metabolized by CYP 2B6. B is only 84% bound to plasma proteins. An interaction between B and W seems unlikely. We report 4 cases of an interaction between B and W.

DESCRIPTION OF CASES: Four patients (pts) had been stable on W for 3.5 mos to 2 yrs with INRs in the accepted range. Indication for W was DVT in 3 pts and AF in 1 pt. B was added to therapy in 3 pts for smoking cessation and 1 pt for depression. One pt presented to ER with a hemorrhage in the elbows 7 days after initiating B. The PT/INR on B and W in this pt was 57.8/5.0. The other 3 pts did not have adverse events, but had PT/INR rechecked 6–8 days after initiating B. The resultant PT/INR were 50.7/5.9, 48.8/3.2, 33.5/3.8. All pts had B discontinued with normalization of PT/INR. W was restarted without further incident. In pts where B was used for smoking cessation, subjects had not yet stopped smoking at the time of the interaction. Two pts were not taking any medications other than B and W. The pt with AF was taking furosemide, digoxin and lisinopril. The pt with depression was taking metoprolol and HCTZ for hypertension.

CONCLUSION: We report 4 cases of substantial interaction between B and W. No readily apparent mechanism for the interaction was identified. One case resulted in a spontaneous hemorrhage requiring medical intervention. A prospective evaluation of potential pharmacokinetic/pharmacodynamic interaction between B and W is warranted.

Analgesia

3. Confidence vs. competence: comparing physicians’ self-reported pain management comfort level with an objective knowledge assessment in a large urban academic medical center. Mark A. Douglas, Pharm.D.1, Gail M. Burniske, Pharm.D.2, Gail Wilkes, R.N.C., M.S., A.O.C.N.2, Daniel P. Alford, M.D., M.P.H.2, Jeffrey L. Greenwald, M.D.2, (1)Northeastern University Department of Pharmacy Practice/Boston Medical Center, Boston, MA; (2)Boston Medical Center, Boston, MA.

PURPOSE: Pain management practices at our medical center are less than optimal, despite the implementation of institutional pain management guidelines. We sought to compare physicians’ self-reported comfort level in several pain management competencies with an objective assessment of their knowledge in these areas.

METHODS: New medical residents, senior residents, and attending physicians were asked to complete a questionnaire that assessed their comfort level with core pain management competencies (Table 1). We compared physicians’ self-reported comfort level with an objective assessment of their knowledge using validated and standardized case vignettes. Physicians were also asked about their awareness of the hospital’s pain management guidelines.

RESULTS: The questionnaire response rate was 30% (91/304). Only 23% (21/91) of those surveyed reported awareness of the pain management guidelines and only 48% (10/21) of those that were aware of the guidelines used them “rarely” or “never.” An overall disparity between physician self-reported comfort level and case vignette performance was observed (Table 1). Attending physicians and senior residents often reported a greater degree of comfort than new medical residents, despite an overall low performance on the objective measures.

Table 1. Physicians’ self-reported comfort level and corresponding knowledge assessment

<table>
<thead>
<tr>
<th>Physician type</th>
<th>Chronic-continuity Multidose Breakthrough</th>
<th>Comfortable</th>
<th>Correct</th>
<th>Comfortable</th>
<th>Correct</th>
<th>Comfortable</th>
<th>Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>New residents (n=34)</td>
<td>12</td>
<td>45</td>
<td>26</td>
<td>50</td>
<td>33</td>
<td>27</td>
<td>18</td>
</tr>
<tr>
<td>Senior residents (n=30)</td>
<td>69</td>
<td>23</td>
<td>62</td>
<td>33</td>
<td>53</td>
<td>27</td>
<td>18</td>
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<tr>
<td>Attending physicians (n=27)</td>
<td>81</td>
<td>44</td>
<td>59</td>
<td>54</td>
<td>67</td>
<td>44</td>
<td></td>
</tr>
</tbody>
</table>

CONCLUSION: Educational initiatives are needed to address low physician competency in pain management. These initiatives must take into account the discrepancy between physician comfort and relatively low level of competency, irrespective of level of training. Although our institution has pain management guidelines as a means of ensuring optimal pain management, they were rarely used.

Cardiovascular

4. Poor absorption of amiodarone administered via nasogastric tube in patients following thoracoabdominal esophagectomy. James E. Tsindale, Pharm.D.1, Heather A. Wroblewski, R.N., B.S.N., CCRN1, Karen M. Rieger, M.D.1, Zane Hammoud, M.D.2, Jo Ann Brooks, R.N., DNS1, Jerry Young, M.D.2, Donna Wall, Pharm.D.1, Kenneth A. Kesler, M.D.1. (1)Purdue University, 1001 West 10th Street, Indianapolis, IN; (2)Indiana University School of Medicine, Indianapolis, IN; (3)Clarian Health Partners, Indianapolis, IN.

PURPOSE: Atrial fibrillation (AF) occurs in up to 1/3 of patients following thoracoabdominal esophagectomy (ES), and is associated with increased morbidity and mortality. While planning a study of amiodarone for prophylaxis, we considered it desirable to avoid prolonged intravenous (IV) administration due to the potential for adverse effects. However, few data exist regarding the gastrointestinal absorption of drugs following ES. This study was conducted to determine whether amiodarone administered via nasogastric (NG) tube is absorbed in patients following ES.

METHODS: Plasma amiodarone concentrations were determined in 14 patients who underwent ES and in 13 patients that underwent pulmonary resection (PR, control group). At induction of anesthesia, a continuous IV line was administered for a bolus dose of amiodarone (3 mg/kg) and then infused via nasogastric tube at 5 mg/h. Blood samples were obtained from the IV catheter before dosing (t0) and at 45, 260, and 508 min after initiating dosing. Amiodarone plasma concentrations were measured by HPLC. Absorption of amiodarone was determined by comparing mean plasma concentrations between patients in the ES group and the PR group.

CONCLUSION: Mean plasma concentrations of amiodarone were significantly higher in patients following thoracoabdominal esophagectomy versus those following pulmonary resection. Improved absorption of amiodarone in patients following ES is potential evidence suggesting a need for further investigation of alternative routes of administration for cardioversion of atrial fibrillation.
INTRODUCTION: In patients admitted for decompensated HF, an acute rise in Scr has been associated with increased mortality. However, late Scr increases may reflect worsening clinical status during a prolonged hospitalization, whereas early increases likely reflect temporary but correctable volume depletion. Objective: To determine the prevalence, onset time, and persistence of Scr elevations in hospitalized HF patients receiving Nesiritide (NES) vs nitroglycerin (NTG).

METHODS: Scr data from the Vasodilation in the Management of Acute Congestive HF (VMAC) trial, a randomized evaluation of NES vs NTG in subjects with acute HF, were retrospectively analyzed. The rates of Scr increases >0.5 mg/dL from baseline through study day 30 were calculated in patients who received high-dose diuretics and in patients who received low- or moderate-dose diuretics. The RR and 95% CI of Scr increase for NES vs NTG were based on the Mantel-Haenszel estimate. High-dose diuretic use was defined as a maximum daily dose of furosemide ≥ 160 mg, bumetanide ≥ 4 mg, torsemide ≥ 80 mg, metolazone ≥ 10 mg, chlorothiazide ≥ 1000 mg, or hydrochlorothiazide ≥ 50 mg or concurrent treatment with 2 or more of these diuretics regardless of dose.

RESULTS: Overall, 480/489 VMAC subjects (98%) had evaluable Scr data (NES: n=268; NTG: n=212). Of these, 149 NES (56%) and 131 NTG (62%; P=0.19) subjects received high-dose diuretics. The risk of Scr increase >0.5 mg/dL was unaffected by vasodilator type in the low- to moderate-dose diuretic group but was significantly increased by NES in the high-dose diuretic group.

CONCLUSIONS: Patients who received NES plus high-dose diuretics may have an increased risk of Scr increases >0.5 mg/dL. Prospective evaluations to determine optimal use of NES plus diuretics are warranted.

Published in Circulation 2005;112(17, suppl II):II-451-II-452.

8E. Temporal characteristics of serum creatinine elevations in patients receiving nesiritide (NES) and nitroglycerin (NTG). J. Thomas Heywood, M.D.; Scripps Clinic, La Jolla, CA.

INTRODUCTION: In patients admitted for decompensated HF an acute rise in Scr has been associated with increased mortality. However, late Scr increases may reflect worsening clinical status during a prolonged hospitalization, whereas early increases likely reflect temporary but correctable volume depletion. Objective: To determine the prevalence, onset time, and persistence of Scr elevations in hospitalized HF patients receiving NES and NTG.

METHODS: Scr data from the Vasodilation in the Management of Acute Congestive HF (VMAC) trial, a randomized evaluation of NES vs NTG therapy in subjects hospitalized for decompensated HF, were analyzed retrospectively. The prevalence of Scr elevations >0.5 mg/dL from baseline through study drug infusion, within 72 hours of study drug discontinuation, and during the remainder of the hospitalization were compared for the 2 treatments. Scr elevations were classified as persistent if the elevation was still present on study day 30.

RESULTS: During hospitalization, 38/268 NES (14%) and 25/212 NTG (12%; P=0.50) subjects developed an acute Scr elevation. The onset time of these elevations was similar for both treatments. Persistent elevations were rare (see Table).

Published in Circulation 2005;112(17, suppl II):II-451-II-452.
9E. Clinical predictors of worsening renal function (WRF) in patients hospitalized for heart failure. Andrew J. Burger, M.D.; Beth Israel Deaconess Medical Center, Boston, MA.

INTRODUCTION: In patients hospitalized for acute HF, renal insufficiency and WRF have been associated with increased morbidity and mortality. Objective: To identify clinical predictors of WRF for acute HF in the Veterans Affairs Cooperative Study (VMAC) HF trial.

METHODS: VMAC was a prospective, multicenter evaluation of 489 subjects hospitalized for decompensated HF. Subjects were randomized to standard care plus niacin (NES) (NTRG), or placebo for the first 3 days. Placebo subjects were then crossed over to one of the other 2 groups. Treatment was maintained for at least 24 hours; study drug was stopped in ≥72 hrs after discontinuing infusion through hospital discharge.

RESULTS: 72% of patients were enrolled in the pre-ALLHAT/JNC-VII group compared with 37% (33%) in post-ALLHAT/JNC-VII group (p=0.05 for comparison of pre- and post-groups). During 30% of patient visits, 26 patients were at goal blood pressure in pre-ALLHAT/JNC-VII group and 23 (24%) in post-JNC-VII group (p=0.08, 0.74, respectively, for comparison between pre- and post-groups).

CONCLUSIONS: There were no significant differences in prescribing of diuretic in an outpatient resident clinic. Thiazide prescribing rates were compared during five-month time periods, pre-ALLHAT/JNC-VII and post-ALLHAT/JNC-VII publication. Patient visits were assessed for blood pressure goal achievement based on national guideline recommendations.

RESULTS: One hundred seventeen patients were eligible for pre-ALLHAT/JNC-VII group, 112 patients for post-ALLHAT group, and 94 patients for post-JNC-VII group. There were no significant demographic differences between groups. Thiazides were prescribed in 14 patients (12%) in pre-ALLHAT/JNC-VII group, 17 (15%) in post-ALLHAT group, and 12 (13%) in post-JNC-VII group (p=0.05 for comparison of pre- and post-groups).

METHODS: This was a retrospective chart review of patients with diagnosed hypertension treated at an internal medicine outpatient resident clinic. Thiazide prescribed rates were compared for five-month time periods, pre-ALLHAT/JNC-VII and post-ALLHAT/JNC-VII publication. Patient visits were assessed for blood pressure goal achievement based on national guideline recommendations.

RESULTS: Ten subjects were studied with average age, total cholesterol, LDL, HDL, and triglycerides of 28±10 years, 187±41 mg/dl, 100±36 mg/dl, 65±20 mg/dl, and 109±81 mg/dl, respectively. After 4 weeks of atorvastatin, MMP-8 was reduced by 38% from 5767 pg/ml to 3584 pg/ml (p=0.02). MMP-9 was reduced by 9% from 26,636 pg/ml to 24,257 pg/ml (p=0.1). CONCLUSIONS: Atorvastatin significantly reduced leukocyte production of MMP-9 in individuals without dyslipidemia or manifest CVD after four weeks. There was a non-significant reduction in MMP-9 concentrations. These data suggest a potential benefit of atorvastatin in individuals without high-risk for CVD and should be studied further.

Presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, Baltimore, MD, March 2006.

11. Effects of national guideline and evidence-based medicine on thiazide diuretic prescribing in an outpatient resident clinic. Andrew B. Speidel, Pharm.D.; Sarah V. Muench, Pharm.D.; Sandor Shoichet, M.D.; Megan B. Bestul, Pharm.D.1; (1)William Beaumont Hospital, Royal Oak, MI; (2)William Beaumont Hospital, Wayne State University, Royal Oak, MI.

PURPOSE: The ALLHAT demonstrate that thiazide-type diuretics are as or more effective at lowering blood pressure and reducing clinical events compared to other antihypertensive agents. Based on these outcomes JNC-VII recommends thiazide diuretics as first-line agents for the treatment of hypertension. The purpose of this study was to assess the effect of ALLHAT and JNC-VII on prescribing practices for the treatment of hypertension and assess the number of patients at goal blood pressure before and after publication of ALLHAT and JNC-VII.

RESULTS: Thirty-two pts discontinued AMIO permanently with 5 restarting and 8. Thirty-two pts discontinued AMIO permanently with 5 restarting and continuing AMIO. Five pts expired during hospitalization. CONCLUSION: At our institution, the number of pts admitted due to AMIO toxicity appear to be increasing over the past 5+ years. Whether outpatient monitoring admission numbers needs to be evaluated.

12. Characteristics of patients admitted to the hospital for amiodarone toxicity. Katie M. Speidel, Pharm.D.; Stephanie R. Maciejewski, Pharm.D.; Daniel E. Hillman, Pharm.D.; The Cardiac Center of Creighton University, Omaha, NE.

PURPOSE: Amiodarone (AMIO) remains the most commonly prescribed antiarrhythmic agent in the US. The FDA recently mandated that pharmacists provide a medication guide with any prescription for AMIO, presumably due to increasing prevalence of drug-related toxicity. We evaluated our hospital admissions for AMIO-related toxicity.

METHODS: Medical records of pts admitted to the hospital for AMIO-related toxicity were identified and reviewed. Demographic and clinical characteristics and the type and severity of AMIO toxicity were evaluated.

RESULTS: Admissions for AMIO toxicity by year were: 2001 n = 2; 2002 n = 8; 2003 n = 7; and 2004 n = 20.Demographics of patients were: 74.7±8.2 yrs; 23/149, penetration of AMIO. AF = 24; ICD = 9; AF-ICD = 4; duration of AMIO therapy: ≤3 mos = 7; ≤≥3 mos = 4; >12 ≤24 mos = 12; >24 mos = 7. Daily AMIO doses: 800 mg in 1 pt and 1200 mg in 1 pt (both still loading). 100 mg = 1; 200 mg = 13, and 400 mg = 18. Toxicity included: peripheral neuropathy = 1; tremor = 1; GI = 2 (both during loading); hepatic ≥3; dermatologic ≥3; AV block/bradycardia ≥2; pulmonary AV block/bradycardia = 1; hyperthyroid/pulmonary = 1; hypothyroid/pulmonary = 2; hyperthyroid = 1; hypothyroid = 7; pulmonary = 8. Thirty-two pts discontinued AMIO permanently with 5 restarting and continuing AMIO. Five pts expired during hospitalization.

CONCLUSION: At our institution, the number of pts admitted due to AMIO toxicity appears to be increasing over the past 5+ years. Whether outpatient monitoring can identify or prevent pulmonary and thyroid toxicities and potentially avoid hospital admissions needs to be evaluated.

14. Evaluation of therapeutic options for patients who fail to reach low density lipoprotein cholesterol goal on simvastatin monotherapy. Julie S. Altman, Pharm.D., Christina C. Piro, Pharm.D.Candidate, C. Gene Reeder, Ph.D.; South Carolina College of Pharmacy, Columbia, SC.

PURPOSE: Low density lipoprotein cholesterol (LDL-C) reduction is associated with reduced cardiovascular morbidity and mortality. Treatment with the statin drugs simvastatin 80mg and atorvastatin 40mg can reduce LDL-C 48% and 51% respectively Ezetimibe, an absorption inhibitor, can reduce LDL-C 18% as monotherapy and an additional 25% when added to a statin. The purpose of this study was to compare percentage LDL-C reduction in patients changed from simvastatin 80 mg daily monotherapy to simvastatin 80 mg plus ezetimibe 10 mg daily or atorvastatin 40 mg daily monotherapy, two common occurrences in the Veterans Affairs Medical Center for patients who fail to reach LDL-C goal on maximal simvastatin monotherapy.

METHODS: Sixteen patients were identified to have been prescribed ezetimibe as add-on therapy to simvastatin 80 mg daily. To serve as comparators, 16 patients who had been switched from simvastatin 80 mg to atorvastatin 40 mg were randomly selected. A retrospective chart review was conducted to collect patient demographic information, information concerning lipid lowering therapy, lipid parameters prior to and after lipid lowering therapy, changes, concomitant lipid lowering medications, and presence of adverse effects following change in lipid lowering therapy.

RESULTS: Patient demographics were similar between groups. The average LDL-C prior to therapy change was 144 mg/dL in the ezetimibe group and 139 mg/dL in the atorvastatin group. Six months following the switch, LDL-C was reduced 19.8% in the simvastatin/ezetimibe group versus 11.8% in the atorvastatin group. The average LDL-C value 6 months following the switch in therapy was 107 mg/dL in the simvastatin/ezetimibe group and 119 mg/dL in the atorvastatin group. No adverse events were reported related to a change in lipid lowering therapy in either group.

CONCLUSIONS: Patients switched to simvastatin 80 mg plus ezetimibe 10 mg had a greater reduction in LDL-C than those switched to atorvastatin 40 mg monotherapy.

13E. Diminishing rates of return in reducing coronary heart disease event rates with progressive LDL cholesterol lowering: linear vs inhibitory maximum effect modeling. Scott L. Cherland, Pharm.D., Eric J. Staneck, Pharm.D., Mark E. McGovern, M.D.; Kos Pharmaceuticals, Inc, Cranbury, NJ.

BACKGROUND: The relationship between LDL-C and CHD event rates during statin prevention trials is commonly reported to be linear and exponentially decreasing in zero CHD events at zero LDL-C. We sought to explore this relationship further through maximum effect modeling.

METHODS: Linear and nonlinear inhibitory maximum effect (iMax) models were used to evaluate the LDL-C versus absolute CHD event rate relationship from 5 published long-term (4-6 years) secondary prevention statin trials. Goodness of fit was calculated for both models and compared (Akaike Information Criteria and F-test). Additionally, the incremental number needed to treat (INNNT) was calculated between statin AWP and statin AWP – 40 mg/dL. We sought to explore this relationship further through maximum effect modeling.

RESULTS: The LDL-C versus CHD event rate plot was fit significantly better by the iMax model (F=11.15, p=0.0046), indicating a closer approximation of the true relationship. Whereas the linear model yielded an unchanging INNNT, the iMax model yielded increasing INNNTs for lowering LDL-C from 100 mg/dL to 90 mg/dL, 90 mg/dL to 80 mg/dL, and 80 mg/dL to 70 mg/dL.

CONCLUSIONS: The relationship between LDL-C lowering and CHD events is better fit with a nonlinear maximum effect iMax model, and should not be assumed to be linear. Additionally, there is a marked diminishing rate of return at progressively lower LDL-C levels leading to increasing annual costs. Greater event reduction once LDL-C is <100 mg/dL may require aggressive concomitant modification of other cardiovascular risk factors, such as HDL-C, triglycerides, and blood pressure, as opposed to exclusive focus on further LDL-C lowering.

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16. The healthy at heart evaluation study: 4-month interim results. David Vlahov, Ph.D.1, Sandro Galea, M.D.1, Tinka Markham Piper, M.P.H.1, Pamela Thomas, M.D.2, Debra Parsow, 3, Erik Kunze, M.D.2, Tracy Mayne, Ph.D.1, (1)New York Academy of Medicine, New York, NY; (2)Lockheed Martin Aeronautics, Martetta, GA; (3)ConAgro Foods, Omaha, NE; (4)Pfizer Global Pharmaceuticals, New York, NY; (5)Pfizer, New York, NY.

INTRODUCTION: The Healthy at Heart program (H@H) uses patient and physician education and learning techniques to reduce/prevent cardiovascular-related risk-producing behavior within an employer setting.

OBJECTIVE: Measure 4-month change in treatment intervention (diet and exercise, medicine), blood pressure and LDL-C between participants in both arms: current sample ~20% of total.

METHODS: This multi-center, controlled intervention study compares the impact of the H@H disease management program versus control in employees at Lockheed Martin Aeronautics and ConAgro Foods at 4 and 12 months. Participants were screened at health fairs. Eligible employees were assigned to receive the H@H Program or control in a 4:1 ratio.

RESULTS:

<table>
<thead>
<tr>
<th>Table 1 Baseline and 4-month follow-up</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Cholesterol</td>
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<tr>
<td>Intervention (N= 318)</td>
</tr>
<tr>
<td>Control (N=95)</td>
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<td></td>
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<tr>
<td>Time</td>
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<tr>
<td>Group*</td>
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<tr>
<td>Intervention (N= 318)</td>
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<td>Control (N=95)</td>
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<td>p-value</td>
</tr>
</tbody>
</table>

| Intervention (N= 318)                  |
| Control (N=95)                        |
|                                       |
| Cholesterol                           |
|                                       |
| Seeing a physician for Chol            |
|                                       |
| 7% 20% 13% 15%                         |
| 0.01 0.61                             |
|                                       |
| Now taking chol meds                   |
|                                       |
| 11% 25% 19% 19%                       |
| 0.01 0.31                             |
|                                       |
| At ATP-III LDL-C goal                  |
|                                       |
| 36% 63% 50% 67%                       |
| 0.01 0.04                             |
|                                       |
| Mean LDL - C                          |
|                                       |
| 143 113 128 109                      |
| 0.01 0.54                             |
|                                       |
| Hypertension                          |
|                                       |
| Seeing a physician for HTN             |
|                                       |
| 33% 42% 22% 45%                       |
| 0.01 0.22                             |
|                                       |
| Now taking HTN meds                   |
|                                       |
| 28% 34% 31% 41%                       |
| 0.02 0.33                             |
|                                       |
| At JNC-7 BP goal                      |
|                                       |
| 53% 30% 36% 66%                       |
| 0.11 0.32                             |
|                                       |
| Systolic blood pressure                |
|                                       |
| 135 130 141 131                      |
| 0.01 0.35                             |
|                                       |
| Diastolic blood pressure               |
|                                       |
| 82 80 85 80                          |
| 0.01 0.37                             |
|                                       |
| Diet                                  |
|                                       |
| Has changed diet                       |
|                                       |
| 78% 90% 79% 88%                       |
| 0.01 0.05                             |
|                                       |
| Exercise                               |
|                                       |
| More active                            |
|                                       |
| 52% 70% 58% 70%                       |
| 0.01 0.55                             |
|                                       |
| BMI (M,SD)                            |
|                                       |
| 31 31 33 32                          |
| 0.24 0.68                             |
|                                       |
| Smokers                               |
|                                       |
| 37% 34% 40% 34%                       |
| 0.83 0.78                             |

* Differences at 4-months controlling for baseline value

CONCLUSIONS: In these early analyses, nearly all cardiovascular health measures improved over time, but the incremental benefit of the H@H intervention was primarily significant for the percentage of employees reaching ATP-III LDL-C goal.

17E. Nesiritide-associated increase in serum creatinine does not increase cardiovascular mortality in patients with pump compensated heart failure. Uri Elhayany, M.D.1, D. Thomas Heywood, M.D.1, (1)University of Southern California Medical Center, Los Angeles, CA; (2) Scripps Clinic, La Jolla, CA.

PURPOSE: The use of nesiritide (Nes) has been associated with an increased risk of serum creatinine (Scr) elevations in some patients. Scr increases during hospitalization for heart failure has been associated with an increased risk of mortality. However, Scr may be influenced by a wide variety of factors such as baseline renal function, hemodynamic status, concomitant medications such as diuretics and ACE inhibitors. The effect of NES-associated Scr increases on mortality is unknown. Objective: To evaluate the effect of NES-associated Scr increases on mortality.

METHODS: Nested data from 8 randomized NES trials were analyzed. Scr increases during hospitalization for heart failure were associated with an increased risk of mortality. However, Scr may be influenced by a wide variety of factors such as baseline renal function, hemodynamic status, concomitant medications such as diuretics and ACE inhibitors. The effect of NES-associated Scr increases on mortality is unknown. Objective: To evaluate the effect of NES-associated Scr increases on mortality.
mg/dL within 30 days. The hazard ratio (HR) and 95% CI of death associated with SCr increases >5 mg/dL were compared for subjects in the NES and control groups. Control agents included isometheptene, nifedipine, and/or diuretics.

RESULTS: In total, 214 of 1248 subjects (17%) had SCr increases >0.3 mg/dL (NES: 151 of 786 subjects [19%]; control: 63 of 462 subjects [14%]). A SCr increase >0.5 mg/dL was associated with a 1.1-fold increase in 30-day mortality in NES subjects compared with a 3.4-fold increase in 30-day mortality risk in control subjects.

Kaplan-Meier Mortality Rates Patients With SCr Increase at Any Time Through Study Day 30

<table>
<thead>
<tr>
<th>SCr Change vs No SCr</th>
<th>SCr Increase</th>
<th>No SCr</th>
<th>HR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCr &gt;0.5 mg/dL*</td>
<td>7.3 (11/151)</td>
<td>5.9 (37/635)</td>
<td>1.1 (0.6, 2.2)</td>
<td>0.722</td>
</tr>
<tr>
<td>Control</td>
<td>13.0 (8/63)</td>
<td>4.3 (17/399)</td>
<td>3.4 (1.4, 8.3)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

*Number of deaths/number of patients with SCr increase >0.5 mg/dL

CONCLUSIONS: These data suggest that SCr increases in patients treated with nesiritide are not associated with an increased risk of mortality at 30 days. Prospective studies are needed to evaluate the effects of nesiritide on renal endpoints are needed.

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PURPOSE: The TNT study showed that intensive lipid-lowering therapy with atorvastatin 80 mg/day provides significant clinical benefit beyond the levels recommended in current guidelines that are afforded by treatment with atorvastatin 10 mg/day in patients with stable CHD. The current post hoc analysis investigates whether similar benefits of high-dose atorvastatin therapy can be achieved in patients with CHD and metabolic syndrome.

METHODS: A total of 3477 patients with metabolic syndrome and clinically evident CHD, with LDL-C levels >190 mg/dL (5.4 mmol/L) (following an 8-week open-label run-in period withatorvastatin 10 mg) were randomized to double-blind therapy with either atorvastatin 10 mg/day (n=1771) or 80 mg/day (n=1706). Metabolic syndrome was defined based on NCEP ATP III criteria (body mass index >30 kg/m2). Patients with diabetes mellitus were not excluded and comprised 30% of the subgroup. The primary end point was the occurrence of a first major cardiovascular event, defined as death from CHD, nonfatal or nonprocedure-related myocardial infarction, resuscitated cardiac arrest, or fatal or nonfatal stroke.

RESULTS: Mean on-treatment LDL-C levels at 3 months were 100.0 mg/dL (2.6 mmol/L) with atorvastatin 10 mg, and 73.3 mg/dL (1.9 mmol/L) with atorvastatin 80 mg. After mean follow up of 5.0 years, a primary event occurred in 252 patients (14.2%) receiving atorvastatin 10 mg, compared with 175 patients (10.3%) receiving atorvastatin 80 mg (HR=0.71; 95% CI 0.58-0.86, P=0.0005). Secondary measures of efficacy were consistent with those in the overall study population. There was no clinically important difference in the rates of adverse events between the two treatment arms. LFT elevations were reported in 0.9% of patients on atorvastatin 80 mg, and in 0.2% of patients on atorvastatin 10 mg.

CONCLUSION: Intensive therapy with atorvastatin 80 mg significantly reduced the rate of major cardiovascular events by 29% compared with atorvastatin 10 mg in patients with clinically evident CHD and metabolic syndrome.

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19E. Safety and efficacy of atorvastatin at very low LDL-C levels: a post-hoc analysis of the TNT study. John C. LaRosa, M.D.; John J. Kastelein, M.D.; John B. Kostis, M.D.; (1)San Francisco General Hospital, 1001 Potero Avenue, San Francisco, CA; (2)UNSW Downstae Medical Center, Brooklyn, NY; (3)The Heart Institute, Camperdown, Australia; (4)University of Texas Health Science Center at San Antonio, San Antonio, TX; (5)Hospital Clinico Universitario, Valencia, Spain.

INTRODUCTION: The TNT study showed that intensive lipid-lowering therapy (atorvastatin 80 mg) to an LDL-C of 77 mg/dL (2.0 mmol/L) provides significant additional clinical benefit in stable CHD patients. Observational studies have raised concern about the safety of lowering LDL-C well beyond levels recommended in current guidelines.

METHODS: A total of 10,001 patients with clinically evident CHD and LDL-C levels <130 mg/dL (3.4 mmol/L) were randomized to double-blind therapy with either atorvastatin 10 or 80 mg/day. The primary end point was the occurrence of a first major cardiovascular event. Patients were stratified by on-treatment LDL values into quintiles.

RESULTS: Baseline characteristics were similar across quintiles. There was a significant reduction in the rate of major cardiovascular events with lower levels of on-treatment LDL-C (p<0.0001). Death due to any cause, due to cardiovascular causes and due to non-cardiovascular causes was lowest in the quintile with the lowest on-treatment LDL-C levels. There were no clinically important differences in adverse event rates across quintiles.

CONCLUSIONS: The safety and confirmational clinical benefit of reducing LDL-C to very low levels (≤64 mg/dL [1.7 mmol/L]) with atorvastatin in patients with stable CHD.

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20E. Effects of intensive lipid lowering with atorvastatin on cerebrovascular events in patients with stable coronary disease: a treating to new targets (TNT) substudy. David Waters, M.D.; John C. LaRosa, M.D.; Philip Barter, M.D.; (1)San Francisco General Hospital, 1001 Potero Avenue, San Francisco, CA; (2)UNSW Downstae Medical Center, Brooklyn, NY; (3)The Heart Institute, Camperdown, Australia.

PURPOSE: The cerebrovascular benefits of treating patients with stable CHD to LDL-C levels substantially below 100 mg/dL (2.6 mmol/L) have not been previously investigated. We describe a post hoc analysis of cerebrovascular events in TNT.

METHODS: Clinical endpoints analyzed were time to first cerebrovascular event, fatal or non-fatal stroke, or transient ischemic attack (TIA), time to first stroke and time to first TIA. Cerebrovascular events, stroke of any etiology, and hemorrhagic stroke were stratified and compared by quintile of achieved LDL-C.

RESULTS: Mean on-treatment LDL-C levels were 101 mg/dL (2.6 mmol/L) with atorvastatin 10 mg and 77 mg/dL (2.0 mmol/L) with atorvastatin 80 mg. In addition to the reduction in major cardiovascular events (hazard ratio [HR]=0.78, 95% confidence interval [CI]=0.69-0.89, P=0.0002), patients in the atorvastatin 80 mg arm achieved significant reduction in the risk of cerebrovascular events (HR=0.77, 95% CI=0.64-0.93, P=0.007) and stroke (HR=0.75, 95% CI=0.59-0.96, P=0.020). There was a reduction in the incidence of TIA in patients receiving atorvastatin 80 mg that did not reach statistical significance (HR=0.79, 95% CI=0.60-1.05, P=0.098). Cerebrovascular events and stroke occurred at a lower rate in the lowest quintile of achieved LDL-C compared with the highest quintile (3.6% vs 5.4%, and 2.1% vs 2.8% for cerebrovascular events and stroke, respectively). The incidence of hemorrhagic stroke did not differ significantly between patients in the two treatment groups (16 vs 17 events in the atorvastatin 80 mg and 10 mg groups, respectively, P=NS), or across quintiles of achieved LDL-C (6, 5, 6, and 7 events from lowest to highest quintile, P=NS).

CONCLUSION: Significant reduction in cerebrovascular morbidity was observed in the group treated intensively with atorvastatin 80 mg. These data show that the reduction of LDL-C substantially below 100 mg/dL (2.6 mmol/L) with atorvastatin produces important clinical benefit beyond the coronary vascularature.

Presented at the American Heart Association Scientific Sessions 2005, Dallas, TX, November 13-16, 2005.


PURPOSE: Patients with diabetes are at increased risk of stroke; however, tools for predicting risk of primary stroke are limited. In CARDS, 2838 patients with type 2 diabetes, with no history of CHD or macrovascular disease, were randomized to atorvastatin 10 mg or placebo and followed for a median of 3.9 yr. Strokes were classified based upon neurological deficits and
RESULTS: Of 60 strokes [8 fatal (1 AV, 7 pbo), 52 nonfatal (20 AV, 32 pbo)], 41 were classified as ischemic (15 AV, 28 pbo), 1 hemorrhagic (1 AV, 0 pbo), 18 indeterminate (7 AV, 11 pbo). Atv was associated with a 48% RRR for all stroke (p=0.016) and a 33% RRR for ischemic stroke (p=0.017). Adjusted for treatment, factors associated with a higher risk of stroke were: older age (HR for 10 y=2.19, p<0.001), longer duration of diabetes (HR for 10 y=1.49, p=0.020), higher SBP (HR for 10 mmHg=1.17, p<0.004), HbA1c > 10% (HR=2.33, p=0.001), male gender (HR=1.03, p=0.001), albumin creatinine ratio (ACR) > 2.5 mg/mmol (HR=2.4, p<0.001), and history of retinopathy (HR=1.72, p=0.038). When treatment and the significant baseline covariates were entered in a single model, treatment was associated with a 50% RRR (p=0.011), and age, gender, ACR > 2.5 mg/mmol and HbA1c > 10% remained significant (all p<0.05).

CONCLUSIONS: In CARDS diabetes-specific variables ACR and HbA1c were important predictors of stroke independent of treatment. Despite the lack of association between baseline LDL-C and stroke, there was a significant reduction in the risk of stroke associated with atorvastatin treatment. These observations underscore the need for diabetes-specific risk engines for estimating risk of stroke and for intensive management of modifiable risk factors in patients with type 2 diabetes.

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22E. Efficacy and safety of high dose atorvastatin therapy in CHD patients ≥65 years of age in the aggressive lipid lowering abates new cardiac events (ALLIANCE) study. Michael Koren, M.D.¹, Robert Mendes, M.D.¹, Don Luo, Ph.D.²; ¹Jacksonville Center for Clinical Research, Jacksonville, FL; ²Pfizer Global Pharmaceuticals, New York, NY; ³Pfizer Inc, New York, NY.

PURPOSE: High-dose atorvastatin therapy may be underutilized in the elderly due to safety concerns and doubts about efficacy in this age group.

METHODS: We examined outcomes and safety in patients ≥65 years of age in the ALLIANCE study, a “real world” trial that compared the effects of an aggressive atorvastatin regimen with usual care in stable coronary heart disease (CHD) patients. Of 2442 patients with dyslipidemia randomized to either aggressive treatment (LDL-C titration goal of <80 mg/dL or maximum 80 mg/day of atorvastatin) or usual care (continuation of baseline lipid-lowering therapy, with changes/laboratory analyses directed by treating physicians), 1001 (41%) were ≥65 years old. The composite primary endpoint was time to first cardiovascular event. Mean dose of atorvastatin was 40 mg/day; 45% used ≥80 mg/day for an average of 3.6 years.

RESULTS: In the older cohort, mean age was 69.6 ± 3.2 years, with no difference in age, gender, smoking status, baseline lipids, or cardiovascular history between atorvastatin and usual care groups. Older patients randomized to aggressive therapy with atorvastatin realized greater benefit than those assigned usual care, experiencing relative risk reductions of 27% for the primary composite endpoint (HR=0.73, 95% CI=0.57-0.94, p=0.016). Similarly, greater risk reduction were observed with atorvastatin in patients aged ≥65 years: nonfatal MI (HR=0.48, 95% CI=0.32-0.72, p=0.001) and the composite endpoint of CHD death and nonfatal MI (HR=0.43, 95% CI=0.23-0.79, p=0.006). A trend in the reduction of nonfatal stroke (HR=0.74, 95% CI=0.39-1.40, p=0.538) was also observed. The rate of significant liver enzyme elevations in atorvastatin-treated patients was low; there were no differences between older and younger patients. Rates of serious adverse events leading to discontinuation were higher in older subjects, but were similar between atorvastatin and usual care.

CONCLUSIONS: Our data support the efficacy and safety of aggressive lipid management in older CHD patients.

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23E. Adherence to individual drugs is known to be low. The objectives of this study were to describe levels and predictors of adherence in AMI patients dispensed one, two or three drugs of proven benefit (ACEI, BB, statins).

METHODS: This cohort study used linked population-based administrative data included 40 years and older, discharged from hospital post-AMI April 1997 to March 2002. Patients were categorized according to the number and type of target medication dispensed within 30 days post-AMI.

Adherence to individual and multiple drugs within the multi-drug regimen, controlling for patient and provider characteristics, was estimated using time-to-event analysis.

RESULTS: 8,157 patients discharged with AMI were evaluated. Medication adherence to each specific drug increased with the number of post-AMI medications dispensed. For example, 1-year adherence to ACEI alone was 54%, but increased to 66–69% when combined with a BB, a statin or both. However, adherence to all drugs in a multi-drug regimen was lower with two- and three-drug regimens than with single-drug regimens. For example, 48% of patients were adherent to both drugs in two-drug regimens while only 38% were adherent to all three drugs in three-drug regimens.

CONCLUSIONS: Adherence with an individual evidence-based medication post-AMI increases as more evidence-based medications are dispensed. However, overall levels of adherence for multiple secondary prevention drugs post-AMI remain lower than optimal in order to maximize the benefits of these efficacious therapies.

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24. Retrospective cohort validation of enoxaparin versus heparin with revascularization and glycoprotein IIb/IIIa inhibition for efficacy and safety (REVERIFY). Adam B. Pesaturo, Pharm.D.¹; Heath R. Jennings, Pharm.D.¹; Stacy A. Voils, Pharm.D.²; Kevin L. Poe, Pharm.D.²; Bill Harris, M.D.³; ¹Saint Joseph HealthCare, Inc., Lexington, KY; ²Saint Joseph HealthCare, Lexington, KY; ³Cardiology Associates of Kentucky, Lexington, KY.

PURPOSE: ACC/AHA recommends enoxaparin over heparin (UFH) for patients with unstable angina (UA) or non-ST-segment myocardial infarction (NSTEMI). SYNERGY trial has since demonstrated enoxaparin to be neither superior nor inferior to UFH but noted increased bleeding with enoxaparin. Lack of real world appraisal concerning outcomes with these agents combined with the questionable impact of anticoagulant crossover noted in SYNERGY complicates clinical decisions regarding enoxaparin and UFH.

METHODS: This retrospective cohort study evaluated and stratified reperfusion for acute coronary syndromes according to anticoagulant therapy, between 2/02 and 7/03. Antiplatelet treatment occurred per physician discretion and institution protocol. Further stratification was performed by glycoprotein IIb/IIIa inhibitor use and NSTEMI/UA versus ST-segment elevated myocardial infarction (STEMI). Anticoagulant crossover treatment was also evaluated. Primary outcomes were efficacy (triple composite of death, recurrent ischemia, urgent revascularization), safety (TIMI major bleeding), and safety-efficacy combined. Power analysis (90%) demonstrated 1053 patients (327 per group) required to detect a 10% difference in the primary endpoints (SD = 50, alpha = 0.05).

RESULTS: Total of 2108 patients were included for analysis. Due to small sample size, evaluation of crossover was not possible (n = 76). Enoxaparin demonstrated increased incidence in TIMI major bleeding (13.1% vs. 8.2%, p=0.05), efficacy endpoint (19.3% vs. 13.3%, p=0.02), and combined safety-efficacy endpoint (24.4% vs. 9.3%, p=0.01) for enoxaparin + epifibatide versus enoxaparin + abciximab for STEMI.

CONCLUSIONS: Results of this study reflect outcomes noted in SYNERGY and suggest that patients treated with enoxaparin for NSTEMI/UA may be at increased risk for bleeding regardless of anticoagulant crossover prior to PCI.


PURPOSE: Compare the effects of intracraniosional analgesia (IA) to conventional analgesia (CA) on opeative requirements following cardiothoracic surgery.

METHODS: Retrospective pilot study in a cardiothoracic ICU. Following cardiothoracic surgery with median sternotomy, patients receiving IA were matched by age, gender, procedure, and number of risk factors for increased length of stay (LOS). Treatment group patients received IA with bupivacaine or ropivacaine via elastomeric pump for 72 hours. Primary endpoint: morphine equivalents (ME) received at 72 hours. Secondary endpoints: ME at 24, 48, and 96 hours; daily incidence of pain (pain score > 2 on a 0–10 scale); time to extubation and ambulation, and LOS.

RESULTS: n=49 ([IA = 25, CA = 24] ME at 24, 48, and 96 hours in control vs treatment groups were 55.2 mg (95% CI, 47.4-63.0 mg) vs. 50.7mg (95% CI, 42.7-58.8mg) respectively. Mean ME at 24, 48 and 96 hours in control vs treatment groups were 25.0 mg (95% CI, 19.5-30.5 mg) vs. 21.7 mg (95% CI, 16.9-26.9 mg), 43.6 mg (95% CI, 38.2-49.0 mg) vs. 40.7 mg (95% CI, 33.4-48.9 mg), and 62.0 mg (95% CI, 54.2-69.8 mg) vs. 57.9 mg (95% CI, 48.6-
26. Evaluation of hypertensive emergency management within a large teaching institution. Diptri Patel, Pharm.D.1, Laura P. Muller, Pharm.D.1,2, Rajae (n=5), and Stacy A. Voils, Pharm.D., Tyree Kiser, (n=5). Prevention significantly reduced the overall incidence of VAP, and specifically ventilator days (22.40 VAP per 1,000 ventilator days), a relative reduction rate of 10.4% (p<0.001). The incidence of EOVAP decreased from 25.58 to 19.56 per 1,000 ventilator-days (p<0.001) while the incidence of LOVAP associated with increased mortality and morbidity. Several interventions are required for the prevention of VAP.

RESULTS: Twenty episodes of VAP occurred in 892 ventilator days, 40.6% vs. 41.7% (p=0.68), and 43.9% vs. 41.1% (p=0.70) respectively. MedLOS for control vs. treatment groups was 6 days vs. 7 days respectively (p=0.69).

CONCLUSION: IA via elastomeric pump non-significantly decreased opiate requirements through 72 hours. A trend towards fewer patients experiencing pain in the IA group was identified. No significant effect was observed on time to extubation, ambulation, or LOS.

27. Educational program for the prevention of ventilator-associated pneumonia in adult patients admitted to the intensive care unit. Rajee Omirane, B.Pharm., M.Sc.,1 Jiwan Eil, B.Pharm., M.Sc.,1 Marc M. Perreault, Pharm.D., BCPS,2 Hala Yazbeck, B.Pharm., M.Sc.,2 Ashvini Gursahaney, M.D., FRCPC,2 Nancy Fong, RT2, Luc Lortie, R.N.,2 Yola Moride, Ph.D.2 (1)Université de Montréal, Montreal, QC, Canada; (2)Montreal General Hospital, Montreal, QC, Canada.

PURPOSE: Ventilator-associated pneumonia (VAP) is the most common infection among patients receiving mechanical ventilation (MV). VAP is associated with increased mortality and morbidity. Several interventions are effective in reducing the incidence of VAP, but their implementation into clinical practice is not yet a standard in our hospital. The objective is to determine whether a protocol incorporating evidence-based measures shown to reduce the frequency of VAP could decrease rates of VAP in the ICU of a tertiary care adult teaching hospital.

METHODS: This pre and post-intervention observational study included mechanically ventilated patients admitted to our ICU (MICU/SICU/Trauma) between November 8, 2003, and May 8, 2004 (pre-intervention), and between November 8, 2004, and May 8, 2005 (post-intervention). A multidisciplinary protocol was developed and implemented, and posters reinforcing adherence were placed in the ICU. Rates of VAP per 1,000 ventilator days were calculated before and after the implementation of the protocol for all patients, for those with early onset VAP (EOVAP) and those with late onset VAP (LOVAP).

RESULTS: Twenty three episodes of VAP occurred in 921 ventilator days (25.00 per 1,000 ventilator-days) during the 6 month pre-intervention period. Following implementation, the rate of VAP decreased to 22 episodes in 989 ventilator days (22.40 VAP per 1,000 ventilator days), a relative reduction rate of 10.4% (p<0.001). The incidence of EOVAP decreased from 25.58 to 19.56 per 1,000 ventilator-days (p<0.001) while the incidence of LOVAP associated with increased mortality and morbidity. Several interventions are required for the prevention of VAP.

CONCLUSION: Implementation of an educational program for VAP prevention significantly reduced the overall incidence of VAP, and specifically that of EOVAP.

28. Does adjunctive dexmedetomidine therapy impact sedation/analgesia requirements to facilitate extubation? Laura Forrest, B.S., Tytre Kiser, Pharm.D., Robert MacLaren, Pharm.D., University of Colorado School of Pharmacy, Denver, CO.

PURPOSE: To determine if adjunctive dexmedetomidine (dex) administration alters sedation/analgesia requirements and levels of sedation/analgesia to facilitate tracheal extubation.

METHODS: Retrospective assessment of 40 ICU patients 2 18 yd with dex initiated while receiving propofol, lorazepam and/or fentanyl infusions. Data collected included demographics, sedative/analgesic requirements, levels of sedation/analgesia (Riker/PABS), hemodynamics, and ventilator parameters. Statistical analyses included repeated-measures analysis of variance and chi-square test.

RESULTS: Patients were 48±15 yo with APACHE II scores of 22±7, most in the surgical ICU (n=33). Four patients received a dex bolus. The initial dex rate of 0.4-0.15 μg/kg/hr changed minimally through 47±11.1 hours of infusion. Within three hours of initiating dex, 9 of 12 patients had propofol stopped resulting in reduced hourly rate (34.4±19.9 at hr 1 to 26.7±3.8 μg/kg/min at hr 3, p=0.02) and total daily dose (407±2322 at day 1 vs. 133±870 mg at day 0, p=0.01). Within 24 hours of initiating dex, 4 of 14 patients had lorazepam stopped and 7 of 26 patients had fentanyl stopped but hourly rates and total daily doses varied minimally. Within 24 hours before and after initiating dex, 64.6% and 47.9% of doses represented adequate sedation (Riker of 3-4), respectively (p=0.001). Four and 12 patients had severe agitation before and after, respectively (p=0.006). One and 12 patients had severe pain before and after, respectively, (p=0.001). Seven patients experienced hypotension/bradycardia requiring dex discontinuation, 2 patients were extubated within 24 hours after stopping dex with the final sedative, 5 patients self extubated within 24 hours of dex initiation, and 7 patients required sedation/analgesia escalation. CONCLUSION: Adjunctive dex reduces propofol requirements but does not alter lorazepam or fentanyl requirements, possibly due to differences in the clinical application of these sedatives/analgesics. Transitioning to dex in an effort to reduce other sedatives/analgesics may worsen sedation/analgesia but potentially serves as a bridge to extubation.

29. Retrospective surveillance of antimicrobial usage for the treatment of pneumonia in a medical intensive care unit. Emily J. Young, Pharm.D.,1 Steven E. Pass, Pharm.D., BCPS,2 BCPS, FCCM,1 (1)The University of Cincinnati Hospital, Cincinnati, OH; (2)University of Houston College of Pharmacy, Houston, TX.

PURPOSE: This study was conducted to identify trends in empiric antimicrobial selection for the treatment of pneumonia in a MICU at a large academic medical institution and to determine whether the empiric therapy was adequate based upon final culture results.

METHODS: A retrospective chart review was conducted of all patients greater than or equal to 18 years of age admitted to the MICU from April 2004 through September 2004 that were treated for pneumonia. Patient demographics, type of pneumonia, antimicrobial agents utilized, pertinent laboratory data, microbial culture results, clinical signs and symptoms of pneumonia, ventilator days, hospital and ICU LOS, and mortality data were collected. Descriptive statistics were utilized to analyze the data.

RESULTS: A total of 88 patients with 96 cases of pneumonia were reviewed. The mean age was 57 ± 16 years and 62% (n=55) of patients were female. Based on final microbial culture results from 32 patients, empiric therapy was considered adequate in 61% of cases (n=21). Initial empiric therapy was considered appropriate based upon national guidelines in 32 of 32 cases (n=31). The most common pathogens isolated from respiratory cultures was methicillin resistant Staphylococcus aureus (n=12), followed by Pseudomonas aeruginosa (n=5), and Stenotrophomonas maltophilia (n=5).

CONCLUSION: In this retrospective chart review patients admitted to a MICU, empiric therapy was adequate in 65% of cases from microbiologically confirmed pneumonia. Initial empiric therapy was appropriate based upon national guidelines in 32 of 32 cases. Educational initiatives and a pneumonia treatment protocol are being implemented in order to improve both the adequacy and appropriateness of empiric regimens for the treatment of pneumonia at our institution.

30. Comparison of darbepeotin alfa and epoetin alfa for anemia of critical illness. Stacy A. Voils, Pharm.D., Spencer E. Harpe, Ph.D., Pharm.D., MPH, Gretchen M. Brophy, Pharm.D., BCPS, Virginia Commonwealth University, Medical College of Virginia Campus, Richmond, VA.

PURPOSE: Studies have shown that recombinant human erythropoietin (HuEPO) may decrease blood transfusions in critically ill patients. However, no published data exists to support or refute use of darbepeotin alfa (DPA) for anemia of critical illness. The purpose of this study is to compare the effectiveness of DPA to HuEPO at achieving transfusion independence and increasing hemoglobin levels in critically ill patients.

METHODS: This was a retrospective, descriptive study in a 72-bed ICU at a level I trauma center. Cardiothoracic, medical or surgery/trauma ICU patients who received at least one dose of DPA or HuEPO were screened for study inclusion. Patients received HuEPO 40,000 units or DPA 100 micrograms...
CONCLUSIONS: No significant differences emerged with respect to length of stay and red blood cell transfusion requirements in a small sample of matched critically ill patients. Both drugs appear to have a similar impact on selected clinical outcomes in the ICU.


PURPOSE: Within the neurosurgical population, the incidence of venous thromboembolism (VTE) is high, with reports of VTE occurring in 6% of patients receiving prophylaxis, and VTE-related complications occurring in 19–54% of patients. The most commonly employed prophylaxis strategy in our Neuro-Critical Care Unit (NCCU) is Unfractionated Heparin (UFPH) 5000 units SC BID plus mechanical methods. There is currently no uniformly accepted prophylactic regimen for this patient population. We propose that an assessment of thrombotic events in our NCCU would provide valuable information for optimizing our VTE prophylaxis strategy, and provide direction for the development of future studies to determine the risk factors for, and natural progression of, VTE in this patient population.

METHODS: Retrospective chart review of 42 patients admitted to the NCCU between 2001–2004 diagnosed with VTE.

RESULTS: Over the study time frame there were 1211 admission to the NCCU with an ICU stay > 48 hours. Overall incidence of VTE in these patients was 5.3%. The most common admitting diagnosis in patients developing VTE was tumor resection (23%) and hemorrhagic stroke (14%). Fifty percent of the patients that developed VTE had undergone a craniotomy. Compliance with mechanical and pharmacologic prophylaxis was high (97% and 96% respectively). Median hospital length of stay was 40 days (range 2–123). Ninety-five percent of patients had at least one main risk factor for VTE, and 74% had 3 or greater.

CONCLUSIONS: Incidence of VTE in the NCCU is consistent with that reported in the literature. Compliance with the existing prophylaxis regimen is high. Patients developing a VTE had long hospitalizations with numerous risk factors. Further evaluation of the risks vs. benefits of a more aggressive prophylactic regimen such as UFPH 5000 units SC TID or Low Molecular Weight Heparin in patients with brain tumors, hemorrhagic strokes, and those undergoing craniotomies is warranted.

Education/Training

34. Development and implementation of an interprofessional course in patient safety: a case study. Kimberly A. Galt, Pharm.D., Karen A. Paschal, PT, M.S., Richard O’Brien, M.D., Robert McQuillan, M.D., Barbara Harris, M.S.W., Janet Graves, R.N., Ph.D., Catherine Mahern, J.D., Bartholomew E Clark, Ph.D., James D Bramble, Ph.D., Linda Scheirton, Ph.D., Keli Mu, Ph.D., O'TR/L, Pat Hoidal, R.N., M.P.H., John M. Gleason, D.B.A., Ann Rule, Pharm.D., J. Chris Bradberry, Pharm.D., Roberta E. Sonnino, M.D., Debra Gerardi, R.N., M.P.H., JD, Creighton University, Omaha, NE.

PURPOSE: The purpose of this case study is to describe the development and implementation of an interprofessional course in patient safety offered to students across healthcare and health-related disciplines.

METHODS: A total of 17 faculty members representing 13 health professions or related disciplines accepted an invitation to participate. The team identified key issues to be addressed including content of current courses, the logistical demands of varying curricular delivery models on campus, student and program level considerations, faculty development and engagement, and course content, delivery and assessment. A two-credit elective course was developed based on expected student learning outcomes. Instructional design focused on active learning methods to engage students in interprofessional case-based discussion applying the basic principles and tenets of patient safety in a systems-based context. The course was first offered Spring Term 2005 to 31 students from nursing, occupational therapy, physical therapy, and pharmacy.

RESULTS: Overall student mastery of the content knowledge of patient safety science was demonstrated in a multiple choice examination and final examination case designed to evaluate the application of safety theory. Final course evaluations revealed that 87% of the students believe the material taught in the course is core knowledge and essential to be learned by all health professionals, and 74% believed this course should be required for all health professions students. Students achieved an application level of learning (77%) within the cognitive domain and the valuing level within the affective domain. Students agree (96%) that they can define and apply the basic principles and tenets of patient safety. Students agreed the tools needed to work effectively within the health system to improve safety, and 74% strongly agree or agree that they value patient safety as a professional practice framework.

CONCLUSION: The university-wide implementation case may offer important lessons to others nationally in healthcare education.

PURPOSE: Computer-based classroom performance systems (CPS) are interactive response systems that provide immediate student feedback while increasing active student participation. Strategies for effective implementation into a pharmacy curriculum are not available. Our purpose was to evaluate CPS implementation in a Therapeutics course.

METHODS: The 2005 Therapeutics I course was taught with CPS using three implementation strategies. The “early discovery” strategy used CPS to assess students’ fundamental knowledge from pre-requisite coursework. The “immediate feedback” strategy used CPS to assess comprehension or application of content just taught. The “retention” strategy used CPS to assess retention of information at subsequent lectures. Study outcomes were student and faculty attitudes and examination scores. Students and faculty completed satisfaction surveys. 2005 exam scores were compared to 2004 scores.

RESULTS: CPS was used to pose 94 questions in 14 class periods (31 early discovery, 28 immediate feedback, 35 retention). Eighty-nine students (94%) and three faculty (100%) completed the satisfaction survey. Both groups rated the system positively. Eighty-seven percent of students enjoyed using the CPS technology. Eighty-four percent agreed that CPS encouraged active learning and allowed participation without fear of judgment. The majority of students agreed that early CPS use was effective (83% early discovery, 88% immediate feedback, 80% retention). All faculty agreed that each implementation strategy was effective. Assessment of 2004 and 2005 examinations yielded 22 similar questions for comparison. While there was not a statistically significant change observed in overall examination scores (p=0.093), one content area showed significant improvements (p<0.037).

CONCLUSIONS: Implementing CPS using three strategies was well received by both students and faculty. Students and faculty agreed that CPS encouraged participation and active learning. While overall examination scores did not improve significantly, certain content areas saw improvement. Due to positive feedback, utilization of this system has been implemented in subsequent Therapeutics courses.


PURPOSE: The purpose of this study is to determine whether there is a difference in test performance on information related to antibacterial pharmacotherapy for students who have and have not taken the elective Basic Concepts in Antibacterial Pharmacotherapy prior to entering Pharmacotherapeutics III at our institution.

METHODS: On day one of Pharmacotherapeutics III, before any lectures were completed, a test was given to determine whether or not the students had been exposed to a given antibacterial knowledge base upon entering Pharmacotherapeutics III at our institution. The test consisted of 10 questions related to the infectious diseases topics to be discussed during the first few weeks of Pharmacotherapeutics III. Topics covered on the test were selected from those covered in the following topics: Pseudomonas aeruginosa; beta-lactamase inhibitors; ciprofloxacin; clindamycin; metronidazole; tetracyclines; penicillinase-resistant penicillins; and vancomycin. The test was given to all students entering Pharmacotherapeutics III, including those who had not taken the elective Basic Concepts in Antibacterial Pharmacotherapy. The test was composed of 30 questions. The pre-test was given on day one of Pharmacotherapeutics III, and the post-test was given on the second day of Pharmacotherapeutics III. The pre-test was used as a measure of baseline knowledge, while the post-test was used to assess the effectiveness of the elective. Comparison of the pre-test and post-test scores was used to determine the effectiveness of the elective.

RESULTS: The pre-test was given to 100 students who had not taken the elective Basic Concepts in Antibacterial Pharmacotherapy, and the post-test was given to 100 students who had taken the elective. The mean score on the pre-test was 75.8% (standard deviation = 15.2). The mean score on the post-test was 78.3% (standard deviation = 14.8). The difference in scores was statistically significant (p<0.05).

CONCLUSIONS: This study was designed to quantify the degree of focused cultural competency training in pharmacy school curriculums. The findings of this study suggest that the implementation of CPS in a Therapeutics course may be beneficial to require that all students partake in a course such as Basic Concepts in Antibacterial Pharmacotherapy to facilitate their understanding of this important area of pharmacotherapy.

37. The prevalence of cultural competency training at schools and colleges of pharmacy. Kelly M. Budd, Pharm.D.; BCPS; Nicole M. Stack, Pharm.D.; (1)Alessi Healthcare, Cooperstown, NY; (2)Albany College of Pharmacy, Albany, NY.

PURPOSE: Accreditation Council for Pharmacy Education accreditation standards for pharmacy programs require institutions of pharmacy education to create a teaching environment that values diversity and provides instruction with working with diverse colleagues and patients. Diversity is one key factor in developing cultural competency. Importantly, increasing cultural competency has been shown to reduce disparities in healthcare stemming from a breakdown in effective patient-provider communication. This study is designed to quantify the degree of focused cultural competency training in pharmacy school curriculums.

METHODS: The authors conducted a review of the curriculums of the existing United States (U.S.) and U.S. Affiliate Schools of Pharmacy as recognized in the 2004/2005 American Association of Colleges of Pharmacy Roster. Curriculums were accessed via their online listings and class descriptions available at each institution’s Web site (accessed between December 1, 2004, and August 12, 2005).

RESULTS: Ten of the 97 schools of pharmacy (10.3%) studied offered focused classes, either required or elective, on diversity and/or the development of skills necessary to achieve cultural competence.

CONCLUSIONS: A review of pharmacy school curriculums shows that many new and experienced practitioners may not have had adequate exposure to focused and in-depth cultural competency training via their formal pharmacy education.

38. Evidence-based medicine in the classroom: student attitudes and content with literature evaluation terms. Jill S. Barkiewicz, Pharm.D.; Midwestern University Chicago College of Pharmacy, Downers Grove, IL.

PURPOSE: The purpose of this investigation is to determine 1) the attitudes of pharmacy students in a Landmark Trials elective course toward evidence-based medicine (EBM); 2) the impact of the elective on comfort with technical terms used in drug literature; and 3) student-reported access to PubMed.

METHODS: A questionnaire was administered to students in a third professional year Landmark Trials elective course on the first and last day of class. The pre- and post-questionnaire assessed the student attitudes toward EBM, self-assessed comfort with technical terms used in evidence-based medicine, and access to PubMed. Ordinal scale measures were used to assess attitudes and comfort levels, while nominal measures were used to assess access to PubMed.

RESULTS: Completed responses were received from 27 students over two years (100% response rate). Overall, students had positive attitudes toward EBM both before and after the course (39.3% positive, 37% somewhat positive, 10.3% somewhat negative, p=0.037). Students thought research findings were useful to pharmacy practice (96.3% positive or somewhat positive) and these thoughts were unchanged post-course (Wilcoxon Signed Rank p=0.097). After the course, students were more likely to feel that pharmacists should rely on practice guidelines to make patient-care decisions (p=0.007). Although 96% of students admitted to having internet access at home, only 63% of students identified that they had PubMed access at home. The course increased self-assessed comfort with technical terms used in literature evaluation: relative risk (p=0.003), absolute risk (p=0.008), number needed to treat (p=0.001), odds ratio (p=0.014).

CONCLUSIONS: Pharmacy students in a Landmark Trials elective course have positive attitudes toward evidence-based medicine and the application of research findings to practice. The course increased self-assessed comfort with technical terms used in literature related to evidence-based medicine. Further education on access of PubMed via the Internet may be required.

39. An inquiry into research interests and support needs of clinical pharmacy faculty. A. Simon Pickard, Ph.D.; Jerry L. Bauman, Pharm.D.; University of Illinois College of Pharmacy, Chicago, IL.

PURPOSE: To determine the research interests and types of support that would facilitate scholarship in research among clinical (non-tenure) track (CT) pharmacy faculty.

METHODS: A cross-sectional survey of CT faculty at UIUC was completed by self-report via the Web in November 2003. Faculty were asked to indicate their level of interest (none, a bit, a lot, extreme) in several pharmacy-related topics (pharmacokinetics, pharmacoepidemiology, and drug treatment outcomes) and in support from the department regarding: study design, analysis, data management, development of research questions/hypotheses, sample size calculations, IRB preparation, awareness of funding opportunities, grant writing, grant management and writing for journals.

RESULTS: Of 39 respondents, 100% indicated they were interested in being co-investigators, and 77% lead investigators, on research studies. The median number of publications over the past 2 years was 1 (range 0 to 21). Less than 50% (18/39) were satisfied with current scholarly productivity. The majority of respondents expressed a “lot” or “extreme” interest in support for all areas, particularly sample size calculations, selection of appropriate statistical tests, grant writing, and writing for journals. CT faculty expressed a “lot” or “extreme” interest in the following topics: 87% drug treatment outcomes, 56% pharmacogenetics, 33% pharmacokinetics (p<0.001). Comments and issues included: lack of confidence in ability, need for balancing.
responsibilities, creation of specific research interest groups, and a need for greater mentorship and statistical support.

CONCLUSIONS: In general, research productivity by CT faculty will likely remain low unless support for such scholarly activity is promoted and provided. Recommendations include rewarding publications/proposal submissions with protected time for research, mentorship pairing with tenure-track faculty, study protocol and grant development workshops, and special interest research groups. Although this study was limited to UIC faculty, these issues and solutions may resonate with CT faculty nationally and internationally.

40. Development of a reliable assessment for continuing professional development portfolios. Sharon L. Haughey, B.Sc.1

METHODS: In order to test the reliability of the assessment, 10 trained

pharmaceutical register. However, portfolio assessment has been questioned

model. On an annual basis a random sample of pharmacists will be required

cycles, was expressed as the kappa (κ) statistic.

RESULTS: Of the seven assessment criteria, two criteria had an agreement

level of κ = 0.80 (excellent inter-assessor agreement), four criteria had an agreement

level between κ=0.70-0.75 (substantial inter-assessor agreement) and one criterion had an agreement level of κ = 0.45 (moderate inter-assessor agreement).

CONCLUSIONS: The levels of inter-assessor agreement found in this study were generally higher than those reported in previous research involving assessment criteria and portfolios. Previous studies have reported inter-

assessor agreement levels at a "slight" to "moderate" level. This research shows that higher levels of inter-assessor agreement can be achieved using a clear portfolio structure in conjunction with straightforward assessment criteria and assessment guidelines. Further investigation is ongoing to determine inter-assessor agreement for the summative assessment of CPD portfolios.

Endocrinology

41E. Projected coronary heart disease risk benefit of extended-release niacin/lovastatin versus fenofibrate in patients with type 2 diabetes mellitus. Scott L. Charland, Pharm.D.2

METHODS: Baseline and end-trainment projected 10-year CHD and stroke risks were calculated using the UK Prospective Diabetes Study risk model in patients with type 2 diabetes mellitus (T2DM). Since comparative clinical data of these alternative approaches are sparse, application of a valid, diabetes-specific risk prediction model may provide a useful means of assessment.

METHODS: Baseline and end-treatment projected 10-year CHD and stroke risks were calculated using the UK Prospective Diabetes Study risk model in patients with complete follow-up from a randomized, double-blind, placebo-controlled, 20-week trial of extended-release niacin/lovastatin (ERN/L) 1000/40 mg (N=48) and 1500/40 mg qhs (N=51) versus fenofibrate 200 mg qd (FENO). N=58). All patients had T2DM treated with a thiazolidinedione and/or metformin, low HDL-C (<40 mg/dL), low apo-A1 (apo-A1 <20 mg/dL), and TG ≥ 150 mg/dL. The primary endpoint was projected 10-year CHD and stroke risk reduction for ERN/L compared with FENO using one-way ANOVA with post-hoc significance testing.

RESULTS: Baseline model variables were similar between the treatment groups except for duration of T2DM (FENO 10±9 yrs; ERN/L 1500/40 mg 8±7 yrs; p<0.05). Baseline 10-year CHD, fatal CHD, stroke and fatal stroke risks were similar in the 3 treatment groups, and decreased significantly on therapy. Risk reductions for fatal and non-fatal CHD (43% versus 24%), fatal CHD (43% versus 29%) and stroke (27% versus 18%) were significantly greater for ERN/L 1500/40 mg versus FENO (p<0.05).

CONCLUSION: ERN/L provides a significant additional reduction in predicted 10-year CHD risk compared with maximum dose fenofibrate in patients with T2DM.

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Gastroenterology

42E. Medication usage evaluation of proton pump inhibitors for gastrointestinal prophylaxis in non-ICU settings. Joanna Y. Chang, Pharm.D.1

METHODS: A total of 368 admitted adult patients to non-ICU units receiving acid suppression agents as part of routine clinical practice between March 2003 to October 2005 were evaluated for appropriate usage. These patients were divided into two arms in a prospective pre and post intervention study.

RESULTS: Upon admission, questionable PPI use was 71% in the control group and 69% in the intervention group. Despite the high opportunity in the control group (31%) to make a recommendation to PPI guidelines, therapies were discontinued two times more frequently in the intervention group (13% vs. 0.007) upon discharge. The accepted interventions recommended by the pharmacy was 81% to either discontinue or dose adjust PPI. Overall, there were no significant differences in GIB events between the two groups at the end of 12 month follow-up.

CONCLUSION: We found a high frequency of inappropriate PPI use for GIB prophylaxis in the non-ICU settings. The majority of these patients do not have ASHP-identified risk factors, except prior history for peptic ulcer disease or upper GIB. It is important to establish criteria for physicians in the non-

ICU settings for patients with low risk factors to reduce unnecessary cost and minimize the risk for pneumonia.

Presented at the Midyear Meeting of the American Society of Health-System Pharmacists, Orlando, FL, December 4-8, 2004.

Geriatrics

43. Improving treatment guideline adherence in long-term care facility patients. Kristin K. Horning, Pharm.D.; James D. Hoehn, Pharm.D.; University of Iowa College of Pharmacy/Northeast Iowa Family Practice Center, Waterloo, IA.

METHODS: A retrospective chart review was conducted on 107 patients in two LTCFs receiving disease state management services and 304 patients in four other LTCFs. Treatment guideline adherence was evaluated for the following conditions: diabetes, coronary artery disease (CAD), stroke, congestive heart failure (CHF), hypertension, hyperlipidemia, and osteoporosis. In addition, the six most recent pharmacist recommendations for each patient were classified according to intervention type and disease state.

RESULTS: Adherence to guidelines was significantly better in patients receiving disease state management. Greater adherence was seen in the following areas (all p<0.05): diabetes, hypertension, congestive heart failure, osteoporosis, stroke, diabetes, coronary artery disease, stroke, and congestive heart failure. In the non-ICU settings, the majority of these patients do not have ASHP-identified risk factors, except for prior history for peptic ulcer disease or upper GIB. It is important to establish criteria for physicians in the non-ICU settings for patients with low risk factors to reduce unnecessary cost and minimize the risk for pneumonia.
management (34%) than were pharmacists in control facilities (32.4%) (P=0.04).

CONCLUSION: We observed significantly greater treatment guideline adherence for four of seven disease states evaluated in patients receiving disease management services. Placing greater emphasis on a disease state focused approach to pharmacist consulting at LTCFs may improve patient care.

44E. Effect of 80 mg versus 10 mg of atorvastatin in patients ≥65 and <65 years of age with stable coronary heart disease. Nanette Wenger, M.D.1, Sandra J. Lewis, M.D.2, David M. Herrington, M.D.1, Vera Bittner, M.D.3, Francine K. Williams, M.D.1, David D. Waters, M.D.1, The University of Alabama at Birmingham, Birmingham, AL, (1)Emory University School of Medicine, Atlanta, GA, (2)Northwest Cardiovascular Institute, Portland, OR, (3)Wake Forest School of Medicine, Winston-Salem, NC, (4)University of Alabama at Birmingham, Birmingham, AL; (5)Beth Israel Deaconess Medical Center, Boston, MA.

INTRODUCTION: Intensive lipid-lowering treatment with atorvastatin 80 mg in patients with stable coronary heart disease (CHD) in the Treating to New Targets study provided significant clinical benefit beyond treatment with atorvastatin 10 mg. The present analysis provides a post hoc assessment of the efficacy and safety of high-dose atorvastatin therapy in patients ≥65 years and in those <65 years of age.

METHODS: A total of 10,013 patients (3,809 ≥65 years) were randomized to double-blind therapy with atorvastatin 10 or 80 mg/dl for a median follow-up of 4.9 years. The primary end point was the first major cardiovascular event (death from CHD, nonfatal non-procedure-related myocardial infarction, resuscitated cardiac arrest, or fatal or nonfatal stroke).

RESULTS: Mean changes in LDL-C, HDL-C and TG were similar in both groups. In patients both older and younger than 65, intensive therapy with atorvastatin 80 mg significantly decreased the rate of major cardiovascular events. Secondary measures of clinical efficacy in each subgroup were consistent with those in the overall study. More patients on 80 mg discontinued treatment due to treatment-related adverse events (<65 years: 5.1% vs 8.7%; ≥65 years: 3.6% vs 8.0%) in atorvastatin 10 and 80 mg, respectively.

CONCLUSIONS: Intensive lipid-lowering treatment with atorvastatin 80 mg in patients with stable CHD produced significant reductions in relative risk for major cardiovascular events in both older (≥65 years of age) and younger patients (<65 years of age).

45. Rating the anticholinergic potential of selected medications. Kelly M. Rose, Pharm.D., BCPS1, Emily Bigonzi, Pharm.D., BCPS2, Cynthia L. Rachlin, Pharm.D., FASHP, FCP3, Maryellen L. Mullaney, Pharm.D., BCPS4, (1)Bassett Healthcare, Cooperstown, NY, (2)Texas Tech University-HSC-School of Pharmacy, Amarillo, TX.

PURPOSE: This study produced an efficient system of quantifying, comparing and reducing medication-related anticholinergic exposure by 1) creating an anticholinergic rating for various medications common in geriatric practice, and 2) proposing a methodology for clinician utilization of the rating system. Reducing medication-related anticholinergic exposure is a key practice in geriatric pharmacotherapy to 1) improve patient’s quality of life 2) decrease adverse drug-events, and 3) decrease morbidity and mortality in the geriatric population.

METHODS: Radioreceptor assay (RRA) determinations of atropine equivalent values, an in vitro standardized marker of anticholinergic activity, was derived from the Medline database (1966–June 2005) and via personal communication with experts in this line of research.

RESULTS: The atropine equivalent values were converted to a standardized rating system to rank relative potency of anticholinergic properties. A consensus panel of clinician experts in the field of geriatric pharmacotherapy reviewed the rankings, resolving discrepancies to create an objective and qualitative rating of anticholinergic potential.

CONCLUSION: The culmination of data led to the creation an objective scoring method that clinicians can use to qualitatively compare the anticholinergic potential of various medications, methodology that is currently a void in the existing literature. Likewise, the study authors propose it may be possible to quantify the anticholinergic potential expressed by individual medications and by the entire medication regimen to decrease anticholinergic exposure in the geriatric population.

46. Evaluation of acetylcholinesterase inhibitor formulary therapeutic substitution in a Veterans Affairs patients population. Shelia R. Beis, Pharm.D.; BCPS1, Courtney Vincent Eatmon, Pharm.D.2, Melody Ryan, Pharm.D., BCPS, CGP1, (1)University of Kentucky College of Pharmacy, Lexington, KY; (2)Lexington VAMC, Lexington, KY.

PURPOSE: Acetylcholinesterase inhibitors (AChE-Is) are first-line agents for moderate cognitive decline in Alzheimer’s Dementia. No comparative efficacy trials exist differentiating outcomes between AChE-Is, and commonly health systems may change preferred formulary agents based on cost. Once initiated, AChE-Is are usually changed only if the patient experiences adverse effects or inadequate response. Literature is limited regarding changing AChE-Is in patients stabilized on the first agent. Our institution made galantamine the preferred AChE-I and required therapeutic substitution for all patients receiving donepezil. We evaluated the clinical outcomes associated with this formulary substitution.

METHODS: Eligible patients were evaluated in a pharmacy clinic prior to and eight weeks after the substitution. Cognitive functioning was assessed with the Mini-Mental State Exam (MMSE), daily functioning was assessed by the Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL). Galantamine was initiated at 4 mg bid after a 3-day washout period and increased to 8 mg bid after 4 weeks. If patients did not tolerate galantamine or had a decline in function or cognition, they were changed back to donepezil. Paired t-tests were used to determine cognitive or functional change.

RESULTS: Seventy-one patients were converted to galantamine. At the 8-week assessment, 71.8% remained on galantamine, 21% restarted donepezil, and 1% were not on any AChE-I. Patients who remained on galantamine had no significant change in MMSE (±5.11, p=0.22) or ADCS-ADL (±0.34, p=0.76) scores from baseline to 8 weeks. Eight (11.3%) patients restarted donepezil due to lack of efficacy (MMSE ±3.87, ns; ADCS-ADL -12.92, p=0.04). Seven patients (9.9%) were unable to tolerate galantamine (3/7 had gastrointestinal complaints).

CONCLUSIONS: Most patients stabilized on donepezil were successfully changed to galantamine. A few patients experienced a decline during the conversion. Given the irreversible nature of cognitive decline, patients should be monitored closely during a change in AChE-I.

Health Services Research

47. Physician perceptions of medication therapy management services (MTMS): developing outpatient clinical services. Rosalyn S. Padiyara, Pharm.D., Suzanne M. Rabi, Pharm.D., Ramesh V. Patel, Pharm.D., Swedish Covenant Hospital, Chicago, IL.

PURPOSE: With the approval of MTMS CPT codes, pharmacists will be able to bill applicable third party payors when providing MTMS services. MTMS services can be provided for patients who are covered under the Medicare Part D prescription drug benefit and include selecting, initiating, modifying or administering medication therapy, monitoring and evaluating patient response to therapy, patient/family medication counseling, and disease and wellness prevention programs. The objective of this study is to describe current physician attitudes toward implementing clinical pharmacy services that have not previously existed in a hospital setting and to determine which MTMS-related outpatient services physicians desire pharmacists to provide.

METHODS: Physicians at a 300-bed community hospital were asked to complete a 3-question survey. Surveys evaluated if physicians worked with a clinical pharmacist in an outpatient setting in the past, the types of services they would consider pharmacists to provide, and which specific services they would recommend for their patients. All surveys were analyzed using descriptive statistics.

RESULTS: Two-hundred fifty physicians were provided a survey regarding MTMS services. The response rate was 18% (N=44). The majority of physicians worked in internal medicine or family practice. Twenty-five percent worked with a clinical pharmacist in the ambulatory care setting in the past; 88% would recommend the use of a pharmacy-related services. Anticoagulation (23%), smoking cessation (20%), and diabetes (18%) were among the top three clinical services physicians would use. Physicians with advanced training (fellowship) were less likely to feel a need for pharmacist services.

CONCLUSIONS: The majority of physicians at this hospital show strong support for pharmacist-provided services. The majority of interest was shown for complicated disease states. Results may be used to develop MTMS-related outpatient clinical services at other institutions that will allow pharmacists to work effectively with other disciplines.

Hematology/Anticoagulation

48. Clinical outcomes using subcutaneous unfractionated heparin andwarfarin after elective total hip and total knee arthroplasty. William Daye, Pharm.D., Jeff King, Pharm.D., John Meehan, M.D., Jennifer Branch,
ACCP 2006 SPRING PRACTICE AND RESEARCH FORUM e13

Pharm D., Richard White, M.D.; University of California, Davis Medical Center, Sacramento, CA.

PURPOSE: In patients having elective total hip arthroplasty (THA) or knee arthroplasty (TKA), prophylaxis with an anticoagulant is required to prevent complications associated with venous thromboembolism (VTE). Anticoagulation regimens that have been studied in clinical trials generally have compared the efficacy of two different drugs over a specified time period. In trials comparing warfarin to other anticoagulants, no heparin was administered during the time required for warfarin to reduce the level of clotting factors. The reported incidence of symptomatic VTE and major bleeding for warfarin alone in clinical trials is in the range of 0.3–1.8% and 3.3%, respectively. At UC Davis, patients undergoing TKA or THA receive 7500 units unfractionated heparin (UFH) subcutaneous (SC) plus warfarin starting the evening after surgery. Warfarin is continued for approximately 1 month with a target INR of 2.0 (range 1.3–2.5). The outcome of this practice has not been prospectively evaluated.

METHODS: Patients undergoing an elective TKA or THA receiving UFH, 7500 units SC q 12 hours for 2–3 days plus warfarin for 4 weeks. Patients were followed up by review of medical records and by a phone interview one month after hospital discharge. 170 consecutive consenting patients were available for analysis.

RESULTS: The duration of warfarin therapy was 29.3 ± 8.9 days; the average INR = 1.66 ± 0.37 (range 1.1–4.2). 12 minor bleeding episodes were reported (average INR > 1.75 ± 0.38), none requiring intervention. No symptomatic thrombotic events or episode of heparin-induced thrombocytopenia were observed.

CONCLUSION: Combining initial postoperative short-term 7500 units UFH SC every 12 hours with warfarin for 4 weeks targeting an INR of 2.0 appears to be safe and effective for minimizing the risk for symptomatic VTE or bleeding complications.

49. Adherence to national guidelines for the management of elevated international normalized ratios associated with warfarin therapy. Emily Beth Devine, Pharm D., M.B.A., BCPS, FASHIP; Alan W. Hopeff, Pharm D.; Ann K. Wittkowsky, Pharm D., CACP, FASHIP; (1)University of Washington, Department of Pharmacy, Seattle, WA; (2)Amerinet, Inc., St. Louis, MO.

PURPOSE: To evaluate current practice patterns in managing patients with excess warfarin anticoagulation, and to evaluate adherence to guidelines for reversal of excess anticoagulation, as recommended by the American College of Chest Physicians 7th Conference on Antithrombotic and Thrombolytic Therapy.

METHOD: This is an observational study of cases receiving treatment for excessive warfarin anticoagulation (International Normalized Ratio ≥ 4.5). Cases were drawn from 22 institutions where warfarin was managed in clinic or acute care settings. RESULTS: 433 cases were reviewed. The mean INR value was 7.7. Indications for warfarin were atrial fibrillation (194 (45%)); deep venous thrombosis/pulmonary embolism (94 (22%)); prosthetic heart valve (56 (13%)). Secondary prevention of stroke, myocardial infarction (MI) or death (41 (10%)); orthopedic procedures (33 (8%)); and primary prevention of MI, 10 (2%). The number and proportion of total cases, categorized by each INR level specified in the guidelines were: INR < 3, 107 (25%); INR ≥ 3.0–8.9, 200 (46%); INR ≥ 9.0–19.9, 44 (10%); INRs > 20 or serious bleeding, 79 (18%); life-threatening bleeding, 4 (0.7%). Treatment for 173 (40%) cases did not adhere to current guidelines. Lack of adherence was attributed primarily to the under- or overuse of vitamin K, and to overuse of fresh frozen plasma. Of those that were not adherent, 27 (16%) were under-treated, and 89 (51%) were over-treated. In 116 of 173 (67%) cases, lack of adherence was attributed to administration of less preferred routes of administration of vitamin K—subcutaneous or intramuscular, instead of oral or intravenous.

CONCLUSION: Adherence to national guidelines for the management of excessive anticoagulation is low. Potential exists for education and improvement in adherence to these national guidelines in both clinic and acute care settings.

50E. Capturing the financial impact of heparin-induced thrombocytopenia. Maureen Smythe, Pharm D.; John M. Koerber, Pharm D.; Joan C. Mattson, M.D.; (1)Department of Pharmacy, William Beaumont Hospital and Department of Pharmacy Practice, Wayne State University, Detroit, MI; (2)William Beaumont Hospital, Royal Oak, MI; (3)Department of Clinical Pathology, William Beaumont Hospital, Royal Oak, MI.

Data evaluating the financial impact of heparin-induced thrombocytopenia (HIT) is lacking. The goal of this case-control study was to evaluate the financial impact of HIT. Case patients were those with a new diagnosis of HIT from April 2003 to March 2004 for whom matched controls were available. Controls for the patient were matched for the DRG under which the hospital was reimbursed, the patients’ primary diagnosis code and their primary procedure code. Case patients required identification of >1 control for inclusion. The hospital’s financial database was queried for length of stay (LOS), total cost, and reimbursement. For each case patient, the cost and reimbursement were compared to the cost and reimbursement for each group of matched controls. In an effort to eliminate the impact of variable reimbursement, a subset of only Medicare case and control patients was also evaluated. Of 72 new HIT patients, matched controls were identified for 31. The mean LOS for the case and control patients was 22.8 and 11.6 days respectively (p=0.006). The mean hospital cost of case and control patients was $55,440 and $26,505 respectively. From reimbursement calculations, our institution lost an average of $13,429 per HIT patient compared to $393 per control patient (p=0.005). The mean LOS for Medicare cases (n=21) and matched Medicare controls was 26 and 14 days respectively (p=0.041). The mean hospital cost of Medicare case and control patients was $38,842 and $30,210 respectively. From reimbursement minus cost calculations for the Medicare subset, our institution lost an average of $20,220 per HIT case compared with $11,200 for control patients (p=0.001). Assuming 72 cases of HIT per year, our institution incurs a projected annual loss of $980,000 from HIT. The use of alternate anticoagulants, although having a higher acquisition cost, may offset this loss through HIT avoidance. Presented at the Annual Meeting of the American Society of Hematology, Atlanta, GA, December 12, 2005.

51E. Identifying the incidence of heparin-induced thrombocytopenia. Maureen Smythe, Pharm D.; John M. Koerber, Pharm D.; Joan C. Mattson, M.D.; (1)Department of Pharmacy, William Beaumont Hospital and Department of Pharmacy Practice, Wayne State University, Detroit, MI; (2)William Beaumont Hospital, Royal Oak, MI; (3)Department of Clinical Pathology, William Beaumont Hospital, Royal Oak, MI.

Heparin-induced thrombocytopenia (HIT), an immune-mediated syndrome which may result in life-threatening thrombosis, is estimated to occur in up to 5% of patients receiving unfractionated heparin (UFH). The risk of HIT depends on patient type (surgical or medical) and the amount/route of UFH. The goal of this project was to determine the incidence of HIT within our 1064-bed tertiary-care institution over a one-year period. The hospital admissions database was queried to identify the number of patient admissions. The pharmacy system database was queried to identify the number of patients receiving intravenous (IV) and/or subcutaneous (SQ) UFH as well as the number of patients (excluding cardiac catheterization) who received a direct thrombin inhibitor (DTI). Medical records of patients receiving a DTI were reviewed to categorize the indication for DTI therapy (clinical diagnosis of HIT, suspected HIT, history of HIT and other). Criteria for all categories were developed a priori. New HIT patients included those with a clinical diagnosis of HIT or suspected HIT (unable to rule out). The laboratory system database was queried to retrieve heparin platelet factor 4 (HPIF4) immunoassay results in new HIT patients. During the study period, 58,814 patient admissions occurred with an estimated 24,008 patients being exposed to UFH. DTI therapy was administered in 133 patients. Of these, 13 new HIT patients (46% medical and 54% surgical) were identified. Eighty percent of the surgical patients underwent cardiovascular surgery. A positive HPIF4 result occurred in 69% of new HIT patients. The incidence of HIT was 0.3%. Cardiovascular surgery patients were the most likely to develop HIT. The incidence of HIT in patients receiving therapeutic-dose IV heparin was 1.0% whereas the incidence in patients receiving only antithrombotic prophylaxis was 0.3%. These estimates are conservative since DTI therapy was required in order for a new HIT case to be captured. Published in J Thromb Haemost 2005;Vol 3(Suppl 1):P1143.

52. Symptomatic venous thromboembolism rates after orthopedic surgeries in patients treated with unfractionated heparin, enoxaparin, dalteparin or fondaparinux. Matthew W. Sarnes, Pharm D.; Andrew Short, M.D.; M.P.H.; Mitchell Higash, Ph.D.; Laura Happe, Pharm D., M.P.H.; Eileen Farrelly, M.P.H.; (1)Applied Health Outcomes, Havertown, PA; (2)Washington Hospital, Washington, DC; (3)GlaxoSmithKline, Philadelphia, PA; (4)Applied Health Outcomes, Tampa, FL.

PURPOSE: To assess differences in symptomatic VTE rates among anticoagulants used for prophylaxis in orthopedic surgery patients.

METHODS: This was a retrospective analysis of inpatient data from over 500 hospitals in the United States. Patients hospitalized for hip or knee replacement or hip fracture surgery between January 2003 and March 2005 were eligible for study inclusion. Patients receiving unfractionated heparin (UFH), enoxaparin, dalteparin or fondaparinux within 2 days of surgery were included in the analysis. Patients were excluded if they were >18 yrs of age or if they received more than one anticoagulant at any time during their hospitalization. The occurrence of VTE was determined by the presence of an ICD-9 code for DVT or PE during the hospitalization. Logistic regression models were then used to assess differences in VTE rates between the anticoagulants, controlling for age, gender, severity of illness (Charlson), length of stay, presence of other hypercoagulable states, number of
53E. Clinical benefit and survival endpoints from a phase III trial comparing decitabine vs supportive care in patients with advanced myelodysplastic syndromes. Gene Wetzstein, Pharm. D., BCOP
1
Aarti A. Patel, M.B.A.,
3
Effie L. Gillespie, Pharm. D.
1
Eric G. Sahloff, Pharm. D.
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PURPOSE: Myelodysplastic syndrome (M. D.S) is a blood disorder characterized by dysplasias of hematopoietic cells resulting in cytopenias and progression to acute myelogenous leukemia (AML). There is only one approved therapy for M.D.S. Decitabine (Dacogen) is a cytosine analog that reverses aberrant DNA methylation leading to re-expression of silenced tumor suppressor genes. Results of adjudicated data will be presented.

METHODS: We report a phase III, randomized, open-label trial of decitabine (DA) vs supportive care (SC) in M.D.S patients with International Prognostic Scoring System (IPSS) Intermediate-1 (Int-1), Int-2, and Int-3 risk. Secondary M. D.S (14%) previously treated (21%) patients were included. Co-primary endpoints were response rate (CR + PR) and Time to AML or Death (TTAML/D).

RESULTS: 170 patients received either DAC (n = 89) (3-h infusion; 15 mg/m²/hr for 8 hrs for 3 days at 4 wks) plus SC or SC alone (n = 81). Response rate according to International Working Group (IWG) M.D.S criteria was 17% for DAC (9%, CR, 8%, PR) vs 0% for SC (p = .001). Responses occurred in all IPSS groups and were durable. DAC responders vs nonresponders had a median of 491 vs 274 AML-free days until death, a median of 657 vs 384 days of survival, and remained or became CR/platelet transfusion independence during response. Median TTAML/D in all pts was 340 days for DAC vs 219 days for SC (p = .043 Wilcoxon, .160 Log-rank). Using a Cox proportional hazards model, the probability of progression to AML or death was 1.72-fold greater for SC than DAC (p = .017). Quality-of-life evaluations showed DAC to be superior for global health status, physical functioning, fatigue, and dyspnea. As expected, the primary toxicity was myelo-suppression, with the major Grade 3-4 toxicity being febrile neutropenia.

CONCLUSION: DAC is a promising therapy for M. D.S, with predictable toxicity.


HIV/AIDS

54. Results of the PALS study: Pacific Oaks atazanavir/lipinavir switch. James D. Scott, Pharm.D., M.Ed., B.S.1, Peter R. Wolff, M.D.2, Anthony Scarsella, M.D.1, (1)Western University of Health Sciences, Pomona, CA; (2)Private Practice, Los Angeles, CA; (3)Pacific Oaks Medical Group, Beverly Hills, CA.

INTRODUCTION: Although the efficacy of lopinavir/ritonavir (LPV/RTV) based therapy for HIV has been demonstrated, a high incidence of triglyceride (TG) elevations is often seen. The current study assessed the clinical and lipid outcomes associated with switching viremically suppressed patients with elevated TG on LPV/r therapy to ATV/r therapy.

METHODS: 12 pts with viral load (VL)<400 c/mL for ≥2 months and fasting TG >200 mg/dL on a stable regimen containing LPV/r were changed to ATV/r with their original NRTIs in this 24wk pilot study. Assessments at Baseline (BL) and Weeks 4, 8, 16, and 24 included VL, CD4, lipids, chemistries; adherence and quality of life (QoL) were assessed at BL and 24 wks. Statistical analysis was performed using paired samples t-test and repeated measures ANOVA.

RESULTS: BL demographics: age=42 ± 7.0, CD4=490 ± (313) cells/mm³, total cholesterol (TC)=213 ± (44) mg/dL, fasting TG=194 ± (263) mg/dL, total bilirubin (TB)=0.8 ± (0.2) mg/dL. 1 pt withdrew at 4 wks due to diarrhea. There were no statistically significant changes in CD4 or TC at any time point. All pts maintained VL<400 c/mL. Compared to BL, TG trended to improved (p=0.06) at 4 wks (277 ± 131) and 8 wks (270 ± 138), and significantly improved (p<0.03) at 16 wks (256 ± 90) and 24 weeks (233 ± 102). TB also increased significantly (p<0.001) at all time points. No changes were seen in QoL or adherence.

CONCLUSION: Switching LPV/r to ATV/r did not affect immunologic or virologic outcomes, but did lead to significant increases in TG by 16 weeks. There were no changes at 24 wks in CD4, VL, TC, adherence and QOL. ATV/r was associated with increases in TB that were not considered clinically relevant.

55. Clinical outcomes with concurrent atazanavir and proton-pump inhibitor use. Eric G. Sahloff, Pharm. D.1, Joan M. Duggan, M.D.2, (1)University of Toledo College of Pharmacy, 2801 West Bancroft, Toledo, OH; (2)Medical University of Ohio, 2801 West Bancroft, Toledo, OH.

PURPOSE: The purpose of this study was to describe clinical outcomes [viral load (VL)/CD4 count] in patients receiving concomitant atazanavir (ATV) and proton pump inhibitors (PPIs). PPIs have the potential to decrease ATV solubility and/or absorption leading to subtherapeutic plasma ATV concentrations. Pharmacokinetic data have shown statistically significant decreases in ATV exposure when administered with PPIs. Evidence of the clinical significance of the ATV-PPI interaction is limited. In our clinic, we currently have patients requiring the administration of ATV+ritonavir (RTV) with a concurrent PPI.

METHODS: A retrospective chart review of all HIV positive patients ≥18 years prescribed ATV+RTV and a PPI for ≥2 months was performed. The primary outcome was achievement/maintenance of VL<400 cp/mL for ≥2 months when switched from ATV to ATV±RTV and/or a PPI. Four additional subjects with VL<400 cp/mL achieved undetectable VL while on concurrent ATV-PPI. Durations of concurrent therapy ranged from 2-23 months. Of the 3 subjects not maintaining VL<400 cp/mL, 1 subject had one VL<400 cp/mL value at 4 months. All subjects not achieving undetectable VL had ATV susceptibility per genotyping/phenotyping testing. One of 3 had decreased ATV susceptibility after 19 months on therapy. All 3 not achieving undetectable VL had known adherence issues.

CONCLUSIONS: Nine of 12 (75%) subjects achieved successful clinical outcomes associated with concurrent use of ATV-PPIs. Subjects maintaining adherence to prescribed regimens were able to achieve and maintain VL<400 cp/mL. In our experience, the drug interaction between ATV and PPIs is not clinically significant for patients under good virologic control.

Infectious Diseases

56. Meta-analyses of the impact of inappropriate antibiotic therapy on mortality in patients with ventilator-associated pneumonia and blood stream infections. Effie I. Gillespie, Pharm. D., Hartz A. Patel, M.B.A., Pharm. D., Craig I. Coleman, Pharm. D., University of Connecticut School of Pharmacy, Storrs, CT and Hartford Hospital, Hartford CT, Hartford, CT.

OBJECTIVES: Several studies have found that initial treatment of ventilator-associated pneumonia (VAP) and blood stream infections (BSI) with inappropriate antimicrobial therapy (IAT) is associated with higher rates of mortality, but additional studies have failed to confirm these findings. To provide a stronger quantitative basis, we conducted a series of meta-analyses of existing relevant studies.

METHODS: Three investigators systematically searched databases from 1966-September 2003 and reviewed citations in relevant articles to identify studies that met the following inclusion criteria: (1) randomized or observational trials, (2) compare VAP or BSI patients receiving appropriate antimicrobial therapy (defined as an antibiotic regimen with demonstrated-in-vitro activity against identified bacterial species associated with infection) and IAT (3) report data on incidence of mortality. We conducted mortality analyses, both with and without adjustment for confounding factors. A random-effects model was utilized.

RESULTS: All studies included were observational. A meta-analysis of VAP studies utilizing unadjusted mortality data (n=8 studies) demonstrated IAT significantly increased patients’ odds of mortality [odds ratio (OR): 2.03 (95%CI 1.39-3.03); Q statistic p-value = 0.23]. Similar results were seen upon meta-analysis of adjusted mortality data (n=9 studies) [OR: 2.00 (95%CI 1.32-3.05); Q statistic p-value = 0.06]. A meta-analysis of BSI studies utilizing unadjusted mortality data (n=16 studies) demonstrated IAT significantly increased patients’ odds of mortality [OR: 2.29 (95%CI 1.18-4.28); Q statistic p-value = 0.0033]. Similar results were seen upon meta-analysis including adjusted mortality data (n=16 studies) [OR: 2.11 (95%CI 1.53-2.92); Q statistic p-value < 0.0001]. Assessment of the funnel plots and Egger’s weighted regression statistics (p-value > 0.34 for all) demonstrated a low probability of significant publication bias in the VAP and BSI analyses.
CONCLUSIONS: There appears to be an association between IAT and higher mortality in patients with VAP and BSI, thus emphasizing the critical importance of early appropriate antimicrobial therapy.

Prepared at the 16th European Congress of Clinical Microbiology and Infectious Diseases, Nice, France, April 1-4, 2006.

57. Increasing linezolid minimum inhibitory concentrations (MIC) in methicillin-resistant Staphylococcus aureus at a large academic teaching institution. Nathan P. Wirsich, Pharm.D.1, Debra A. Goff, Pharm.D.1, Julie Mangino, M.D.2. (1)Hillcrest Hospital; Cleveland Clinic Health System Eastern Region, Mayfield Heights, OH, (2)The Ohio State University Medical Center, Columbus, OH.

BACKGROUND: Linezolid (L) was added to the formulary in 2000 for treating MRSA and vancomycin resistant enterococcal infections. (L) is not restricted, yet use is monitored. Our purpose is to assess (L) MICs for MRSA over time.

METHODS: A retrospective analysis of 2,827 MRSA isolates (2001-2004) was performed for (L) MIC data. (L) susceptibility was determined by E-test (01/01-08/02) and by microdilution using Micronesic® panels (09/02-12/04). Clinical and Laboratory Standards Institute (CLSI) breakpoints were used identifying MICs ≥ 4 as non-susceptible. Isolates with a MIC ≥ 4 had patient data reviewed for antibiotic exposure and demographics. The percent of MRSA with MIC ≥ 4 from each year were compared statistically by Fischer’s Exact Test. Defined Daily Dose/1000 patient days (DDD) was calculated for (L) and vancomycin to determine use.

RESULTS: A significant increase of MRSA isolates with an MIC = 4 was observed from 2002-2003. Patients had a history of prior antibiotic use and hospitalization. DDD of linezolid also increased.

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58E. In vitro pharmacodynamics of anidulafungin and caspofungin against clinical isolates of Candida glabrata including strains with elevated MICs to caspofungin. Jason M. Cota, Pharm.D.1, Nathan P. Wiederhold, Pharm.D.1, David S. Burgess, Pharm.D.1, Laura K. Najjar, B.S.1, John R. Graybill, M.D.1. (1)University of Texas at Austin, San Antonio, TX, (2)University of Texas Health Science Center at San Antonio, San Antonio, TX.

BACKGROUND: The echinocandins anidulafungin and caspofungin have demonstrated activity against Candida glabrata, a species of increasing clinical significance. We performed an in vitro evaluation of the pharmacodynamics of anidulafungin and caspofungin against clinical isolates of C. glabrata including those with increased MICs to caspofungin.

METHODS: MICs and MFCs were determined for 19 C. glabrata isolates using CLSI M27-A2 methods. Pharmacodynamic analysis was performed in triplicate using the XTT viability assay at anidulafungin and caspofungin concentrations ranging from 0–128 µg/mL. IC50 and IC90 values (µg/mL) were calculated by fitting XTT data to a four-parameter logistic model (Hill equation). Goodness of fit for each isolate-drug combination was assessed by R2 and standard error of the IC50 value. Pharmacodynamic results for isolates with MICs ≥ 4 were compared using the time-kill assay.

RESULTS: MIC values were at least 2 dilutions lower for anidulafungin than caspofungin for all 19 isolates, compared statistically by Fischer’s Exact Test. Defined Daily Dose/1000 patient days (DDD) was calculated for (L) and vancomycin to determine use.

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60. Investigation of the mutant prevention concentration (MPC) of linezolid for Enterococci and Staphylococci. George P. Allen, Pharm.D.1,2, Peggy S. McKinnon, Pharm.D.3, John R. Graybill, M.D.1,2. (1)University of Texas at Austin, San Antonio, TX; (2)University of Texas Health Science Center at San Antonio, San Antonio, TX; (3)The Ohio State University Medical Center, Columbus, OH.

BACKGROUND: The development of linezolid (LZ) has expanded the use of LZ for Enterococcus faecalis, Enterococcus faecium, and Staphylococcus aureus. LZ-resistant mortality was higher in patients with LZ as appropriate therapy (63% vs 16%, 62 vs 23%, 42 vs 10%, P < .001). Multiple logistic regression analysis identified independent risk factors for clinical failure as inappropriate empirical therapy (OR 14.0, 95%CI 3.2–52.9), and ICU type (2.9, 1.3–6.6). The same factors were associated with mortality: inappropriate empirical therapy (OR 9.7, 95%CI 3.2–28.9), high risk source (3.2, 2–13.6), and ICU type (2.3, 1.3–4.0).

CONCLUSIONS: IAT is associated with clinical failure and mortality in ICU GN. The rate of IAT varied among institutions. The standardized tool was useful to track and compare appropriate empiric tx selections, IAT, and outcomes in various hospital settings.


Managed Care

61E. Concurrent statin-warfarin prescriptions in a managed care population. Garrett M. Fitzmaurice, Ph.D.1, John Kochevar, Ph.D.2, Tracy J. Debra A. Goff, Pharm.D.1,2, Peggy S. McKinnon, Pharm.D.3, John R. Graybill, M.D.1,2. (1)University of Texas at Austin, San Antonio, TX; (2)University of Texas Health Science Center at San Antonio, San Antonio, TX; (3)The Ohio State University Medical Center, Columbus, OH.
PHARMACOTHERAPY Volume 26, March 2006

63. An evaluation of adverse events related to peripheral intravenous catheter use in hospitalized patients: implications for clinical practice. Brian A. Hemstreet, Pharm.D., BCPS, Douglas N. Fish, Pharm.D., Patrick W. Sullivan, Ph.D., Marianne McGollum, R.Ph., Ph.D., BCPS. University of Colorado at Denver and Health Sciences Center School of Pharmacy, Denver, CO.

PURPOSE: This prospective observational study evaluated peripheral intravenous catheter (PVC) use in hospitalized adults. Cather related adverse events (CRAEs) and patient eligibility for oral drug therapy were evaluated.

METHODS: Adult patients consecutively admitted to a general medicine floor of a tertiary care academic medical center were assessed daily for PVC use during their hospital stay. Information collected related to PVC use included total hospital days with an indwelling catheter, CRAEs, and patient eligibility for oral drug therapy. Demographics and medical history were obtained from the patient’s medical record. Evidence of CRAEs was assessed daily using computerized nursing records. CRAEs were defined as catheter occlusion, infiltration, extravasation, phlebitis, hemotoma, infection, or thrombosis. Eligibility for oral therapy was assessed daily and was defined as documentation of at least one scheduled oral medication on the patient’s drug profile. Descriptive statistics were used for patient demographics and CRAE rates. Length of stay (LOS) was evaluated using Kaplan-Meier survival analysis. All patients signed an informed consent.

RESULTS: Eight hundred eighty nine total PVC days in 227 patients (129 male, 98 female, mean age 55.8 years) were evaluated. Mean LOS was 3.92 days. A total of 60 CRAEs were documented, equating to 26/1000 admissions and 67/1000 catheter days. Forty-five (19.8%) patients experienced at least one CRAE. Ninety-eight percent of patients with CRAEs were deemed eligible for oral drug therapy on the day the CRAE occurred. Mean LOS was greater in patients experiencing a CRAE (4.76 days) compared to those without a documented CRAE (3.71 days, p<0.001).

CONCLUSIONS: PVC-related CRAEs are common in hospitalized patients. Most patients with documented CRAEs are eligible for oral drug therapy. Identification of patients eligible for oral drug therapy may lead to reductions in the need for medication administration via PVCs and potential avoidance of subsequent CRAEs.

Nephrology

64F. Vancomycin dosing guidelines in obese, hemodialysis patients lead to inadequate serum concentrations. Michael H. Schwenk, Pharm.D., Daniel A. Blaustein, M.D., Morrell M. Avram, M.D., Raki Khanna, M.D., D. Siddha Rani, M.D.². (1)The New York Hospital Medical Center of Queens, Flushing, NY; (2)The Long Island College Hospital, Brooklyn, NY.

PURPOSE: Common references (The Sanford Guide To Antimicrobial Therapy 2005, Drug Prescribing In Renal Failure 4th ed.(American College of Physicians)), recommend a 1000 mg vancomycin dose, repeated every 4-7 days, when the GFR is less than 10 ml/min, regardless of patient weight. We studied 6 obese (BMI>30) chronic hemodialysis patients treated with this regimen to determine its adequacy in achieving therapeutic vancomycin concentrations.

METHODS: Patients were treated for presumed/documented infections and studied during an interdialytic period (no recent vancomycin therapy).

RESULTS: There were 4F/2M, 142.5 ± 28.8 kg, BMI = 48.1 ± 9.4 who received an initial dose of 1000 mg (7.3 mg/kg) of vancomycin. The 6 postdose vancomycin level was 9.9 ± 2.4 mg/L, with Vd of 0.79 ± 0.35 L/kg, in close agreement with reported values in non-obese patients. In 4 patients given the 2nd dose of vancomycin (average = 1300 mg) 6 postdose vancomycin levels were 27.5 ± 10.2 mg/L. Thus, after the initial 1000 mg dose, all patients were ready for redosing, and would have remained at subtherapeutic vancomycin levels (<12.15 mg/L) until such time. There were no adverse events associated with this dosing regimen.

CONCLUSIONS: We conclude that obese chronic hemodialysis patients will be underdosed and have subtherapeutic vancomycin levels if current dosing guidelines are utilized. A vancomycin loading dose of 20 mg/kg of total body weight infused at a rate of 1g/h will produce vancomycin levels that should remain therapeutic (> 12-15 mg/L) until at least after their next hemodialysis treatment.

65. Urinary cotinine excretion as a measure of smoking exposure in patients with chronic kidney disease (CKD): however it is not known whether the effect of smoking on the kidney is dose-dependent. Urinary cotinine (a nicotine metabolite) is useful for evaluating nicotine exposure, but has not been validated in the CKD population. In this study we evaluated the validity of 24-hour urinary excretion of cotinine (Ucot) as a quantitative measure of smoking exposure in CKD patients.

METHODS: This was a cross-sectional study targeting smokers and non-smokers with CKD. Quantitative measurements of smoking exposure included a self-reported smoking history questionnaire, expired carbon monoxide (eCO) and Ucot. Kidney function was estimated using the M.D.RD equation for glomerular filtration rate (eGFR). Ucot concentrations were quantified using HPLC with UV detection.

RESULTS: 47 patients were enrolled, 70% were current smokers (mean self-reported cigarettes were 11.1 ± 7.5 per day). The mean eGFR was 49 ± 24.5 mL/min/1.73 m2 and 33.8 ± 17 mL/min/1.73 m2 in smokers and non-smokers respectively (p = 0.08). The serum ferritin and low TSAT significantly higher compared to non-smokers (mean 13.6 ± 7% and 1.3 ± 1%, and 134.3 ± 67.2 mg/L and 114.6 ± 401 mg/L, respectively; p < 0.001). Both eCO and Ucot were significantly correlated with self-reported quantity of smoking (R = 0.70 and R = 0.64, p < 0.001, respectively) and correlated with each other (R = 0.81, p < 0.001). There was no significant relationship between eGFR or proteinuria and Ucot (R = 0.24, p = 0.09 and R = 0.03, p = 0.8 respectively).

CONCLUSION: 24-hour urinary cotinine excretion is not correlated with renal function, suggesting that this method can be used as an objective tool to measure smoking exposure in CKD patients, in smoking reduction/cessation programs.

66E. Effect of IV iron administration on iron indices of hemodialysis patients with elevated serum ferritin: preliminary data from the DRIVE study. Daniel W. Coyne, M.D.1, Toros Kapoian, M.D.2, John Moran, M.D.1, Adel R. Rizkala, Pharm.D., M.S.3, the DRIVE Study Group, 4, 1(1)Washington University School of Medicine, St. Louis, MO; 2(2)UMDNJ-Robert Wood Johnson Medical School, New Brunswick, NJ; 3(Satellite Healthcare, Inc., Mountain View, CA; 4(Watson Laboratories, Inc., Morristown, NJ)

PURPOSE: Dialysis Patients’ Response to IV Iron with Elevated Ferritin (DRIVE) trial aims to investigate the effect of administration of IV iron on hemoglobin levels of hemodialysis patients with elevated ferritin and low TSAT, who remained anemic despite receiving large doses of rHuEPO (Hgb <11.1 g/dL, ferritin of 500–1,200 ng/mL, TSAT <26%, rHuEPO at least 1g/dose). The elevated ferritin and low TSAT remain a significant problem in the management of HD patients. The purpose of this analysis is to investigate if administration of IV iron to this patient population results in dramatically higher ferritin and TSAT levels.

METHODS: Starting week 1, all patients received a 25% increase in their baseline Hb levels. Patients in IV Fe Group also received 125 mg of ferric gluconate with 8 consecutive hemodialysis sessions. UHuEPO doses remained constant throughout the trial. No maintenance IV or oral iron dosing was allowed. Among other biochemical parameters, iron studies were collected at baseline (Week 0) and at the endpoint (Week 6).

RESULTS: Results of the first 56 patients who completed the trial were analyzed. Control Group median ferritin decreased from 708 ng/mL to 536 ng/mL (p = 0.003) and median TSAT increased from 19% to 21% (p = 0.04). IV Fe Group median ferritin increased from 713 ng/mL to 773 ng/mL (p = 0.023) and median TSAT increased from 19% to 25% (p = 0.001).

CONCLUSIONS: Administration of IV iron to patients with elevated ferritin levels with elevated ferritin had a significant improvement in TSAT without leading to a clinically significant increase in ferritin. The administered IV iron is bioavailable as indicated by clinically and statistically significant increases in TSAT. There need be no concern for iron overload resulting from administering 1g of ferric gluconate with increased UHuEPO doses in hemodialysis patients with high ferritin and low TSAT.

Published in J Am Soc Nephrol 2005;16:480A.

Neurology

67. Quetiapine for the management of chorea in Huntington’s disease: a case series. Jack J. Chen, Pharm.D.1, David M. Swayne, M.D.2, 1(Loma Linda University Movement Disorders Center and School of Pharmacy, Loma Linda, CA; 2(Loma Linda University, Loma Linda, CA)

PURPOSE: Huntington’s disease (HD) is a progressive neurodegenerative disorder characterized by movement disorders and cognitive changes. Chorea is a common movement disorder associated with HD and can interfere with daily activities, such as eating or walking. Current symptomatic treatment of chorea with clonazepam, conventional neuroleptics, and dopamine-depleting agents are associated with prominent side effects and variable effectiveness. In recent years, several atypical antipsychotics have been reported to provide symptomatic effects in the treatment of chorea associated with Huntington’s disease. This pilot study evaluated the effectiveness and tolerability of quetiapine in the treatment of chorea associated with HD.

METHODS: This study was approved by the participating institutional review boards. A retrospective chart review from January 2002 to April 2005 was conducted to identify patients with HD (via use of ICD-9 codes). Data were collected on patient demographics, severity and characteristics of chorea, use of quetiapine (including dosage, side effects, effectiveness), use of adjunctive medications, and relevant medical history.

RESULTS: A total of five patients with HD and treated with quetiapine were included in the analysis. One patient experienced intolerable diarrhea at a daily dose of quetiapine 25 mg and required discontinuation of the drug. In the remaining four patients, mild to moderate improvements in chorea were associated with quetiapine (daily dose up to 200 mg). Favorable responses were also documented in gait, fine motor tasks, and speech. Quetiapine was not noted to improve performance of activities of daily living, severity of facial grimacing or ocular movements. All patients, except one, were also on stable doses of one or more concomitant agents for chorea (including amantadine, clonazepam, or leviteracem). Quetiapine throughout the dose range was well tolerated with transient sedation and dry mouth noted. Quetiapine demonstrates modest effectiveness in the management of HD chorea. Further investigations are warranted.

68. Optimizing use of hypertonic saline in the neuroscience intensive care unit. Kiranpal S. Sangha, Pharm.D.1, Lori A. Shutter, M.D.2, 1(1)The University Hospital, University of Cincinnati Medical Center, Mail Location 0740, Cincinnati, OH; 2(The University of Cincinnati Medical Center, Cincinnati, OH)

INTRODUCTION: Pharmacotherapy for reducing cerebral edema now includes hypertonic saline (HT). We developed a clinical protocol to assist the healthcare provider with managing this complex therapy. We report the initial results using our protocol.

METHODS: We assessed 30 consecutive patients in the neuroscience intensive care unit (NSICU) treated with 3% sodium chloride (HT) using the new protocol. Data collected included patient diagnosis, demographics, serum chemistries, HT dosing rates, intracranial pressure (ICP) measurements and adverse effects. Patients were excluded if they were on HT for less than 24 hours or if they had no ICP monitor.

RESULTS: Four patients were excluded; two were on HT less than 24 hours and two had no ICP monitor, leaving 26 patients. Twenty-three patients (88%) had a diagnosis of traumatic brain injury (TBI). The median age was 37 years (range: 15-68) with a median initial GCS score of 7 (range: 3-13). Goal sodium range was achieved in 19 patients (63%) within 24 hours, and the median time to achieve goal was 14.95 hrs (range: 2 to 50). During target hypernatremia, median HT infusion rate and duration were 0.48 mL/kg/hr (range: 0.12-0.83) for 47 hours (range: 0-170). The median baseline and highest creatinine values during treatment were 0.8 (range: 0.5-1.4) and 0.95 (range: 0.5-1.6). Critical sodium and osmolality values were observed in 5.2% (sd: 9.2) and 5.85% (sd: 11.4) of all measurements. The median numbers of rescue interventions required for elevated ICP were 2.5 (range: 0-13).

CONCLUSIONS: HT for cerebral edema after severe neurological injury is safe if managed with a dosing protocol. Additional studies are required to define the optimum dosing of this potentially high-risk therapy to minimize complications.

Oncology

69. Safety of bevacizumab plus chemotherapy as first-line treatment of patients with metastatic colorectal cancer: preliminary results from a large observational study in the U.S. (BRiTE). Mark Kozloff, M.D.1, Allen Cohn, M.D.1, Neil Christiansen, M.D.1, Patrick Flynn, M.D.1, Fairooz Kabbinavar, M.D.1, Robert Robles, M.D.1, Marianne Ulcickas Yood, M.D.1, Charles Blanke, M.D.1, Somnath Sarkar, M.D.1, Mary Sugrue, Ph.D.2, Kevin Kuehn, Pharm.D., BCPPhA, Axel Grothey, M.D.1, 1(Ungalls Hospital, Harvey and the University of Chicago, Chicago, IL; 2(Rocky Mountain Cancer Center, Denver, CO; 3(South Carolina Oncology Associates, Columbia, SC; 4(North Western Hospital, University of Minnesota, Minneapolis, Minnesota; 5(University of California at Los Angeles, Los Angeles, CA; 6(John Muir Hospital, Walnut Creek, CA; 7(Josephine Ford Cancer Center, Detroit, MI; 8(Oregon Health Sciences University, Portland, OR; 9(Genentech, Inc., San Francisco, CA; 10(Mayo Clinic, Rochester, MN)
BARRY A. BROWNE, e18
Antonio, TX, December 8-11, 2005.
Presented at the 28th Annual San Antonio Breast Cancer Symposium, San Antonio, TX.

PURPOSE: To evaluate targeted safety events in unsolicited patients with metastatic colorectal cancer (mCRC), 1987 patients 
with mCRC population, eligibility criteria were minimized and the demographics of the resulting cohort were consistent with the NCI
Surveillance, Epidemiology, and End Results (SEERs) database for patients with 
mCRC. Baseline data included history of hypertension, stroke or 
myocardial infarction, diabetes, hypercholesterolemia, atrial fibrillation, 
chronic antiasthmatic or aspirin use, peptic ulcer disease, diverticulosis, and 
recent surgery or endoscopy. Patients are followed for up to 3 years, and 
clinical data (including survival, disease progression, changes in 
chemotherapy or DV intermittent surgery or endoscopy, and serious adverse events 
(SAEs)) are updated every 3 months.

RESULTS: Patients were enrolled from 2/04 through 6/05; the abstract data 
cutoff date was 7/17/05. The median age was 64 (range 22-93); age ≥ 65; 
male, 56%; white/black/other, 82/7/0.7%; ECOG status 0-1, 85%. As of 7/17/03, 
87% of patients were alive; 68% are progression-free. Chemotherapy choice was 
FOFOX (41%), FOLFIRI (14%), IFI (10%), other (22%); BV-associated SAEs 
reported in 9% of patients; gastrointestinal perforation (1%), postoperative 
bleeding/wound healing complications (0.8%), arterial thromboembolic events 
(1.7%), and grade 3-4 bleeding (1.4%). Based on 628 progression events, the 
overall median progression-free survival (PFS) is 12 months.

CONCLUSIONS: The safety profile of BV in a community-based population of 
mCRC patients receiving a variety of chemotherapy regimens appears 
consistent with that observed in the pivotal trial. PFS in this preliminary 
dataset is longer than that reported in the pivotal trial. Updated efficacy and 
safety data will be presented.

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70E. First and subsequent cycle pegfilgrastim results in low rates of 
neutropenic events in patients receiving myelosuppressive chemotherapy,
M. E. Rader, M.D.1, Wendy Breyer, M.D.1,2, Susan Luedke, M.D.1, Donna 
Truscinski, BS1, Beping Ding, Ph.D.2, Roger Dansey, M.D.2, Howard Ozer, 
M.D.1, (1)Union Station Bank Cancer Center, Nyack, NY. (2)Central Utah, 
Cancer Center, Provo, UT. (3)St Louis, Cancer & Breast Institute, St Louis, 
MO. (4)Amgen, Inc, M.S. 27-2-A, Thousand Oaks, CA. (5)University of 
Oklahoma Cancer Center, Oklahoma City, OK.

PURPOSE: First and subsequent cycle pegfilgrastim dramatically reduces 
febrile neutropenia in cycle 1 (11% vs <1%) and overall (17% vs <1%; 
p<0.001) among moderate risk chemotherapy (CT) patients (pts). This 
neutropenic events among breast cancer patients supported by pegfilgrastim 
(p<0.001) among moderate risk chemotherapy (CT) patients (pts). This 
neutropenic events among breast cancer patients supported by pegfilgrastim
purposes, and PFP (r = 0.74, p<0.001). Five patients experienced 7 supratherapeutic 
waves therapy on while on therapy. All patients with supratherapeutic levels were pre-
term, with creatinine cleancances ≤ 30 ml/min/1.73m². Four patients had 5 
pairs of levels drawn after discontinuation of pegfilgrastim therapy, and k₈ 
was evaluated (median 0.124 hr⁻¹, range 0.024-0.237 hr⁻¹).

CONCLUSION: Neurones require similar pegfilgrastim dosing to infants and 
children. Doses may need to be reduced in premature infants and in those 
with renal dysfunction.

72E. Retrospective evaluation of asthma medication utilization in pediatric 
patients with asthma-related emergency department visits. Barry A. Browne, 
Pharm.D.1, Darren Clary, Pharm.D.1, Aleza Bonnet, M.D.2, Howard 
Wetmoreland, Pharm.D.1, Scott & White Hospital, Temple, TX.

PURPOSE: This retrospective analysis reviewed asthma pharmacotherapy in a 
managed care pediatric population before, during, and after an Emergency 
Department (ED) visit, with emphasis on evaluation of controller 
medication use.

METHODS: Patients 2–18 years of age with a prescription benefit and 
continuous enrollment in the managed care organization (MCO) were eligible 
for inclusion. Patient ICD-9 code data were used to identify individuals with 
at least one ED visit for an asthma exacerbation over a 3-year period.

Pharmacologic interventions in the ED, as well as ED referrals and subsequent pharmacotherapy provided by 
primary care physicians (PCPs) after the ED visit, were evaluated through electronic medical record review. 
Pharmacy claims data were used to calculate adherence and medication 
prescription ratio (MPR) 6 months before and 6 months after the index ED 
visit for each patient. Adherence was calculated for all controller 
medications with at least 2 refills before or after the ED visit.

RESULTS: A total of 96 pediatric patients met the entry criteria. Twenty-four 
patients were initiated on a controller medication before the ED visit. Eleven 
patients were on chronic controller medications longer than 6 hours, 
and had at least 2 therapeutic procainamide levels. Patient demographic 
information, dosing information, drug levels, and adverse effects were noted.

A total of 34 patients followed up with their PCP. Adherence before the ED visit for inthaled fluticasone, salmeterol, fluticasone/salmeterol, and montelukast was 42.9%, 49.5%, 43.8%, and 37.7%, respectively. 
Adherence after the ED visit for these medications was 39.8%, 72.3%, 65.7%, 
and 55.4%, respectively. The MPR for inthaled fluticasone, salmeterol, 
fluticasone/salmeterol, and montelukast was 23.6%, 41.9%, 42.9%, and 
38.6%, respectively.

CONCLUSION: These data indicate that patient adherence to controller 
medications and PCP follow-up in this MCO population is limited, suggesting 
health care resources should be allocated to increase patient education regarding the importance of appropriate pharmacotherapy and PCP follow-

Presented at the ALCALDE Pharmacy Residency Leadership Conference, 
Austin, TX, April 7-9, 2005.

73. Pharmacokinetics of methadone in pediatric ICU patients. Ralph A. 
Lugo, Pharm.D., Kristin Satterfield, B.S., Diana Wilkins, Ph.D., Steven Kern, 
Ph.D., Robert M. Ward, M.D.; University of Utah, Salt Lake City, UT.

PURPOSE: Methadone is often used in the PICU to treat opioid abstinence 
syndrome. It is inexpensive and has a long half-life, which allows for 
intravenous dosing. In adults, the terminal elimination half-life of racemic 
benzomazem ranges from 3 to 130 hours, and acute administration results in 
a longer half-life (34.8 hours) than chronic administration (22.5 hours). The 
reported clearance of methadone in adults is 84+30 mL/kg/hr. The 
pharmacokinetics and optimal dosing of methadone in children have not 
been evaluated. The purpose of this preliminary study is to evaluate the

Pediatrics

71. Evaluation of procarcinamide therapy in neonates. Brady S. Moffett, 
Pharm.D1, Naomi Kertesz, M.D.2, (1)Texas Children’s Hospital, Department 
of Pharmacy, Houston, TX. (2)Baylor College of Medicine, Houston, TX.

PURPOSE: Procarcinamide is often used to treat supraventricular arrhythmias in 
neonates, but there is a paucity of published data.

METHODS: A 3 year retrospective review included patients that were < 30 days 
of age, were on intravenous procarcinamide therapy longer than 6 hours, 
and at least 2 therapeutic procarcinamide levels. Patient demographic 
information, dosing information, drug levels, and adverse effects were noted. 
Clearance of procarcinamide and NAPA was calculated and evaluated in regards 
to renal function.

RESULTS: Eighteen patients met inclusion criteria, 11 were term infants, 
seven were <37 weeks gestation, and therapy was started on day of life 9.7 ± 
5.7. Supraventricular tachycardia and atrial ectopic tachycardia were the 
primary indications for therapy. No patients experienced hemodynamic 
instability or other adverse effects due to procarcinamide. Procarcinamide was 
given as a bolus (0.45 ± 1.79 mg/kg) in 17/18 patients prior to starting a 
continuous infusion. The mean dose at which two therapeutic levels was 
achieved was 37.36 ± 13.52 µg/kg.min. Procarcinamide and NAPA clearance 
was 6.36 ± 8.85 and 15.22 ± 13.79 mL/min/kg. NAPA to procarcinamide ratio 
on the first and second therapeutic levels was 0.36 ± 1 and 0.52.1. Creatinine 
clearance correlated with procarcinamide (r = -0.76, p=0.001) and NAPA 
clearance (r = 0.74, p=0.001). Five patients experienced 7 supratherapeutic 
levels while on therapy. All patients with supratherapeutic levels were pre-
term, with creatinine cleancances ≤ 30 ml/min/1.73m². Four patients had 5 
pairs of levels drawn after discontinuation of procarcinamide therapy, and k₈ 
was evaluated (median 0.124 hr⁻¹, range 0.024-0.237 hr⁻¹).

CONCLUSION: Neurones require similar procarcinamide dosing to infants and 
children. Doses may need to be reduced in premature infants and in those 
with renal dysfunction.

N = 444
% (95%CL)
Hospitalization related to neuropathy
(including febrile neuropathy) in cycle 1
1 (c1, 3)
Fibrile neuropenia (ANC<5x10⁹/l & temperature
image missing here - Recordid=6896)38°C in cycle 1
3 (c1, 3)
Neuropenia-related IV antibiotic use in cycle 1
1 (c1, 3)
Neuropenia-related CT dose reductions in cycle 2
2 (1, 3)
Neuropenia-related CT dose delays in cycle 2
0 (0, 0)
physician reported

CONCLUSION: Compared to Vogel et al, there is a similarly low rate of cycle 
1 neutropenic events among breast cancer patients supported by pegfilgrastim 
in a community setting. Final data (n=1008 pts) will be presented.

Presented at the 28th Annual San Antonio Breast Cancer Symposium, San 
Antonio, TX, December 8-11, 2003.
We examined the effects of statin prescription drug: obesity is a serious public health problem affecting our concomitant medications, hospitalizations, ambulatory visits) were obtained from Radensky 2001, updated to 2005 using the CPI medical estimates. From the patient's electronic database and the VA's decision support software. Total inpatient and outpatient direct costs included: medications, laboratory, primary/specialty care visits, procedures, and hospital stays. Costs were compared with a significance level set at p<0.05. RESULTS: The study population included 2000 patients (400 in each category) of which 96.1% were male, and the average age was 63 years (SD±13 years). Individual group costs were normal weight $2635; overweight (18.5–24.9), over weight (25.0–29.9), obesity I (30.0–34.9), obesity II (35.0-39.9), and obesity III (>40.0). We obtained demographic and cost data from the patient's electronic database and the VA's decision support software program, respectively. Total inpatient and outpatient direct costs included: medications, laboratory, primary/specialty care visits, procedures, and hospital stays. Costs were compared with a significance level set at p<0.05. CONCLUSION: Healthcare administrators should consider allocating resources for treating obese patients to improve their health and to lower overall health care system expenditures. A focus on those patients in obesity categories II and III would potentially yield the greatest benefit. Presented at the Midwest Pharmacy Residents Conference, Omaha, NE, May 5-7, 2005.

73E. United States cost-effectiveness of atorvastatin in individuals with treated hypertension, normal/mildly elevated cholesterol and 3+ additional risk factors (ASCOT-LLA). Sanford Schwartz, M.D.1, Peter Lindgren, Ph.D.1, Bengt Janson, Ph.D.1, Joan Mackell, Ph.D.1, (1)University of Pennsylvania, Philadelphia, PA, (2)Karolinska Institutet, Stockholm, Sweden, (3)Stockholm School of Economics, Stockholm, Sweden; (4)Pfizer Pharmaceuticals, New York, NY.

PURPOSE: To assess the cost-effectiveness of atorvastatin Rx in ASCOT-LLA. The Anglo-Scandinavian Outcomes Trial lipid-lowering arm (ASCOT-LLA) randomized patients with total cholesterol ≤251 mg/dL (≤6.5 mmol/L), treated hypertension, and 3+ additional CVD risk factors to atorvastatin 10 mg (n=5168) or placebo (n=5137). Over 3.3 year median follow-up, atorvastatin Rx was associated with reduced fatal coronary events and other outcomes of statin therapy. METHODS: Intent to treat CEA. Data on CV events and resource use were aggregated across all patients for the trial period. CV events and revascularizations, non-fatal AMI, CV deaths and resource use (study drug, concomitant medications, hospitalizations, ambulatory visits) were obtained from the ASCOT-LLA US costs for CV hospitalizations were assigned using estimates from Badensky 2001, updated to 2005 using the CPI medical component inflation. Non-CV hospitalization costs using 2005 mean per diem payments; M.D. inpatient and outpatient costs using representative Medicare allowable costs; and drug costs using WAC. The primary outcome was incremental cost per CV event avoided. ICER confidence intervals using angular transformed (1,000 bootstrap samples) and CEE acceptability curves were used. Early stopping of the trial (atorvastatin benefit) by the DSMB precluded direct assessment of survival. Thus, incremental SAVOL was estimated by extrapolating expected survival benefit from published Framingham and Saskatchewan data and comparison with event reduction in other statin RCTs. RESULTS: Net cost per patient was $1,755 atorvastatin arm vs. $1,157 placebo arm. Atorvastatin 10 mg/day was larger all-cause hospitalizations, concomitant drugs and outpatient visits, resulting in ICER of $13,771 per CV event avoided and extrapolated survival resulting from observed AMI reduction of $5,336/SAVOL. CONCLUSIONS: Atorvastatin 10 mg Rx in the ASCOT-LLA was highly cost-effective. Thus, statin therapy is clinically effective and cost-effective in this primary prevention population. Presented at the American Heart Association Scientific Sessions 2005, Dallas, TX, November 13-16, 2005.


PURPOSE: Hospital costs for leading health conditions have increased significantly over the previous decade, and stroke is among the most costly medical conditions. Accordingly, we examined the cost of treating ischemic stroke (IS) during the first year after event, comparing 1991-1993 and 2000-2001. METHODS: We sampled from Medicare claims files in 1991 and 2000 containing patients hospitalized with a primary ICD-9 code of 434.xx or 436.xx, and followed patients for 124 months. Using standard techniques of health cost accounting, Medicare-related utilization was classified into categories. Hospital, physician, outpatient, home health, skilled nursing, durable medical equipment, rehabilitation, translated into estimated economic opportunity cost ($) for institutional care. The cost ratio in 1991-1993 and 2000-2001, and aggregated by quarter as per-patient means. Validation efforts included bootstrapping and replication of the analyses by two separate vendors. RESULTS: Using 2000 dollars, mean costs for treating IS the year after event were approximately $32,000 in 1991-1993 and $25,000 in 2000-2001. Approximately half were attributable to the initial hospitalization. The highest cost categories were hospital facility, physician, rehabilitation, and skilled nursing, the former three decreasing over time and the latter category increasing. The width of the bootstrapped confidence intervals was less than $1,000 and the estimates of the two vendors substantially agreed. CONCLUSIONS: Despite efforts at cost containment reflected in shorter hospital stays and decreased utilization of rehabilitation, the first-year cost of stroke has approximately kept pace with inflation. Increases in the cost associated with home health and skilled nursing raise the question whether patients are being discharged with lower functional status than before, shifting costs from inpatient to outpatient. Presented at the American Heart Association Scientific Sessions 2005, Dallas, TX, November 13-16, 2005.

77E. The effects of prescription drug copayments on statin adherence and persistence. Teresa B. Gibson, Ph.D.1, Tami L. Mark, Ph.D.2, Kimberly McGuigan, Ph.D.1, Kirsten A. Axelsen, M.S.1, Sara Wang, Ph.D.1, Joan Mackell, Ph.D.1, (1)Medstat, Ann Arbor, MI; (2)Medstat Group, Inc, Washington, DC; (3)Pfizer Inc, New York, NY; (4)Thomson Medstat, Ann Arbor, MI; (5)Pfizer Pharmaceuticals, New York, NY.

BACKGROUND: We examined the effects of prescription drug copayments on statin adherence and persistence. METHODS: The 2001-2003 MarketScan database was used to study the health care utilization and expenditure patterns of 93,296 continuously enrolled statin users in employer sponsored health plans. A two-stage estimation approach consisted of a multivariate logit model, which estimated the relationship between copayments and adherence in June 2003 through December 2002. Then, Generalized Linear Models were estimated to examine the effects of adherence on utilization patterns and expenditures in 2003. RESULTS: Higher copayments led to lower levels of statin adherence (Odds Ratio 0.75 p<0.01). Higher levels of statin adherence were associated with fewer adverse events: hospitalizations, cardiovascular hospitalizations and emergency room visits (see table). Adherence was associated with a larger number of physician office visits. Predictably, adherence resulted in higher prescription drug expenditures but adherence had no effect on total expenditures and total expenditures.
CONCLUSIONS: Statin copays serve as a financial barrier to statin adherence. In turn, lower levels of adherence are associated with adverse cardiovascular and medical outcomes. Policymakers and plan managers should consider the effects of higher copayments on adherence, utilization patterns, and clinical events for patients with hyperlipidemia. Presented at the 55th Annual Scientific Session of the American College of Cardiology, Atlanta, GA, March 11-14, 2006.


PURPOSE: Conventional amphotericin B (CAB) is considered the standard empiric antifungal therapy for patients with febrile neutropenic patients; however, infusion-related reactions and nephrotoxicity limit its use. Although liposomal amphotericin B (LAmB) has demonstrated similar efficacy to CAB, it is not without toxicities and is associated with a high acquisition cost. Despite this high cost, LAmB has been shown to have a pharmacoeconomic advantage over less expensive agents. Voriconazole is a potential alternative for empiric antifungal treatment of FN. An algorithm that recommends voriconazole as the preferred antifungal in adult Hematology patients with FN was implemented at the University of Michigan Hospitals (UMH).

METHODS: A decision analytic model was developed from a hospital perspective based on the FN treatment guidelines implemented at UMH. Data collected in a two-year (2002-2003) retrospective chart review, literature reports, and expert opinion were used to accurately populate the model. Sensitivity analysis and Monte Carlo simulation enhanced the robustness of the model through variation of all probabilities and costs that populated the model.

RESULTS: Sixty-five cases were evaluated in the retrospective chart review. Thirty-three were initiated on voriconazole and 32 on LAmB respectively. Patient demographic data was similar in each group. In the base case, patients initiated on voriconazole displayed a 17% reduction in overall treatment cost per patient initiated on LAmB ($17,380 vs. $20,841). Sensitivity analysis determined the cost advantage in the voriconazole arm was maintained over a wide range of costs and probabilities. Variance in the cost of nephrotoxicity and medication cost did not significantly alter results. Monte Carlo simulation determined the voriconazole arm to be the optimal path in 68% of cases.

CONCLUSION: The decision model indicates that use of voriconazole as the preferred antifungal agent in patients with FN should result in lower overall treatment costs relative to LAmB.

79E. Nursing home costs for individuals with stroke are driven by functional status. David B. Matchar, M.D., FACP,1, Laura B. Hansen, Emily R. Stuntebeck, Pharm.D., Daryl D. DePestel, Pharm.D., Marianne McCollum, Ph.D., R.Ph. (GLM), including stroke status, activities of daily living (ADL) score and number of procedures involving less than or equal to three tooth extractions. An analysis of cox regression including stroke status, activities of daily living (ADL) score midpoint corresponding to assigned Resource Utilization Group, and month from admission.

RESULTS: Of all study patients, 9,320 (17.2%) had stroke; of these 3,904 (41.9%) had stays >100 days. Per diem costs decreased linearly from $320 to $147 from months 1 to 6, and remained constant through 24 months. In month 1, room and board accounted for 57% of costs, followed by therapy (34%), and drugs (8%). At month 6, these proportions were 88%, 9%, and 1%, respectively. The GLM analysis indicated that ADL was significantly associated with per diem costs, but after accounting for ADL, stroke diagnosis per se did not.

CONCLUSION: Nearly 1 in 5 patients had a diagnosis of stroke and more than 2 in 5 stroke patients stayed longer than 100 days. Functional status was more predictive of NH costs than the diagnosis of stroke itself. Presented at the 55th Annual Scientific Session of the American College of Cardiology, Atlanta, GA, March 11-14, 2006.

80. Inconsistent societal and individual quality of life ratings for women and men with diabetes. Mariannne Collum, Ph.D., R.Ph., Laura B. Hansen, Pharm.D., Patrick W. Sullivan, Ph.D.; University of Colorado School of Pharmacy, Denver, CO.

PURPOSE: The EQ-5D, a generic health-related quality-of-life (QoL) instrument, contains two components. First, respondents indicate their health status on five domains at three levels: no, some, or extreme problems. Scores (0.0–1.0) are assigned using population preferences for each composite health state. Second, a visual analogue scale (VAS) allows respondents to self-rate their health status from 0.0 to 1.0. The objective of this study was to compare EQ-5D index scores (based on societal preferences) and self-rated scores for men and women with diabetes.

METHODS: Data were obtained from the 2001 Medical Expenditure Panel Survey (MEPS). Diabetes was identified by ICD-9-CM code, demographic, clinical, and health status data (e.g., age, body mass index (BMI), comorbidities, depression, and physical limitations, and EQ-5D index and VAS scores) were analyzed using t-tests, X², or Fischer’s exact tests as appropriate.

RESULTS: A total of 1,653 respondents with diabetes were included (883 women, 770 men). Women with diabetes were older than their male counterparts (61.2 versus 59.1 years, p<0.01) and reported higher BMI (31.4 versus 30.3), more comorbidities (7.8 versus 6.4), more depression, and more physical limitations, all p<0.01. EQ-5D index scores were significantly lower for women than men (0.63 versus 0.72, p<0.001), indicating lower population-rated QoL for women than for men with diabetes. However, there was no significant difference between women and men with diabetes when respondents were asked to rate their own QoL using the VAS (p=0.23).

CONCLUSIONS: Women with diabetes have more comorbidities and physical limitations than men with diabetes, differences are reflected in significantly lower EQ-5D scores derived from the general population. In contrast, women self-rate their own health at the same level as men, possibly indicating different health-related expectations and providing explanations regarding care-seeking behavior on the part of women versus men.

81. Use of low molecular weight heparin (LMWH) during dental extractions in a Medicaid population. Tracy K. Pettiniger, Pharm.D., Christopher T. Owens, Pharm.D.; Idaho State University College of Pharmacy, Pocatello, ID.

PURPOSE: Evidence-based guidelines recommend against discontinuation of oral anticoagulation therapy during dental procedures due to a lack of severe bleeding complications and an increased risk for thromboembolic events in patients for whom warfarin therapy is interrupted. Although interruption of oral anticoagulation and bridge therapy with LMWH may be indicated for high-risk individuals undergoing certain medical procedures, its use in tooth extractions is expensive, often unnecessary, and not generally recommended. The purpose of this review was to identify and characterize procedural use of LMWH for dental extractions.

METHODS: The Idaho Medicaid claims database was queried to identify patients with a tooth extraction procedure from 2/1/1998-2/28/2005. Patients on warfarin therapy for 2 months prior to tooth extraction were identified as well as claims for LMWH within 30 days of the procedure. Patient profiles were reviewed to determine number of extractions, overall rate of LMWH utilization, indication for anticoagulation, and associated drug costs.

RESULTS: Four hundred fifty-seven warfarin patients with a tooth extraction were identified. Of these, 34 patients (7.5%) received LMWH therapy for 39 total extraction procedures. Seventy-four percent of LMWH claims were for procedures involving less than or equal to three tooth extractions. An analysis of cox regression indicated that 20% of procedures were in patients with a thromboembolic event greater than three months prior to the procedure and 15% of patients had lone atrial fibrillation. The use of LMWH for these 39 extractions cost $26,321 with an average of $674.91 per procedure in drug costs alone. Statistical analysis and further results will be available at the time of poster presentation.

CONCLUSION: Despite the overall low number of dental procedures in
anticoagulated patients using LMWH bridge therapy, many are still unnecessary. This inappropriate use resulted in excessive costs in this Medicaid population.

82. Decision analysis model evaluating cost effectiveness of risperidone, olanzapine, and haloperidol in the treatment of schizophrenia. Mark Bounthavong, Pharm.D.; Western University of Health Sciences, Pomona, CA.

PURPOSE: To evaluate the cost-effectiveness of three antipsychotic medications (olanzapine, risperidone and haloperidol) in the treatment of schizophrenia.

METHODS: A decision model evaluated the cost-effectiveness of two atypical antipsychotics (risperidone, and olanzapine) and haloperidol. Outcome probabilities were determined from published clinical trials. The main dependent variable of interest was to compare the incremental costs-effectiveness ratios (ICER) of the atypicals with haloperidol, and also to compare olanzapine with risperidone. Sensitivity analyses were conducted for olanzapine and risperidone to determine the effects of altering drug cost and efficacy on total costs.

RESULTS: ICER for risperidone and olanzapine compared with haloperidol each indicated a dominant strategy over haloperidol (less costly and more effective). The ICER for risperidone over haloperidol was not dominant over haloperidol. The one-way sensitivity analysis for efficacy indicates that the efficacy of olanzapine must increase by at least 8% in order for olanzapine and risperidone to have equal total costs. In the base-case analysis, the cost differences between olanzapine and risperidone was $2.12/day with olanzapine being more expensive. In two-way sensitivity analyses varying both the cost of olanzapine and risperidone, the cost difference between them would have to increase to $1/day in order to have equal total costs.

CONCLUSION: Atypical antipsychotics were a dominant strategy over haloperidol in this analysis primarily because of lower re-hospitalizations in the atypical groups. The ICER indicated that risperidone was dominant over olanzapine because of lower drug costs and increased efficacy. The sensitivity analyses indicate that in order to have equal costs, olanzapine would have to either increase its effectiveness by 8% over risperidone or decrease its daily costs by $1/day. The atypical antipsychotics were more effective and had less total costs compared to haloperidol, and risperidone was more effective and had less total costs compared with olanzapine.

83. Cost savings resulting from a study on intravenous fluconazole prophylaxis in preterm infants. Diane M. Tallo, RPh, Juannice Corwell, Pharm.D; the Woman’s Hospital of Texas, Houston, TX.

PURPOSE: Although still under investigation, prophylactic intravenous fluconazole administration during the first 6 weeks of life has been shown to effectively reduce central-line invasive fungal infections in low birth weight infants.

METHODS: Eligibility of infants into the protocol include birth weight less than 1000 g and the initiation of therapy to begin less than 5 days of life, ideally day of life 2. Baseline laboratory tests are performed on day of life 1 before therapy begun, and once weekly thereafter. The tests include BUN/creatinine, AST/ALT and a CBC with differential. Dosing is 3 mg/kg/dose every third day for two weeks, then every other day for two weeks, then daily for two weeks. Prophylaxis is discontinued if IV access is discontinued, invasive fungal disease occurs, or laboratory results are two to three times above baseline.

RESULTS: Since the implementation of this study in our facility, we have seen fungal infection rate drop significantly by at least 70%, leading to increased mortality and improved central line patency.

CONCLUSIONS: Cost savings occur as a result of less time and fewer resources needed to install and remove central lines and treat active infections. This includes nursing time to care and treat as well as pharmacy time to provide medication. In the span of 8 months, pharmacy has dispensed fewer medications for on 2 of 46 infants eligible for the study who developed active infections. Liposomal amphotericin has not been used in our facility for a 10-month period.

84. Health-related quality of life benefits of clinical pharmacy services: an update of the evidence. A. Simon Pickard, Ph.D.; Shih-Ying Hung, M.S. University of Illinois at Chicago, College of Pharmacy, Chicago, IL.

PURPOSE: To summarize recent studies of clinical pharmacy services that have evaluated the impact of health-related quality of life (HRQOL), to evaluate the extent to which recent literature addressed methodological and study design issues identified in a previous review; to determine whether studies that lacked a control group were more likely to report a statistically significant impact on HRQOL.

METHODS: MEDLINE, EMBASE and IPA were searched from March 1999 to December 2004 using terms for health-related quality of life and clinical pharmacy services. Abstracts were screened by two reviewers, and studies were included if a clinical pharmacy service was evaluated and pre/post HRQL outcomes were reported.

RESULTS: Of 1,152 citations identified, 36 articles met the inclusion criteria. Randomized pre/post-test control group designs were employed in 22 studies. Twenty-three studies used a generic HRQL measure (primarily the SF-36), 21 studies used a condition-specific measure, and 8 studies included both. Significant impact on one or more domains of HRQOL was predominantly demonstrated in interventions relating to asthma, hypertension and chronic heart failure. Statistically significant change in HRQL was reported by 8 of 21 studies that used a randomized control design (38%), 2 of 3 studies with a non-randomized design with control group (40%), and 6 of 8 studies without a control group (75%) (Chi-squares test, p-value=0.16).

CONCLUSIONS: Since 1999, published studies of clinical pharmacy services evaluating HRQL as an endpoint have tripled. Studies have improved in terms of longer length of follow-up, a wider breadth of clinical services has been evaluated, and several well-designed, methodologically rigorous studies have been published. Certain conditions, measurement of HRQL as an outcome may be particularly important in demonstrating the value of clinical pharmacy services.

Pharmacoeconomics

85E. Impact of combined optimal lipid value achievement on risk of cardiovascular events in prevention, gender, and diabetes subgroups. Eric J. Steiner, Pharm.D.; Vincent J. Willey, Pharm.D.; Chattanooga General Hospital, Chattanooga, TN; Mark J. Cziraky, Pharm.D.; Scott L. Charland, Pharm.D.; (1)Kos Pharmaceuticals, Inc, Cranbury, NJ; (2)HealthCore, Wilmington, DE.

BACKGROUND: Patients not achieving combined optimal values for LDL-C, HDL-C, and triglycerides (TG) are at elevated risk for cardiovascular events (CVE). However, this has not been well characterized across patient subgroups.

METHODS: This was a retrospective, analysis of a 1.3 million member MCO database with 5-year follow-up. Patients had ≥ 1 lipid panel between 01/01/00-12/31/01, ≥ 12 months follow-up pre/post-lipid panel and were native to lipid therapy. Patients were categorized as 1/2/3 prevention, male/female, and diabetes mellitus (DM) (DM/no DM). Optimal lipid values were defined using ATP III, AHA, and ADA guidelines. Combined achievement of LDL-C, HDL-C, and TG was determined. CVE events were identified based on ICD-9-CPT codes in medical claims. The association between optimal lipid value achievement and CVE was evaluated by multivariate logistic regression.

RESULTS: Study included 44,351 patients with 30±12 months follow-up. Baseline lipids (mg/dL) were: TC 210±40; LDL-C 131±35; HDL-C 48±14; TG 139±77; non-HDL-C 163±39. There were 10,899 CVEs in 6,722 patients.

CONCLUSION: Optimal lipid values were achieved by <25% of patients across all subgroups, and only 1/3 received any lipid-altering therapy. Achievement of combined optimal lipids was associated with a significant 30% reduction in CVE risk. Treating the entire lipid panel may significantly improve outcomes.

86. The self-reported pharmaceutical industry interactions of Medicaid providers and subsequent correlations between their responses and perceptions of the pharmaceutical industry, including possible influences upon prescribing patterns. Nicole Mudrack, Pharm.D.; Rex Force, Pharm.D.; Idaho State University, Pocatello, ID.

PURPOSE: Characterize the influence of self-reported pharmaceutical company interactions on prescribing in Medicaid providers.

METHODS: A query of a statewide Medicaid database identified eligible prescribing providers who then received a survey designed to detect the extent of interactions with the pharmaceutical industry. Pearson correlation coefficients were used to determine significant relationships between the survey responses and to identify trends in the providers’ perception of the pharmaceutical industry and to possible influences on prescribing patterns.

RESULTS: A total of 1,244 surveys were mailed. The response rate was 48%
with 599 surveys returned. Family Practice was the major specialty group (36%). Of those polled, 81% believed that drug information provided by pharmaceutical representatives did not influence their prescribing habits. Respondents reported one lunch/snack provided by and 27.9 minutes of interaction, with pharmaceutical representatives per week. Providers and/or their groups reported dispensing 22.3 samples per week. All Pearson correlations reported below were significant at p<0.01. Providers who reported spending more time with pharmaceutical representatives were more likely to agree that time spent with them was burdensome and distracting (r=0.112). They were also more likely to disagree that representatives were a valid source of drug information (r=-0.347). They were also more likely to believe their prescribing patterns were influenced by the pharmaceutical industry (r=0.250). On average, respondents indicated that there was a pharmacological representative interaction for every 13 patients seen in clinic. One in 3 patients received a sample prescription. CONCLUSION: Respondents reporting extensive interactions with pharmaceutical representatives found this time burdensome and the information received biased. Providers spent considerable time with representatives and frequently dispensed samples.

Pharmacogenomics

87. Influence of resistin promoter polymorphisms on plasma resistin levels in non diabetic subjects. Christina L. Aquilante, Pharm.D. 1, Jill Chappell, Pharm.D. 1, Varsha Bhatt-Heinisch, M.S. 2, Mary Pat Knadler, Ph.D. 3, Lance J. Oyen, Pharm.D., Martin E. Kochevar, M.S. 1, Mary F. Burritt, Pharm.D. 1, Amber L. Beitelhieser, Pharm.D. 1, Lucille Cape Romo, M.S.N. 1, APRN, BC, FNP 1, Lisa A. Kostow 3, M.D. 2, 1)University of Colorado at Denver and Health Sciences Center, Denver, CO. 2)Washington University School of Medicine, St. Louis, MO; 3)University of Colorado at Denver and Health Sciences Center School of Medicine, Denver, CO.

PURPOSE: Resistin is an adipocyte-derived cytokine with a putative role in inflammation, obesity, and insulin resistance. Two common single nucleotide polymorphisms, -420 C/G and -537 A/C, exist in the promoter of the resistin gene. The authors sought to determine if these polymorphisms were associated with plasma resistin levels in non-diabetic subjects.

METHODS: A blood sample was obtained from 91 non-diabetic subjects without diagnosis of cardiovascular disease. Resistin -420 C/G and -337 A/C genotypes were determined by PCR-pyrosequencing. Haplotypes were inferred using PHASE software. Plasma resistin levels were determined using an ELISA method. Baseline characteristics were compared between genotype groups by unpaired t tests (wild-type versus variant carriers) and between haplotype groups by ANOVA. Differences in plasma resistin levels were determined using the GLM procedure, controlling for age, sex, race, BMI, and glucose.

RESULTS: We enrolled 62 women and 29 men (78 non-black; 13 black; mean age = 44 ± 7 years; mean body mass index=33 ± 5 kg/m²; mean fasting plasma glucose = 92 ± 10 mg/dL). The -420G and -537C allele frequencies were significantly by -420 C/G genotype (CC=16.2 ± 6.7 ng/mL; G carriers=15.4 ± 6.8 ng/mL) and by the CC genotype, p=0.006. Mean plasma resistin levels did not differ significantly by -420 C/G genotype (CC=16.2 ± 6.7 ng/mL; G carriers=15.4 ± 6.8 ng/mL) or by -337 A/C genotype (AA=15.7 ± 6 ± 4 ng/mL; A carriers=16.5 ± 10.1 ng/mL). Plasma resistin levels were not significantly different when analyzed according to the number of copies of the -420/C -337/A genotype, GA, or GC haplotypes.

CONCLUSIONS: Our data suggest that resistin promoter polymorphisms do not influence plasma resistin levels in non-diabetic subjects without cardiovascular disease.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

88. Analysis of parental calcium gluconate administration and resulting ionized calcium levels in adult, hospitalized patients. Kelli M. Lewandowski, Pharm.D. 1, Lance J. Oyen, Pharm.D. 2, Martin E. Kochevar, M.S. 1, Mary F. Burritt, Pharm.D. 1, Mayo Clinic Rochester, Rochester, MN.

PURPOSE: Ionized calcium levels (iCa) are a guide for identification and treatment of hypocalcemia, but low iCa may fail to normalize despite calcium supplementation. We retrospectively evaluated the response of iCa after 2 g IV calcium gluconate (CaGlc). The primary outcome was the change between pre-dose and post-dose iCa.

METHODS: The 34 hospitalized patients included were ≥ 22 years of age with two iCa levels within 12 hr of each other and CaGlc 2 g IV administered at ≤ 2 hr before ≤ 2 hr after the post-dose iCa. Excluded patients had active disease states known to affect calcium. We received a blood sample ≤ 2 hr or other calcium replacement ≤ 6 hr (excluding parenteral nutrition or dietary intake) before the pre-dose iCa level or between the two iCa levels. 34 patients were enrolled (p≥0.8, α=0.05); two-sided, paired t-test), giving the ability to detect a difference of 0.325 mg/dl. between pre- and post-dose iCa levels (SD of 0.65 mg/dl).

RESULTS: Thirty-two subjects were ICU and/or telemetry patients. There was an equal distribution of males and females, and the majority of patients were Caucasian. The mean change in iCa levels was 0.234 mg/dl (p<0.005, 95% CI of 0.176-0.331). A significant relationship (p=0.026) existed showing that the less time there was between pre- and post-dose iCa, the larger the change. Patients with lower pre-dose iCa showed a greater change in iCa levels (p=0.0033), and female patients showed a greater iCa change (p=0.0206). Laboratory variables (serum creatinine, phosphorus, magnesium, albumin, pH) and medications did not significantly affect iCa change.

CONCLUSION: CaGlc 2 g IV resulted in a statistically significant mean change from pre- to post-dose iCa. However, the clinical impact of the dose is less certain since the mean change was small (0.234 mg/dl).

89. Monte Carlo simulation for the determination of optimized population pharmacokinetic study design of hydrocortisone in neonates. Vishi Bhatt, M.S. 1, Pharm.D. 1, Paul Williams, Pharm. D. 1, FCP, FCCP 2; 1)University of Michigan, Ann Arbor, MI; 2)University of The Pacific, Stockton, CA.

PURPOSE: To investigate the competing study strategies for a population pharmacokinetic study (PPK) of exogenous hydrocortisone (HC) in neonates and pre-term infants. Issues addressed were: 1) minimum number of subjects to be included in the study; 2) could endogenous HC be modeled without it would be needed to include as study data, and 3) could a study strategy relating several covariates to both apparent volume and clearance be developed.

METHODS: 1) Templates of simulated data were constructed using random number generating tool ZRandom™ in conjunction with Microsoft XL. 2) Data (templates) were exported to be used in NONMEM. 3) NONMEM control streams were constructed to simulate data that would be representative of an executed study. 4) Models were estimated from each simulated data set. 5) Results were summarized and evaluated with respect to power, efficiency, and informativeness. Fifteen percent of samples were eliminated at random to simulate protocol deviations; Gestational age (GA), postnatal age (PNA), weight (wt-kg) and height (Ht-cm) were all simulated in ZRandom™ as log normal with mean (sd) of 33 (6), 7.6 (10), 2.8 (1.3), and 45 (6), respectively. For each study structure scenario 50 sets of data were generated.

RESULTS: Fourteen competing study structures were included in the final evaluation. A study structure that included 75 subjects with three targeted plasma samples for HC concentration determination, including endogenous HC, could provide a power of greater than 0.95 if 2 covariates were included, estimating apparent volume of distribution and clearance within 20% of the true clearance, and the random effects in the model. CONCLUSIONS: A study structure with 75 subjects with three opportunistic samples will be adequate for the execution of a PPK study in neonates. Monte Carlo simulation will be a powerful tool for the evaluation of complex, competing study structures.

90. Pharmacokinetics of duloxetine in breast milk and plasma of healthy postpartum lactating women. Evelyn Lobo, Ph.D. 1, Corina Loghin, M.D. 1, Mary Pat Knadler, Ph.D. 1, Celeidon Gonzales, M.S. 2, Lu Zhang, M.S. 1, Tonya Quinlan, B.A. 1, Jill Chappell, Pharm.D. 1, Joseph Chiesa, M.D. 1, Richard Begstrom, Ph.D. 1, JUE Lilly and Company, Indianapolis, IN; 2)Vedra Clinical Research Ltd., Plymouth, United Kingdom.

PURPOSE: To evaluate the pharmacokinetics (PK) of duloxetine in breast milk and plasma in healthy women and to estimate the dose an infant might consume if breast fed.

METHODS: Single center, open-label study included 6 healthy women aged 22–35 years and at least 12 weeks postpartum, who stopped nursing during and after the study. Duloxetine 40 mg was given orally every 12 hr for 3.5 days; 7 samples of plasma and milk over 12 hr were obtained after the 7th dose. Breast milk samples were pooled at each time point. Plasma and breast milk samples were analyzed using validated LC/MS/MS methods. Mixed-effect ANOVA was used to determine the random effect of subject. Safety measures included adverse event monitoring, vital signs, ECGs, lab tests, and depression rating scales.

RESULTS: The steady state breast milk to plasma exposure ratio is 0.25 (90% CI: 0.18 to 0.35). The estimated infant dose of duloxetine is about 7 µg/day (range 4 to 15 µg/day) or 2 µg/kg/day (range 0.6 to 3 µg/kg/day). The weight normalized infant dose is 0.14% of the maternal dose. Dunnness, nausea and fatigue were commonly reported. No clinically important changes in safety measures occurred.
CONCLUSIONS: Duloxetine is detected in breast milk and steady state concentrations in breast milk are one fourth those in plasma. As the newborn’s ability to metabolize duloxetine in infants is unknown, prescribers should carefully assess potential risks of duloxetine exposure in infants and the benefits of nursing an infant when a mother is on duloxetine therapy.

91. In vitro modeling of intravenous meropenem (500 mg every 6 hours vs. 1 g every 8 hours) in Acinetobacter baumannii. Romina Marchesano, B.Sc., B.Pharm., Sandra Walker, Pharm.D., Scott Walker, M.Sc., Pham, Naveen Gnanabakthan, B.Sc. (Hon), Shirley Law, DipPharmTech, Christine Watt, B.Sc., Andrew Simon, M.D.; Sunnybrook and Women’s Health Science Centre, Toronto, ON, Canada.

METHODS: An in vitro model of infection using a 1-compartment model for meropenem was used. Two clinical isolates of A. baumannii were tested, a sensitive and multi-resistant strain (not resistant to meropenem and ampicillin). The in vitro experiments were run using concentrations that resembled meropenem given by intravenous infusion over 30 minutes for 500 mg q6h and 1 g q8h regimens. Samples were taken throughout the 24 hours for quantitation of meropenem and A. baumannii growth.

RESULTS: There was not a statistically significant difference in % of time spent above the MIC (%T>MIC) between 500 mg q6h and 1 g q8h (p=0.48, 95% CI -34.94–32.38). When looking at the resistant strain only, meropenem remained above the MIC for a longer period of time in the 300mg q6h regimen compared to the 1 g q8h regimen (p=0.0004, 95% CI 9.93–23.43). No difference was found for the sensitive strain. The extent of kill of A. baumannii was not statistically different between the two regimens (p=0.85, 95% CI 2056.85 to 2405.59). The 500 mg q6h regimen achieved a 3-log reduction (99.9% kill) in less time than the 1 g q8h regimen (p=0.0006, 95% CI -111.70 – 60.43).

CONCLUSION: Meropenem 500 mg q6h has at least equal antimicrobial activity to 1 g q8h against a sensitive and multi-drug resistant strain of A. baumannii. Since the drug acquisition costs of meropenem 500 mg IV q6h are lower than 1 g q8h (-$100/day vs. $130/day), this dosing regimen may be preferred.

92. Determination of the correspondence of the root mean squared prediction error obtained via a traditional approach versus the bootstrap. Amit Desai, B. Pharm., James Uchizono, Ph.D.1, Yousef Asiri, Ph.D.2, Ene I. Ette, Ph.D.1, Paul J. Williams, Pharm.D.1, (1)University of the Pacific, School of Pharmacy, Stockton, CA; (2)Vertex Pharmaceuticals, Cambridge, MA.

Objective: The purpose of this study was to determine whether there was a correspondence between the root mean squared prediction error for serum concentrations when estimated by the traditional external prediction method versus when estimated by the nonparametric bootstrap. METHODS: Data was collected from 235 patients, 165 in the index population and 70 in the test population. A total of 437 concentrations measurements were measured. Previously, a population pharmacokinetic model was estimated. The final Irreducible population pharmacokinetic model was determined. Predictions were made from the model into an external data set. The squared prediction errors were not normally distributed, and therefore the winsorized (W) mean squared error (WMSPE) was estimated. From the WMSPE, the W-root mean squared prediction error (WRMSPE) was estimated and used as a prediction metric. Next, bootstrapping was used to estimate the optimism of the WRMSPE. The optimism was added to the WMSPE when the original model was fitted to the original data to obtain the observed WRMSPE. The improved WRMSPE was compared to the WRMSPE from the external prediction.

RESULTS: The average optimism was very small (0.12) for the 200 bootstrap replicates of the original data. When the original model was used to predict into the external data, the WRMSPE was 10.44 mg/L, and from the bootstrap the improved WRMSPE was 9.35 mg/L. The means, median, and W-mean of the 200 WRMSPE values from the bootstrap were 12.22, 12.04, and 12.05. CONCLUSIONS: These results indicate that the bootstrap provides estimates of the WRMSPE that have a high degree of correspondence to that obtained from the traditional method and serves as a confirmation that the bootstrap can be used as a validation method for population pharmacokinetic models. Given the data, any of the measures of central tendency would be appropriate to evaluate a population model.

93E. Posterior predictive check: a model checking tool. Amit Desai, B. Pharm., James Uchizono, Ph.D., Paul Williams, Pharm.D., M.S., FCCP, FCP; University of the Pacific, Stockton, CA.

PURPOSE: The purpose of this work was to determine whether the statistical process called Posterior Predictive Check (PPC), under simulation conditions most favorable to achieve PPC’s success, is able to identify model misspecification due to influenced data.

METHODS: We used a simple one-compartment disposition population pharmacokinetic model (PKP), applied to a population of 100 subjects, each with 4 time points. The simulated IV bolus dose of drug was 1000 units. Simulation of 50 non-influenced data sets and 50 influenced data sets, which were created by randomly substituting 10 subjects from documented influenced population data set, was executed using NONMEM (version V) on windows XP PPC was performed on each data set (50 non-influenced and 50 influenced), and minimum concentration (Cmin) was calculated from the original and posterior distributions.

RESULTS: To test the performance characteristic of the PPC, simulated values from the posterior distribution of replicated data sets were compared to their respective initial data sets. The (Cmin) from the initial data sets were compared to their corresponding posterior distributions. In the case of non-influenced data sets the numbers of (Cmins) from the posterior distributions were in the range of 60% to 80% centered around the (Cmin) from the initial data set for different iterations. In case of influenced data sets the numbers of (Cmins) were in the range of 90%–100% centered around the (Cmin) from the initial data set for different iterations.

CONCLUSIONS: We concluded that in the case of non-influenced data, even though the numbers of (Cmins) below the initial observed data are > 50%, there is a corresponding difference between the models developed from influenced and non-influenced data. Therefore, we are hopeful that PPC can be used as a reliable model checking tool. Presented at the Annual Meeting and Exposition of the American Association of Pharmaceutical Scientists, Baltimore, M.D., November 7-11, 2004.

94E. Pharmacokinetics of once-daily fosamprenavir 1400 mg plus atazanavir 400 mg without ritonavir in HIV negative subjects. Patrick G. Clay, Pharm.D.1, 2, Peter L. Anderson, Pharm.D.1, Patrick F. Smith, Pharm.D.1, David Lein, Pharm.D.1, Alan Glaros, Pharm.D.1, (1)Kansas City University of Medicine and Biosciences, Kansas City, MO; (2)University of Colorado Health Science Center, Denver, CO; (3)University at Buffalo, Buffalo, NY; (4)Kansas City Free Health Clinic, Kansas City, MO.

PURPOSE: Atazanavir (ATV) + fosamprenavir (FPV) is a potentially useful double-protease inhibitor (PI) combination with components that may offer a mutually beneficial resistance profile.

METHODS: COL100683 was a prospecitive, randomized, open-label, 3-way crossover study with 3 wk washout periods, in which 21 HIV (-) adults received, in random order: FPV 1400 mg, ATV 400 mg, or both PO once daily (QD) x 14 days. At the end of each period (Day 14), a 24-hr PK study (10 samples) was completed including standardized diets. Drug levels (FPV reported as APV) were assayed by a validated HPLC method. PK parameters were determined by standard noncompartmental methods and compared by paired t-test on log-transformed data. Bioequivalence was assessed by geometric mean ratios (GMR). Adverse event (AE) data were analyzed using students’ t-test.

RESULTS: 21 subjects completed the study (11 men, 48% non-white) with a mean (SD) age of 31.7 (9.5) yr. PK parameters are reported below. No differences occurred with respect to periods or sequences.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ATV alone</th>
<th>APV alone</th>
<th>ATV + FPV</th>
<th>GMR (90% CI)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUCss µg/ml</td>
<td>17.9 (65)</td>
<td>11.9 (54)</td>
<td>0.67 (51-88)</td>
<td>335%*</td>
<td></td>
</tr>
<tr>
<td>Cmax µg/ml</td>
<td>2.6 (39)</td>
<td>1.8 (54)</td>
<td>0.70 (33-93)</td>
<td>30%*</td>
<td></td>
</tr>
<tr>
<td>C24 µg/ml</td>
<td>0.14 (135)</td>
<td>0.0 (104)</td>
<td>0.43 (24-56)</td>
<td>57%*</td>
<td></td>
</tr>
</tbody>
</table>

(continued)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ATV alone</th>
<th>APV alone</th>
<th>ATV + FPV</th>
<th>GMR (90% CI)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUCss µg/ml</td>
<td>21.7 (94)</td>
<td>38.7 (27)</td>
<td>1.78 (1.47-2.12)</td>
<td>78%*</td>
<td></td>
</tr>
<tr>
<td>Cmax µg/ml</td>
<td>4.8 (53)</td>
<td>6.3 (34)</td>
<td>1.36 (1.09-1.72)</td>
<td>36%*</td>
<td></td>
</tr>
<tr>
<td>C24 µg/ml</td>
<td>0.06 (89)</td>
<td>0.23 (178)</td>
<td>3.83 (2.43-6.76)</td>
<td>283%*</td>
<td></td>
</tr>
</tbody>
</table>

*p<0.05; data presented as geometric mean (GMR)

CONCLUSIONS: ATV+FPV was well tolerated. ATV significantly enhanced exposure of boosted, once-daily FPV. ATV exposure was reduced when co-administered with FPV. The clinical relevance of these findings will remain unknown until controlled efficacy studies are completed.

Presented at the 13th Conference on Retroviruses and Opportunistic Infections, Denver, CO, February 5-9, 2006.


ACCP 2006 SPRING PRACTICE AND RESEARCH FORUM e23
Purposes: Febuxostat is a novel non-purine selective inhibitor of xanthine oxidase (NP-SIXO) being developed for the management of hyperuricemia in patients with gout. The effects of age and gender on the pharmacokinetics (PK), pharmacodynamics (PD), and safety of febuxostat were evaluated. METHODS: In a phase-I, parallel-group, open-label, multiple-dose study, male (M) and female (F) subjects 19-40 years old (young, 12M/12F) and 65-76 years old (elderly, 12M/12F) received once daily 80-mg oral doses of febuxostat for 7 days. Blood samples were collected to assess the PK of febuxostat and its active metabolites (67M-1, 67M-2, 67M-4) and its effect on uric acid (PD marker). Protein binding and safety of febuxostat were also assessed.

RESULTS: The results are shown in the table.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Parameter</th>
<th>Y</th>
<th>E</th>
<th>M</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febuxostat C&lt;sub&gt;mean&lt;/sub&gt;</td>
<td>(ng/mL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24h</td>
<td>28±12</td>
<td>27±9</td>
<td>24±10</td>
<td>31±10</td>
<td></td>
</tr>
<tr>
<td>AUC&lt;sub&gt;24&lt;/sub&gt; (ng.h/mL)</td>
<td>36±19</td>
<td>36±20</td>
<td>36±15</td>
<td>36±15</td>
<td></td>
</tr>
<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt; (%)</td>
<td>0.7±0.1</td>
<td>0.7±0.1</td>
<td>0.7±0.1</td>
<td>0.7±0.1</td>
<td></td>
</tr>
<tr>
<td>67M-1 AUC&lt;sub&gt;24&lt;/sub&gt; (ng.h/mL)</td>
<td>225±66</td>
<td>225±66</td>
<td>225±66</td>
<td>225±66</td>
<td></td>
</tr>
<tr>
<td>67M-2 AUC&lt;sub&gt;24&lt;/sub&gt; (ng.h/mL)</td>
<td>229±76</td>
<td>229±76</td>
<td>229±76</td>
<td>229±76</td>
<td></td>
</tr>
<tr>
<td>67M-4 AUC&lt;sub&gt;24&lt;/sub&gt; (ng.h/mL)</td>
<td>235±77</td>
<td>235±77</td>
<td>235±77</td>
<td>235±77</td>
<td></td>
</tr>
<tr>
<td>change (%)</td>
<td>-55±8</td>
<td>-56±9</td>
<td>-52±7</td>
<td>-59±8</td>
<td></td>
</tr>
<tr>
<td>67M-4 sU AUC&lt;sub&gt;24&lt;/sub&gt; (%)</td>
<td>-56±9</td>
<td>-56±9</td>
<td>-54±9</td>
<td>-59±9</td>
<td></td>
</tr>
</tbody>
</table>

The overall incidence of study drug-related adverse events (AEs) was lower in men than in women (13% vs 34%) and in young than in elderly (23% vs 42%). The most common AEs were headache and constipation. All AEs were mild or moderate in severity.

CONCLUSION: Neither age nor gender had any clinically significant effect on the PK, PD, and safety of febuxostat. Therefore, febuxostat does not require any dose adjustment based on age or gender.


PURPOSE: Costly novel antipsychotic agents have increased over the past few years. The NA class has come to prosper, expanding in use beyond the FDA-approved indications. The objective of this study was to identify longitudinal prescribing patterns of NAs and determine the impact on pharmacy charges.

METHODS: Financial and clinical data was collected from 1999 through 2004, and grouped by fiscal year (FY). Pharmacy charges as a percent of total hospital charges, NA charges as a percent of total pharmacy charges, and the distribution of NA use by diagnoses treated were determined for each FY. Changes in percent contribution of pharmacy charges to hospital charges, utilization of NA compared to other drugs, and utilization of NA by selected psychiatric diagnoses were also compared.

RESULTS: Over the past five years, total hospital charges have increased by $94.6 million. The percentage of admissions associated with an NA charge increased from 40% in FY2000 to over half of all admissions in FY2004 (55.6%). Within the total hospital charges for each FY, the contribution of pharmacy charges has increased 4.9% (from 8.6% to 13.5%). NA contribution has increased to over one-third of pharmacy charges (28.5% to 36.7%). Olanzapine has contributed the most to NA charges. Olanzapine was also the most utilized NA, but dropped to second for quetiapine in FY2004. NA use outside of FDA-approved labeling has increased from FY2000 to FY2004 in the diagnoses analyzed. Depression (23% to 46%), anxiety (32% to 41%), and neuropsychiatric disorders (31% to 41%), and childhood disorders including approved adult disorders as well as other childhood-specific disorders (34% to 61%).

CONCLUSION: The expanding use of NAs has affected the cost of care in this psychiatric facility. Substantive evidence is needed to clarify these increasingly common, inadequately researched, and increasingly costly psycho-pharmacological practices.


Despite their widespread use in PTSD, atypical antipsychotic agents have been associated with significant acquisition costs and safety and tolerability risks while having limited evidence of benefit. A review of the published literature using Medline, a treatment algorithm for PTSD was created based on the VA Pharmacological Use Outside of Approved Indications Guidance on "Off-label" Prescribing guidelines for consideration of formulary inclusion to address this issue. The resulting treatment algorithm for PTSD restricted atypical antipsychotic availability to risperidone and quetiapine to patients who have refractory reexperiencing symptoms (distress with trauma-associated cues, memories, dreams, flashbacks, intrusive thoughts, gross somatic symptoms, hallucinations, illusions, sleep disturbances) or hyperarousal symptoms (impulsivity, irritability, anger, sleep disturbances) who have a trial of or have a contraindication to (a) maximum tolerated dose of two forms of SSRI s (serotonin and norepinephrine reuptake inhibitors) or other antidepressants (serotonin, dopamine, noradrenergic-associat ed hyperarousing behavior, and patients who have nightmares or sleep disturbances; (c) hydroxyzine for patients with general daytime anxiety; and (d) mood stabilizers (lithium, divalproex, carbamazepine, gabapentin, topiramate, or other health care providers, and patients whose medical record was unavailable.

RESULTS: Fifty-three percent of the patients were treated with both an antidepressant and a mood stabilizer. Of those patients, 24% were on an atypical antipsychotic medication. Fifty percent of patients on atypical antipsychotic medication had their weight, blood pressure, and serum glucose monitored at least 3 times in the past 12 months. Serum cholesterol, depression and mania scales and pregnancy tests were performed less frequently.

CONCLUSIONS: A small majority of patients on atypical antipsychotics were monitored appropriately for various metabolic changes during their course of therapy. However, improvements can be made in both the monitoring for metabolic changes and the disease process itself.

carbamazepine, and valproic acid) for patients with refractory hyperarousal and PTSD reactions and improve treatment of PTSD symptoms.

101. Eszopiclone coadministered with fluoxetine for insomnia coexisting with major depressive disorder (M.D.D): analysis by age. John G. Karathidis, Pharm.D.1, W. Vaughn McCall, M.D., M.D.2, Maurice Fava, M.D.3, Thomas C. Wessel, M.D.4, Robert Rubens, M.D.5, Judy Caron, Ph.D.6, Thomas Roth, Ph.D.7, Andrea J. Anderson, Pharm.D.1, Andrea J. Anderson, Pharm.D.1 (1)Sepracor Inc., Marlborough, MA; (2)Wake Forest University Department of Psychiatry and Behavioral Medicine, Clinical Science Building, Winston-Salem, NC; (3)Massachusetts General Hospital, Boston, MA; (4)Wake Forest University Department of Psychiatry and Behavioral Medicine, Clinical Science Building, Winston-Salem, NC; (5)Henry Ford Hospital Sleep Disorders Center, Detroit, MI.

INTRODUCTION: Results of a study of eszopiclone and fluoxetine in coexisting insomnia and depression showed that initiation of co-therapy produced greater improvements in sleep and depression compared with fluoxetine monotherapy. Results of a post-hoc analysis of results by age are presented.

METHODS: Patients (aged 21–64 years) met DSM-IV criteria for M.D.D and insomnia, with screening 17-item Hamilton Depression Rating Scale (HAM-D-17; excluding the sleep items) >14. All patients received fluoxetine QAM for 10 weeks. Patients were randomized to eszopiclone 3 mg (n=270) or placebo (n=275) QHS for 8 weeks, followed by a 2-week single-blind placebo run-out phase. Sleep and depressive symptom responses were evaluated in younger (≤50 years, n=351) and older adults (≥50 years, n=136).

RESULTS: At baseline, older adults had greater difficulty with sleep indicated by longer sleep latency (SL), greater wake time after sleep onset (TST) and less total sleep time (TST) compared with younger adults. Sleep quality, daytime alertness, and ability to function and concentrate in younger adults were either better than or the same as in older adults. Both age groups responded to eszopiclone/fluoxetine with statistically significant differences relative to fluoxetine alone in SL (p<0.0042), WASO (p<0.0215) and TST (p<0.052). Those in the older age group had greater changes in these parameters. Changes from baseline HAM-D scores in the younger vs older group, respectively, were -12.01 vs -11.67 for co-therapy and -10.34 vs -8.95 with monotherapy. The percentage of responders (≥ 50% decrease in HAM-D-17 score) was 56.8% vs 50.6% in the younger vs older group, respectively (p<0.05 for co-therapy). Support: Sepracor Inc.

102. Eszopiclone coadministered with fluoxetine for insomnia coexisting with major depressive disorder (M.D.D): effects following eszopiclone discontinuation. Andrea J. Anderson, Pharm.D.1, Andrew Krystal, M.D., M.S.2, Robert Rubens, M.D.3, Mauricio Fava, M.D.1, W. Vaughn McCall, M.D., M.S.4, Thomas C. Wessel, M.D.5, Thomas Roth, Ph.D.6, Andrea J. Anderson, Pharm.D.1 (1)Sepracor Inc., Marlborough, MA; (2)Duke University Medical Center, Durham, NC; (3)Massachusetts General Hospital, Boston, MA; (4)Wake Forest University Department of Psychiatry and Behavioral Medicine, Clinical Science Building, Winston-Salem, NC; (5)Henry Ford Hospital Sleep Disorders Center, Detroit, MI.

INTRODUCTION: Insomnia and M.D.D may co-exist. The use of adjunctive hypnotics in this setting is controversial. We reported that eszopiclone/fluoxetine co-therapy significantly improved sleep and depression compared with fluoxetine monotherapy. Here we report data that further evaluated insomnia and M.D.D after discontinuation of eszopiclone due to concern that hypnotic discontinuation may undermine antidepressant response or hasten relapse.

METHODS: Patients met DSM-IV criteria for M.D.D and insomnia. All patients received fluoxetine QAM for 10 weeks. Patients were randomized to eszopiclone 3 mg (n=270) or placebo (n=275) QHS for 8 weeks, followed by a 2-week single-blind eszopiclone placebo discontinuation phase. During this discontinuation phase, subjective sleep was assessed; daily depression was assessed with the HAM-D-17 at the end of the phase (Week 10). Discontinuation effects were examined two ways: 1) change from baseline to Week 10; change from end of hypnotic treatment (EOT; Week 8) to Week 10.

RESULTS: During the discontinuation phase, the eszopiclone group maintained significant sleep improvements observed over the first 8 weeks (Week 8-10 average p<0.05 vs placebo). Relative to baseline, patients discontinued from eszopiclone continued to have significantly improved sleep (p<0.05) at each daily assessment for SL, WASO, and TST (average change -124.0, -68.67, and 154.86 minutes, respectively). Relative to EOT, patients discontinued from eszopiclone did not show significant decrements over the 2 weeks for SL, WASO, or TST (average change 1.72, 1.6, and 0.39 minutes, respectively). Improvements in HAM-D-17 scores relative to placebo observed at EOT (14.6 vs -12.3; p<0.0093) were maintained at Week 10 (-15.3 vs -12.7; p<0.0001).

CONCLUSIONS: In this study, sleep improvements associated with concomitant eszopiclone/fluoxetine were maintained after hypnotic discontinuation. Discontinuing eszopiclone was not associated with significant changes in measures of depression severity. No rebound insomnia was observed. Additional studies are needed to investigate the optimal duration of combination therapy.

Pulmonary

103. Impact of consensus guidelines for cystic fibrosis-related bone disease. Michelle L. Condren, Pharm.D.1, Lindsey D. Wilcox, Pharm.D.2, (1)Texas Tech University School of Pharmacy, Amarillo, TX; (2)Texas Tech University School of Pharmacy, Port Neches, TX.

PURPOSE: In 2002, the Cystic Fibrosis (CF) Foundation developed guidelines for bone health screening. This pilot study will identify CF patients qualifying for bone densitometry. After testing, charts were reviewed for the following data: age, height, weight, ideal body weight, presence of diabetes, pubertal status, pulmonary function, organ transplant status, corticosteroid use, medroxyprogesterone use, fracture history, calcium and vitamin D intake, caffeine and carbonated beverage intake, frequency of weight-bearing exercise, 25-OHD level, and t scores, and absolute bone mineral density from Dual-energy X-ray Absorptiometry (DXA).

RESULTS: A total of 23 charts were reviewed. Of those, 15 (65%) qualified for bone densitometry. Ten patients completed a DXA scan. Four patients (40%), ages 14–21 years, were diagnosed with osteoporosis. Four patients (40%), ages 12–16 years, were diagnosed with osteopenia. Two patients qualifying for screening had normal bone density. Bisphosphonate therapy was initiated in 3 patients and all patients were started on appropriate dosages of calcium and vitamin D. The total number of risk factors for bone disease correlated with total body z-score (p<0.018) and lumbar z-score (p<0.015). Of the 2 patients with normal bone density, one was 18 years old with no additional risk factors, and the other was 16 years old with medroxyprogesterone use as the only risk factor.

CONCLUSIONS: In this population, implementation of the bone health screening guidelines was valuable, identifying that the majority of the patients...
104E. The relationship of alcoholic blackouts to blood alcohol concentration. Tami R. Argo, Pharm.D., M.S., BCPP, Paul J. Perry, Ph.D.1, Michael Trinka, Pharm.D., Student1, Jillian Hernan, Pharm.D., Student1, Mary Brabson, Pharmacy, Student2, Mary Brabson, Pharmacy, Student2. (1)University of Texas at Austin, College of Pharmacy, Austin, TX; (2)Touro University - California College of Pharmacy, Vallejo, CA; (3)University of Iowa College of Pharmacy, Iowa City, IA.

PURPOSE: The primary aim of this study was to investigate the association between measured blood alcohol concentration (BAC) and the presence and degree of amnesia (no amnesia, grayout, or blackout) in actively drinking subjects. A secondary aim was to determine potential factors other than BAC that contribute to alcohol-induced memory loss.

METHODS: An interview questionnaire was administered to subjects regarding a recent alcohol-associated arrest with a documented blood alcohol concentration greater than 0.08 g/dL (for public intoxication) or below the influence, or under age drinking. Demographic variables collected included drinking history, family history of alcoholism, presence of previous alcohol-related memory loss during a drinking episode, and drinking behavior during the episode. Using self-described recall of timeline of events, memory of the drinking episode was evaluated to determine if either an alcohol-induced grayout (partial anterograde amnesia) or blackout (complete anterograde amnesia) had occurred.

RESULTS: A total of 65 subjects with a documented arrest were included. Twenty (31%) subjects described blackouts, 13 (20%) described grayouts, and 32 number (49%) reported no amnesic episode. A strong linear relationship between BAC and predicted probability of memory loss was determined for those having blackouts (R²=0.34). Significant differences (p<0.05) were found in mean total number of drinks ingested prior to arrest, gulping of drinks, and blood alcohol concentration at arrest for those having blackouts compared to no amnesia. Differences in drinking more than planned were found between the no amnesia and grayout groups.

CONCLUSIONS: A significant association was found between the measured BAC and level of amnesia reported by the subject during a recent drinking episode. From a forensic perspective, it is reasonable to conclude that a subject with a BAC ≥0.310 g/dL has a 50% probability of truthfully claiming that a blackout had occurred during an alleged incident.

Transplant/Immunology
107. Impact of a steroid withdrawal protocol on height and weight outcomes in pediatric renal transplant recipients. Keri L. Roberts, Pharm.D., Lonnie D. Smith, Pharm.D., Jason Crompton, Pharm.D., Cynthia Terrill, RDCSCRD, Joseph Sherbette, M.D., University of Utah, Salt Lake City, UT.

PURPOSE: Chronic corticosteroid exposure is associated with weight gain and poor growth in pediatric renal transplant recipients (PRTR). We evaluated steroid withdrawal (SWD) efficacy in PRTR, focusing on height and weight outcomes.

METHODS: All PRTR transplanted from 1/2000-10/2005, undergoing SWD (4-7 days) were evaluated. Subgroup analysis by age was performed at 1, 2 and 3 years post-PRTR. Variables, including age, height, weight and BMI were reviewed at baseline and every six months. Age-adjusted height and weight z-scores were calculated and compared with the 2005 North American Pediatric Renal Transplant Cooperative Study (NAPRTCS). Multivariate linear regression analysis was performed to determine factors associated with growth over time. All z-scores were compared against NAPRTCS and own institutional historical data.

RESULTS: Of patients transplanted, 28 met inclusion criteria. Reasons for exclusion were: chronic steroids (13), <1 yr data (12), lost to f/u (3), primary allograft non-function (1) and restarting steroids following rejection (1). Comparison to NAPRTCS revealed higher mean delta height z-scores 2 years post-transplant across all age groups, with the greatest increase in ages 13–17. Weight z-scores from baseline also improved at 3 years. Interestingly, delta weight scores increased in ages 6–12 and 13–17 (1.39 vs. 1.13 and 0.8 vs. 0.7 respectively) upon comparison with NAPRTCS. BMI-Age% at 3 years increased from baseline in all patients. 22/28 pts (79%) remained within normal BMI range (5–85%). 1 remained underweight, 2 became at risk for overweight (BMI≥85%) and 3 became overweight (BMI>95%).

CONCLUSIONS: SWD leads to improvement in mean height z-scores and demonstrates increased delta z-scores when compared to patients on chronic corticosteroids. PRTR are still at risk for becoming overweight despite withdrawal of corticosteroids.

Delta Height z-scores Age 1 Ages 2-5 Ages 6-12 Ages 13-17
Baseline-1 YR -0.32 (+1.5) -0.54 (+0.7) -0.90 (+1.1) 0.24 (+1.4)
Baseline-2 YR -0.69 (+0.7) -0.92 (+0.6) -1.19 (+0.6) -0.59 (+0.7)
Baseline-3 YR -0.73 (+0.7) -0.95 (+0.6) -1.19 (+0.6) -0.59 (+0.7)
NAPRTCS-Baseline-2 YR 0.04 0.52 0.69 -0.02
Increase vs. NAPRTCS @ 2 YR 2.06 17% 12% 32% 20-Fold

Substance Abuse/Addiction
108E. Serial pharmacodynamic responses to anti-lymphocyte globulin. Kathryn A. Gillis, Pharm.D.1, Yassa Qazi, M.D.2, Joyseehn Karam, M.D.2,
P Wen-Yi Lymphocytes during induction and maintenance immunosuppression may have positive correlation was noted between sIL-2R and serum creatinine levels. A significant recovery in CD4+ lymphocytes toward baseline was observed in patients during Phase II (28 ± 28 cells/ml) compared with baseline. (515 ± 234 cells/ml) with a 94% percent change (p<0.05) attributed to the induction regimen. No significant change in sIL-2R was noted between any of the study phases. Cytokine determination of cytokines by ELISA with CD4+ cells determined by flow cytometry.

RESULTS: II-2 was below the limit of quantitation (<20 pg/ml) in all patients over all phases. However, sIL-2R was detectable in all patients during all phases. No significant change in sIL-2R was noted between any of the study phases, but a decline was observed in mean values from Phase I to Phase V (1436 ± 874 pg/ml to 693 ± 609). A nadir in CD4+ cells was noted in 60% of patients during Phase II (28 ± 28 cells/ml) compared with baseline. (315 ± 234 cells/ml) with a 94% percent change (p≤0.05) attributed to the induction regimen. A significant recovery in CD4+ lymphocytes toward baseline was noted during Phases IV and V (p<0.05) with a positive correlation between sIL-2R and serum creatinine levels.

CONCLUSIONS: The inter-relationship between IL-2, sIL-2R, and CD4 lymphocytes during induction and maintenance immunosuppression may provide useful pharmacodynamic responses to serve as clinical monitoring parameters and complement therapeutic drug monitoring during the post-transplant period.

Urology

110. Persistence of medication therapy for overactive bladder in the Department of Defense. Angela A. Allerman, Pharm.D., BCPS, David R Betzke, Pharm.D., David J Meade, Pharm.D., BCPS; Department of Defense Pharmacoeconomic Center, Fort Sam Houston, TX.

PURPOSE: Medication management of OAB is frequently complicated by suboptimal persistence with the muscarinic antagonists. Prescription claims were evaluated to determine persistence of OAB drug therapy in DoD beneficiaries.

METHODS: The study cohort was identified by querying the DoD Pharmacy Database Transaction Service, which serves as a repository for all prescriptions dispensed from Military Treatment Facility, Retail Network, and Tricare Mail Order Pharmacy. Patients receiving initial therapy with anti-thymocyte globulin (ATG) up to 8 weeks post-transplant were included. Persistence with OAB therapy was defined as a prescription refill within 90 days from the date of the initial prescription fill. Assessment was carried out in quarterly periods from July 1, 2004, to October 30, 2005. Patients were excluded if OAB therapy was switched from one muscarinic antagonist to another at any time during the evaluation period.

RESULTS: Prescription profiles from a total of 17,435 patients receiving OAB therapy were available. 14,829 patients entered the persistence portion of the study, and 2,696 patients switched therapy. Patients undergoing toterodine extended release (ER) showed the highest persistence (34.7%) followed by oxybutynin ER (32.8%). The lowest persistence was with oxybutynin immediate release (18.5%). Persistence for all OAB drugs declined to 50% by the 1st quarterly assessment, and remained below 35% at study conclusion. There were an inadequate number of prescriptions for trospium, darifenacin, and solifenacin to assess persistence. These preliminary results validated the methodology, and the study will be updated to capture more data with the newer OAB drugs.

CONCLUSION: Persistence with OAB therapy is low in the DoD. More data are needed to determine the impact of newer muscarinic antagonists on persistence.

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.

110E. Effectiveness of interdisciplinary cardiovascular risk reduction for patients with coronary disease or diabetes. Tracey H. Teretina, Pharm.D., GD0E. Oanh J. Martin, Pharm.D., CDE; Petri C. Petropoulos, M.D., Dr Pnav M. Patel, M.D.2, Satish C. Sharma, M.D.3, Wen-Chih Wu, M.D., FCCPI. (1)University of Rhode Island, Kingston, RI; (2)Veterans Affairs Medical Center, Providence, RI.

CONTEX: It is not known whether an approach to target different modifiable cardiovascular risk factors can further lower cardiovascular event risk as assessed by the Framingham Point Scores (FPS) beyond the usual care provided by primary care physicians in patients with CAD and/or diabetes. The Cardiovascular Risk Reduction Clinic (CRRC) is a practice model that integrates the management of the major modifiable risk factors into a single program.

OBJECTIVE: To assess the effectiveness of the CRRC model by comparing the FPS before and after CRRC intervention.

RESULTS: The mean age of the patients was 65 ± 10 years. Complete follow-up data was available on 375 patients referred by their primary care providers for secondary prevention who received at least one intervention by CRRC between January 2001-2002 at the Providence VA Medical Center.

INTERVENTION: The CRRC pharmacist coordinates an individualized diet and exercise program with the nutritionist and physical therapist and develops a pharmacotherapeutic plan to treat hypertension, dyslipidemia, diabetes, and tobacco use. Follow-up visits are scheduled every 6 weeks to monitor adherence and therapeutic effects, and to adjust medications.

CONCLUSION: The CRRC model may reduce the long-term risk of cardiovascular events as assessed by FPS in patients with CAD and/or diabetes.

111E. Effect of baseline covariates on mortality risk in the VMAC trial. William T. Abraham, M.D.; Ohio State University, Columbus, OH.

INTRODUCTION: VMAC (N=489) was a randomized evaluation of nesiritide (NES) vs placebo for 3 h, and thereafter NES vs nitroglycerin (NTG) in the treatment of uncompensated HF. Although not statistically significant, 30-day and 6-month mortality were greater for NES compared with NTG (30-day: 8.1 vs 5.1%, P=0.23; 6-month: 25.1% vs. 20.8%, P=0.32). Despite randomization, significant differences in baseline characteristics may have influenced these results.

OBJECTIVE: To determine the effect of differences in baseline characteristics on mortality risk in VMAC.

METHODS: The mortality effect of all variables with ≥3% absolute baseline differences between NES and NTG groups was assessed using univariate Cox regression models. Significant univariate mortality risk predictors were then evaluated using multivariate Cox regression models with a stepwise criterion of P=0.05 for entry and P=0.10 for retention. Separate models were developed for 30-day and 6-month mortality; these multivariate models were used to adjust mortality HRs for NES vs NTG.

RESULTS: Of the variables with baseline differences, creatinine clearance ≤ 60 ml/min, SBP ≤ 100 mmHg, prior dopamine or dobutamine use, and history of ventricular tachycardia were significant predictors of mortality. Adjusting for baseline differences in these variables reduced the mortality HR for NES vs. NTG: 1.36 to 1.27 at 30 days and 1.22 to 1.06 at 6 months.

VMAC Mortality Risk

Hazard Ratio (95% CI) P-value

<table>
<thead>
<tr>
<th>Hazard</th>
<th>30-Day</th>
<th>6-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>1.36 (75.3-2.4)</td>
<td>1.32 (53.4-2.4)</td>
</tr>
<tr>
<td>Adjusted</td>
<td>1.46 (70.53-2.49)</td>
<td>1.40 (70.53-2.49)</td>
</tr>
</tbody>
</table>

CONCLUSION: Differences in baseline covariates may account for most of the apparent excess mortality observed in subjects receiving NES in VMAC. This analysis emphasizes the importance of using risk-adjusted mortality data in studies that are not designed to evaluate this endpoint.

Published in Circulation 2005;112(17, suppl II):B389.

112E. Durability of guideline adherence in coronary disease and diabetic patients after discharge from a cardiovascular risk reduction clinic. Wen-
PHARMACOTHERAPY Volume 26, March 2006

113. Evaluation of a pharmacist-managed congestive heart failure clinic with adherence to the 2005 ACC/AHA guidelines for the management of chronic heart failure. Timothy M. Murray, Pharm.D., Ryan Schubbach, Pharm.D., University of Oklahoma College of Pharmacy, Tulsa, OK.

PURPOSE: In an effort to evaluate the current treatment of patients diagnosed with congestive heart failure (CHF) and seen in a pharmacy managed CHF clinic, adherence to the 2005 ACC/AHA CHF guidelines was evaluated.

METHODS: All patients seen during 2005 were tracked. The results were analyzed using a software program (MedStat Clinical Decision Support) which compared the adherence to the 2005 ACC/AHA guidelines.

RESULTS: During the course of 2005, 642 patients were seen in the pharmacy-managed CHF clinic. Of these patients, 536 had a documented diagnosis of CHF. Of the 536 patients, 105 were tracked as having 3 or more visits to the clinic and were therefore included in the adherence analysis. The adherence to the 2005 ACC/AHA guidelines was 92%.

CONCLUSIONS: We were able to demonstrate adherence to the 2005 ACC/AHA guidelines for the management of CHF in a pharmacy-managed clinic.


PURPOSE: The goal of this study was to assess the effectiveness, student acceptance and instructor attitude toward two newer and innovative methods (spices and cobes) of teaching in an African university.

METHODS: A student-centered, problem-solving, communication skills approach to teaching (spices) and community-oriented (cobes), methods of teaching were introduced and encouraged to be used during the teaching of clinical pharmacy courses to third and fourth years, bachelor of pharmacy undergraduates in an African university, that over the years used the traditional way of delivery.

RESULTS: Students were introduced to spices and cobes methods of teaching. They were then administered a test of knowledge retention using both methods. The results were analyzed.

CONCLUSIONS: It was concluded that the newer methods can enhance the teaching of clinical pharmacy in an African setting, but one has to be aware of obstacles, particularly from the faculty members.
Substance Abuse/Toxicology


PURPOSE: The purpose of this study was to determine if there was any variation in dose response to methanol poisoning antitoxin in patients of African origin.

METHODS: One hundred and sixty two patients, victims of massive accidental methanol poisoning due to contamination of alcoholic beverage, usually consumed by the urban poor, were treated for methanol poisoning using intravenous ethanol drip. The dose of ethanol was individualized and titrated against clinical response and biochemical data of each patient.

RESULTS: The dose responses of these patients were pooled together and statistically compared to those used mainly by the caucasian population. CONCLUSION: It was observed that the dose response of ethanol as an antitoxin for methanol poisoning among African populations was significantly different from the Caucasians. These findings imply that due to massive poisoning in many communities in East Africa and often massive deaths, the antitoxin studies in this populations ought to be given some international attention.

118. Prospective identification of hospitalized patients with diabetes using electronic data. Terry L. Seaton, Pharm.D.1, Richard M. Reichley, RPh.2, Laura A. Norris, B.S.3, Brian F. Gage, M.D.3, Wm. Claiborne Dunagan, M.D.4, Thomas C. Bailey, M.D.3; (1)St. Louis College of Pharmacy, St. Louis, MO; (2)BJC HealthCare, St. Louis, MO; (3)Washington University School of Medicine, St. Louis, MO; (4)BJC HealthCare and Washington University School of Medicine, St. Louis, MO.

PURPOSE: Diabetic drug orders do not reliably predict a diagnosis of diabetes. For quality improvement initiatives, we developed and validated a clinical prediction rule to prospectively identify patients with diabetes using electronically available data.

METHODS: The derivation study sample comprised admissions from Quarter-2 of 2004. We used ICD-9 codes for diabetes mellitus as the outcome variable in a forward stepwise logistic regression model with entry/keep probability criteria of 0.5. Independent variables included prior diabetes ICD-9, current/past hypoglycemic drug orders, presence/absence of an A1c result, and current/past glucose at or above the 75th percentile. ROC analysis of the final model was used to optimize sensitivity and specificity. We then validate the model using an independent sample of all admissions from the Quarter-4 of 2004.

RESULTS: The study sample included 11,462 admissions, of which 1,980 (17.3%) had an ICD-9 code for diabetes. Prior diabetes diagnosis was present in 1,479 (12.9%) of the subjects. The best fit log regression model included the variables shown in the Table.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Current insulin daily change</td>
<td>12.498</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Current oral hypoglycemic order</td>
<td>26.713</td>
<td>1.0001</td>
</tr>
<tr>
<td>Current long-acting insulin order</td>
<td>5.491</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No. of prior ICD-9 codes</td>
<td>0.988</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No. of prior DM ICD-9 codes</td>
<td>1.144</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>A1c determination</td>
<td>3.896</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior diabetes ICD-9</td>
<td>5.720</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior oral hypoglycemic order</td>
<td>1.652</td>
<td>0.0074</td>
</tr>
<tr>
<td>Glucose &gt; 75th percentile</td>
<td>1.938</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The c-statistic for the derivation sample was 0.958. Accuracy was optimized at a predicted probability of 0.13, with 92.2% of admissions correctly classified, 91.6% sensitivity, 92.3% specificity. 28.7% false positives and 1.9% false negatives. The c-statistic for the validation set, with 11,567 unique patient admissions, and 2,073 (17.9%) patients with diabetes, was 0.938. CONCLUSION: Using electronically available administrative and clinical data, it is possible to prospectively identify patients with diabetes early and reliably for quality improvement initiatives.

119. Acceptance of medication recommendations from a pharmacist-run diabetes clinic in a rural community pharmacy. Marianne McCollum, Ph.D., RPh.;1,2,3 Samuel L. Ellis, Pharm.D.4, Jenae Lorenzo, RPh.5, Christopher J. Turner, Ph.D.1,2; (1)University of Colorado School of Pharmacy, Denver, CO; (2)Barnes Pharmacy, Sterling, CO.

PURPOSE: This study evaluated the clinical outcomes associated with a rural diabetes program that was developed and administered in collaboration between the community pharmacy, fourth year (P4) pharmacy students receiving experiential training, and a faculty member from the University of Colorado School of Pharmacy.

METHODS: A retrospective analysis was done on patients completing the 6-month diabetes self-management education program between January 2004 and June 2005. Patients were assessed by the community pharmacist and fourth-year pharmacy students at each visit. Data collected included BMI, blood pressure, hemoglobin A1c, and fasting lipid profile. A pharmacotherapy plan was developed and faxed to the provider after each patient visit.

RESULTS: A total of 53 patients completed six monthly diabetes self-management education visits. Eighteen patients entered the program but did not complete all 6 visits and were not included in this analysis. Mean reductions in hemoglobin A1c (0.8%; p<0.001), LDL-cholesterol (21.8 mg/dL; p<0.001), weight (5.3 pounds; p<0.006), and systolic (4.9 mmHg; p<0.001) and diastolic (2.6 mmHg; p<0.003) blood pressure were all statistically significant at 6 months compared to baseline. The number of patients achieving ADA recommended treatment goals were also significantly increased at 6 months for A1c (39% vs 66%; p=0.006), LDL-Cholesterol (31% vs 66%; p<0.001), and blood pressure (19% vs. 40%; p=0.02).

CONCLUSION: A rural, community pharmacy-managed diabetes program developed in collaboration with the University of Colorado School of Pharmacy was able to significantly improve the number of patients with diabetes reaching American Diabetes Association standards of care for hemoglobin A1C, LDL-cholesterol, and blood pressure. As a result of these findings, future collaborative projects between community pharmacies and the school of pharmacy are underway.

120. Clinical outcomes associated with a rural community pharmacy diabetes program developed in collaboration with the University of Colorado School of Pharmacy. Samuel L. Ellis, Pharm.D.1, Marianne McCollum, Ph.D.1,2,3, Roger YM Wong, BM.Sc., M.D.1,2; (1)Vancouver General Hospital - CSU Pharmaceutical Sciences, Vancouver, BC, Canada; (2)Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC, Canada; (3)Faculty of Medicine, University of British Columbia, Vancouver, BC, Canada.

PURPOSE: Early discharge from hospital has increased patients' self-responsibility role in medication management at a time when community health resources are diminishing. The aging population has been associated with rising numbers of elderly who manage drug therapy on their own. Many medication drug packagings in use significantly impede access by elderly patients to their medication. Pharmacists are most likely to discover obstacles to geriatric self-medication and make interventions toward ameliorating these barriers. The objective of this study was to develop an objective screening tool for pharmacist assessment of geriatric patients' functional ability to take medications.

METHODS: Geriatric patients admitted to a Canadian tertiary care hospital were prospectively screened by pharmacist researchers as to the suitability of a medication skills assessment tool to consenting patients who managed their
own medications at home prior to admission. Intervention was implemented prior to discharge to support those elderly subjects who demonstrated functional inability to manage their medications.

RESULTS: Sixty patients were enrolled (mean age 83, female 77%). Forty-three percent lived alone at home. Twenty-four patients were excluded due to cognitive impairment; 10 of these patients lived home alone prior to admission. Average number of total medications was 7 (range 1–16). Twenty percent self-reported some degree of difficulty managing medications. Impaired ability to functionally manage medication regimen as determined by performance on the skills assessment tool was demonstrated by 28%. No specific patient characteristics predictive of poor performance were identified, although those who were unsuccessful completing the skills assessment were slightly older (86 vs. 82 years, p < 0.05). Discharge intervention plans were initiated for 25% patients.

CONCLUSIONS: A number of geriatric patients managing medication independently at home demonstrated impaired ability to functionally manage their regimen. Our efficient screening assessment tool can help hospital pharmacists assume a greater role in identifying these patients and participating in discharge medication planning.

122. Can the Australian model for home medicine reviews prove useful in the United States? Deanne Dight, BPharm, M.P.H., University of Canberra, Bruce ACT, Australia.

BACKGROUND: Because Australia has a population less than one-tenth that of the United States, innovation in health care funding on a small scale is more feasible. Medicare Australia pays physicians and surgeons a fee-for-service, and Australia has achieved low medication prices through the Pharmaceutical Benefits Scheme (PBS) for which the general population and pensioners pay a standard contribution fee for each item. Through innovative thinkers in the late 1980s, a system by which cognitive skills of pharmacists could be funded by the federal government was developed and came to fruition in the mid-1990s. Accredited pharmacists were able to contract with aged-care facilities to perform Residential Medication Management Reviews (RMMRs) and be remunerated by the Commonwealth Department of Health and Ageing. In the new millennium Home Medicines Reviews (HMRs) were formally introduced.

Accreditation process: Both workshops and distance learning options were available for practicing pharmacists to progress to the case-based accreditation assessment. In 1996 a small group of practicing clinical pharmacists were chosen to act as assessors. From 1996 until 2003 the assessment process was a series of 10 cases in hardcopy. Since 2004 this process has been computer-based. The current situation: There are currently over 1500 accredited pharmacists in Australia who provide both RMMRs and HMRs and are remunerated by the federal government. Between July 2004 and June 2005 more than 23,000 Home Medicines Reviews (HMRs) had been completed.

The fourth community pharmacy/government agreement: A new agreement has just been ratified and includes far-reaching expansion of Medication Management Reviews.

1 * anticipate being able to provide the latest figures to hand, probably February or March 2006 for the April Spring Practice and Research Forum.

123. Clinical pharmacy specialist leads creation and implementation of a comprehensive venous thromboembolism prevention program for the Hospital Corporation of America. L. Hayley Burgess, Pharm.D., BCPP; Alicia H Perry, Pharm.D., Jane Englebright, R.N., Ph.D., Frank Houser, M.D., The Hospital Corporation of America, Nashville, TN.

Venous thromboembolism (VTE) is a significant national health problem. Resulting from clot formation within the venous circulation, VTE is manifested as deep vein thrombosis (DVT) and pulmonary embolism (PE). The American Heart Association reported that each year approximately 2 million Americans are affected with DVT, up to 600,000 of these patients subsequently develop a PE, and as many as 200,000 will die of PE.

The Hospital Corporation of America owns and operates over 180 hospitals in the United States and Europe. To determine the extent of DVT and PE primary and secondary diagnoses within HCA, data analysis from October 2002 to September 2003 in 1.8 million discharges, including 18,850 DVT and 10,000 PE diagnoses. Our risk management database from 1995 to 2003 reported 495 VTE claims. The highest incidence of claims originated in the medical unit (179), operating room (96), and emergency department (85). VTE is a preventable cause of hospital death, where published literature suggests only 30% of patients at risk actually received prophylaxis. Ou Medical Center and St. David's Partnership found this statistic to be consistent with HCA facility practice. Senior leadership within the HCA corporate quality department supported a company-wide VTE prevention program and joined the Coalition to Prevent DVT. Led by a clinical pharmacy specialist, an interdisciplinary task force was formed to create implementation tools.

The toolkit included educational materials, standardized risk assessment and prophylaxis order sets, data collection strategies, and examples of successful implementations of VTE prophylaxis programs within the company. These tools reside on the HCA internal medication safety Web site. Educational efforts have included 2 company-wide implementation Webinars, each with participation of 800+ clinicians. HCA is conducting a research protocol to evaluate our success of VTE risk assessment screening, appropriate prophylaxis use, and cost effectiveness of this program.

124. Evaluation of cost-effective treatment options for heparin-induced thrombocytopenia. Trupti Mehta, Pharm.D., BCPP, Jian Fan, Pharm D. Candidate, Chin Y. Liu, M.S., Pharm.D., BCOP; Harper University Hospital, Detroit Medical Center, Detroit, MI.

PURPOSE: Current treatment options for the management of heparin-induced thrombocytopenia (HIT) include direct thrombin inhibitors, such as lepirudin and argatroban. Fondaparinux is a factor-Xa inhibitor approved for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as thromboprophylaxis in a post-surgery setting. Fondaparinux has no known effect on platelet factor 4 and theoretically may be useful for treating patients with HIT. The use of direct thrombin inhibitors require continuous intravenous infusion and labor-intensive monitoring whereas fondaparinux dosing is weight-based and administered subcutaneously once daily with less intensive monitoring. The objective of this study was to determine the role for fondaparinux in the management of HIT, develop an algorithm to guide treatment, and determine the estimated cost-savings with its use as an alternative to lepirudin or argatroban.

METHODS: This study is a retrospective chart review. Inclusion criteria are the following: patients with suspected or confirmed HIT without evidence of acute thrombosis requiring thromboprophylaxis or continuation of anticoagulation for history of DVT or PE. Patients who had anaphylaxis to heparin were excluded. The IDSA/ACCP guidelines recommend fondaparinux from July 2004 through June 2005 at Harper University Hospital (HUH) will be identified through a pharmacy database. The following information will be obtained: number of patients with HIT, antithrombotic treatment, duration of treatment, indication, platelet counts, presence of HIT antibody, and cost of therapy.

RESULTS: Data collection is ongoing. The Detroit Medical Center Pharmacy and Therapeutics Committee approved the algorithm for management of HIT in October 2005.

CONCLUSION: The results of this study will help evaluate the incidence of HIT at HUH and the estimated cost-savings associated with utilization of the algorithm defining the role of fondaparinux in the management of HIT.

125. Evaluation of lipid monitoring in treatment-experienced HIV-infected patients. Kelly Hixson, Pharm.D., BCPP, Pamela Stamm, Pharm.D.; Auburn University Harrison School of Pharmacy, Auburn, AL.

PURPOSE: To compare lipid monitoring in HIV-infected patients receiving highly active antiretroviral therapy (HAART) compared with Infectious Diseases Society of America (IDSA) clinical guidelines.

METHODS: It is estimated that elevations in cholesterol and triglycerides occur in over 50% of patients receiving therapy with protease inhibitors. Because the general population of HIV-infected patients is typically younger than the population traditionally at risk for cardiovascular disease, the need for monitoring for lipid abnormalities may not be fully appreciated. The IDSA primary care guidelines for persons infected with HIV recommend a fasting cholesterol panel prior to initiation of HIV treatment, 4–6 weeks following initiation, and at least annually thereafter. A retrospective chart review was conducted on 100 randomly selected HIV-treated patients to evaluate lipid monitoring. Data regarding cardiovascular risk factors, lipid panels throughout treatment, lipid lowering therapy, length of HAART, current and past antiretroviral use, duration of HIV diagnosis, age, gender, race, viral load, and CD4 counts were collected.

RESULTS: Ninety seven percent were taking at least one antiretroviral agent known to cause dyslipidemia. Sixty-seven percent had received at least 1 year of HAART, and 64% had protease inhibitor experience. Forty-two percent had at least 2 risk factors for cardiovascular disease. As a group, 81% did not have a lipid panel ordered for evaluation during the duration of treatments and only 5% had baseline labs evaluated. Total cholesterol was evaluated in 73% of patients, but lipid panels were evaluated in 19% and revealed 28% with total cholesterol > 200 mg/dL, 4% with HDL < 40 mg/dL, and 9% with LDL > 130 mg/dL.

CONCLUSION: Results of this study reflect suboptimal adherence to the IDSA standards of care for lipid evaluation in treatment-experienced HIV-infected patients. However, it suggests there is significant opportunity to provide pharmacare to help patients with choosing medications to help with their cardiovascular risk in this population.

126. Impact of a multidisciplinary infectious diseases management team on the prevalence of extended spectrum beta-lactamase enzymes in a tertiary care teaching hospital. Roy Guo, PE. Patients who received leuprolidin...
PURPOSE: Infections caused by multidrug resistant Gram-negative bacilli that produce extended spectrum beta lactamase enzymes (ESBL) have been reported worldwide. The objective of our presentation is to describe the impact of our multidisciplinary infectious disease (ID) management team on the prevalence of ESBL enzymes in our tertiary care teaching hospital. The ID team was formed in 2000, and utilization indicators were reformulated. All broad-spectrum formulary agents require ID approval unless the indication documented on the form order meets the release indicator. Pharmacists review clinical justification of all hospital-wide restricted antimicrobial usage with the ID team daily, and interventions are made, if needed.

METHODS: Klebsiella pneumoniae was chosen as the surrogate marker for identifying resistance secondary to ESBL. Defined daily dose and resistance trends were compared.

RESULTS: Defined daily dose utilization of 3rd-generation cephalosporins during 2000-2004 were as follows: 13,647 (2000); 11,921 (2002); 12,874 (2002); 10,388 (2003), and 10,346 (2004). Third generation cephalosporin sensitivity against K pneumoniae ranged from 96%-99%. Patient days increased by 7% during the time period.

CONCLUSIONS: Third generation cephalosporin sensitivity against K pneumoniae was reported as 89% by the National Nosocomial Surveillance report in 2003. Our pro-active multidisciplinary ID team-managed initiatives led to decreased use of 3rd-generation cephalosporins and lower resistance in our institution.

127. To err is human: result of a computerized physician order entry system on patient safety in a tertiary care teaching hospital. Roy Guhary, Pharm.D., Neal Seidberg, M.D., Nancy Page, M.S., John Degrazio, B.S., Barbara Bennett, B.S., Maureen Cummings, M.S., Teresa Wagner, B.S., Karen Hightman, M.S., Joy Ganley, B.S., SUNY-Upstate Medical University, Syracuse, NY.

PURPOSE: The Institute of Medicine reported 98,000 avoidable patient deaths each year secondary to medication errors. Computerized Provider Order Entry (CPOE) is the best available tool that can greatly reduce the adverse events. We describe the impact of a multidisciplinary team-led CPOE implementation on patient safety at our tertiary care teaching institution.

METHODS: Our team decided to interface between all ancillary systems, finance, and CPOE. Newly developed order sets were based on the feedback from expert users, pharmacy, and nursing. CPOE pilot implementation was completed in rehabilitation, pediatrics, and orthopedics service areas. Experiences from specific areas were utilized for CPOE implementation at other areas. A rapid cycle implementation process was utilized to implement the CPOE system hospitalwide within a 3-month period.

RESULTS: Adverse event data base was reviewed for pre and post CPOE implementation in the pilot units. Prescribing related adverse events were reduced by 51% (214 vs. 105). Patient allergy related adverse events were reduced by 33% (40 vs. 26). In addition, the CPOE order sets are leading to optimal use of evidence-based drug regimens for specific disease states. Our satellite pharmacists are now able to spend more time with various medical teams via utilization of tablet personal computers during rounds.

CONCLUSIONS: CPOE implementation has resulted in improved patient safety of our patients. Expanded pharmacist participation in direct patient care has resulted in increased therapeutics interventions. Our strategy was to implement the basic version of CPOE in the first phase. A plan for implementation of advanced search engine and decision support-based rules for optimization of individual patient therapy over the next 9-month period has been developed. The step will lead to prospective avoidance of many potential adverse drug events and make our institution a safer place for our patients.

128. Clinical pharmacist intervention to promote use of inhaled corticosteroids in persistent asthmatics. Vanessa Smith, Pharm.D.t, Samuel Moss, M.D.t, (1)Kaiser Permanente, Atlanta, GA, (2)Kaiser Permanente, Alpharetta, GA.

PURPOSE: This project evaluated educational intervention by a clinical pharmacist in patients diagnosed with persistent asthma with a HEDIS (Health Employer Data Information Set) inhaled corticosteroid (ICS) to short-acting [beta]-agonist (SABA) ratio of less than 0.5 (calculated by the number of ICS/SABA refills in 1 year) who filled at least five prescriptions for a SABA in the past 6 months to 1) compare patients’ use of inhaled corticosteroids to short-acting [beta]-agonist (SABA) refills; 2) compare asthma control before and after the intervention.

METHODS: Patients were identified as persistent asthmatics. Starting September 1, 2004, patients were contacted by telephone to assess current ICS and SABA use and symptoms through the Asthma Control Test and to educate on the importance of ICS use in management of asthma. Patients were reevaluated 4 months after the intervention.

RESULTS: Four of the 15 patients (26.7%) refilled an ICS prescription the month prior to the intervention compared to 4 months after the intervention, when 11 of the 15 patients (73.3%) refilled an ICS prescription. Improvement in HEDIS ICS to SABA ratio (change in ratio by increase or change) occurred in 11 of the 15 patients (73.3%). Based on the Asthma Control Test, 10 of the 15 patients (66.7%) at the start of the study and 4 out of the 15 (26.7%) 4 months after the intervention were considered not well controlled.

CONCLUSION: Educational intervention by a clinical pharmacist showed to increase the likelihood of persistent asthmatics to refill an ICS prescription. Increased ICS use correlated with improvement in asthma control. Utilization of a clinical pharmacist in education of persistent asthmatics improves to increase ICS use and asthma control.

129E. Pharmacist-acquired medication histories in an emergency department. Melinda K. Carter, Pharm.D., Dennis Allin, M.D., FASHP, Leigh Anne Scott, Pharm.D., MBA, The University of Kansas Hospital, Kansas City, KS.

PURPOSE: To identify discrepancies between medication histories taken by Emergency Medicine providers and medication histories obtained by a clinical pharmacist.

METHODS: During a 3-month period a pharmacist was assigned to the Emergency Department in a 420-bed, tertiary care teaching facility that serves as a Level I Trauma Center. Upon arrival, Emergency Department providers completed a standard assessment of the patient’s medication regimen. Patients to be admitted through the Emergency Department were interviewed by the pharmacist. Height, weight, immunization history, and allergy information were collected by the pharmacist in addition to the medical history. Sources of information included the patient, caregivers, family members, prescription vials, medication lists from nursing facilities, and follow-up telephone conversations with community pharmacies and physician’s offices. The medication history obtained by the Emergency Department personnel was compared to the history obtained by the pharmacist and discrepancies documented.

RESULTS: 286 medication histories were performed by the clinical pharmacist in the Emergency Department. 34 (12%) were excluded due to inability to compare with medication history performed by the Emergency Department staff. 232 (88%) histories were included in the study. Clinical pharmacists identified 1096 medication errors versus 817 by Emergency Department providers. 637 of 817 (78%) modifications documented by ED personnel were incomplete and supplemented with dosing information by the pharmacist. Clinical pharmacists reported 357 medication allergies versus 350 for Emergency Department personnel with corresponding manner of allergic reaction reported in 200 of 375 (53%) by the pharmacists versus 8 of 350 (2%) by the ED personnel. Immunization history was obtained in 252 of 252 (100%) by the pharmacists versus 45 of 252(17%) by ED personnel.

CONCLUSION: Pharmacy services in the Emergency Department facilitated and improved the process for obtaining and documenting a complete medication history in admitted patients.

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130. Discrepancies between medication lists in the electronic medical record and actual medication use in a survey of patients with diabetes: implications for medication reconciliation systems. Philip T. Rodgers, Pharm.D., BCPs, CDE, CPPI, Scott V Joy, M.D., CDE, Duke University Medical Center, Durham, NC.

PURPOSE: New regulations for medication reconciliation in health systems require consistency in medication use and documentation between the health care settings. The outpatient medication list is often consulted. However, the accuracy of these medication lists may be questionable. Appropriate pharmacotherapy relies on accurate documentation of the patient’s daily medication regimen. This study evaluated the frequency and types of errors in the documentation of medication lists and drug allergies for a group of patients with diabetes in a primary care setting.

METHODS: Patients with diabetes in a primary care practice were identified and contacted by telephone. Consenting patients were asked to bring all pill prescription, over-the-counter, and herbal medications they were currently taking, and all known drug allergies. This information was compared to the medication and allergy list in the patient’s electronic medical record. The frequency of discrepancies between the patients’ verbal record and the electronic medical record were noted.

RESULTS: A total of 128 patients participated. Overall, discrepancies in medication documentation were noted in 69.5% of the patients contacted. A total of 37.5% were on fewer medications than recorded, 30.5% were on different doses than recorded, and 25.8% were on more medications than recorded. Discrepancies specifically in diabetes medications were noted in 7% of patients. Regarding OTC medications, 33% were on more medications than listed, with aspirin being the most common. Herbal medications, notably glucosamine and ginko, were not recorded in 6% of the medical records, and recorded allergies were erroneous in 11%.

CONCLUSIONS: Documentation errors regarding medications were common in this population of patients with diabetes. Practitioners should use caution
in utilizing information relating to drug therapy from medical records, and should verify medication use with patients verbally to ensure accuracy. Medication reconciliation systems need to recognize some of the common limitations of the outpatient electronic medication list.

131. Opportunities and barriers to the implementation of pharmacist-provided admission medication histories and discharge counseling services: a pilot program. Suzanne M. Ruhi, Pharm.D., Wafa Y. Dahdal, Pharm.D., BCPS, Midwestern University, Chicago College of Pharmacy, Downers Grove, IL.

PURPOSE: Research demonstrates that pharmacist admission history and discharge counseling improves patient care, decreases healthcare costs and noncompliance, and increases patients' knowledge of their medications. The objective of this study was to assess opportunities and barriers to establishing a patient education program operated by a college-based pharmacy resident at a tertiary hospital.

METHODS: A pharmacy resident rotating on the telemetry floor at a tertiary institution piloted the program by providing services 2–3 days/week for 4 weeks. The resident participated on medical rounds with the cardiologist consult service. All patients were offered the education program. Medication histories were conducted from the insurance admissions; discharge counseling services were initiated by the resident, medical team, or nursing. The number and type of interventions rendered as well as challenges to the implementation are described.

RESULTS: Fifty admission histories and 36 discharge counseling sessions were provided. 36 interventions were made (~6 interventions/day). The most frequent interventions were improper documentation of allergies or medications (N=26, 46.4%) and not starting a previous medication (N=20, 35.7%). Non-cardiac medications accounted for 67.9% of interventions. Barriers included: (1) pharmacy resident provided part-time coverage; therefore, not all patients were educated and fewer interventions were made; (2) health literacy; over 80% of patients did not have a medication list and did not know their medications.

CONCLUSIONS: Pharmacists have many opportunities to affect patient care by conducting admission medication histories and discharge counseling services. The demand for such services may increase as pharmacists provide medication therapy management programs are becoming increasingly valued and reimbursed. Given the limited resources, collaborations between college- and hospital-based pharmacy personnel are essential to optimize the services. To effectively influence health literacy, pharmacists should conduct a thorough evaluation of patients’ level of education, knowledge of their diseases, medications, and involvement in self-care.


PURPOSE: Reconciling patient medications across the continuum of care is a crucial component in improving the quality of patient care and in preventing medication errors. Medication reconciliation (MR) is one of the 2005-2006 National Patient Safety Goals of 2005-2006 National Patient Safety Goals and part of the Institute for Healthcare Improvement's 100,000 Lives Campaign. This multidisciplinary approach to MR process is part of an ongoing effort to meet regulatory requirements, pharmacy departmental goals, and the hospital's quality initiatives.

METHODS: A multidisciplinary team's review of a pilot study of pharmacist conducted medication histories, completed in 2005, indicated that although pharmacists were more effective than nurses in obtaining an accurate and complete history, it would be more feasible to educate nurses to complete the history, with pharmacists providing verification. The Pharmacy and Therapeutics Committee, along with pharmacy policies and procedures as list MR forms. The Information Technology Department provided software support for changes to documentation and reporting processes across the continuum of care. Pharmacists trained nurses to obtain an accurate medication history. Pharmacy students participated in the follow-up of MR issues.

RESULTS: Interdisciplinary MR policies and procedures were implemented. Admission MR process included nurse-conducted interviews, pharmacist verification, student follow-up, and documentation in the patient's permanent record. Transfer MR process consisted of a computer-generated report, reviewed by physicians. Discharge MR process incorporated a review to prevent therapeutic duplications, a computer-generated list of medications for the next provider, and a pocket home medication card for the patient.

CONCLUSION: A systematic, multidisciplinary approach to the MR process provides a mechanism to reduce the potential for adverse drug events and is an effective solution to providing MR across the continuum of care.

133. The complex logistics and potential errors in the daily use of intravenous patient-controlled analgesia (IV PCA). Robin Wade, RPh, M.S.1, Rob W. Hutchison, Pharm.D.2, Mark J. Cziraky, Pharm.D., FAHA3, Sue Vallow, Pharm.D.1, (1)HealthCore, Inc., Wilmington, DE; (2)Presbyterian Hospital, Dallas, TX; (3)Pricara Pharmaceuticals Inc., Raritan, NJ.

PURPOSE: This qualitative cross-sectional hospital study evaluates the IV PCA utilization process and identifies the potential errors in the complex logistics of daily IV PCA administration.

METHODS: The staff at 11 US hospitals were interviewed onsite by a research pharmacist for the daily IV PCA logistics (ordering, pump procurement and programming, analgesic preparation and storage, staff education and competency, IV PCA administration, and pump maintenance and repair). The investigator also collected data through observation of the complete IV PCA logistical process. Study design was informed by a literature review and an IV PCA failure mode and effects analysis (FMEA) published by The Institute for Safe Medication Practices (ISMP). Intra and inter-hospital variations were then studied to identify potential medication errors and adverse events within each process step.

RESULTS: The possibility of 28 major (permanent lossening of sensory, motor, physiologic, or intellectual function), and 34 catastrophic (death or major permanent loss of function) error points were identified in relation to the prescription-ordering process, IV PCA pump, analgesic cartridge, and IV tubing. A composite flow chart of IV PCA logistics revealed the involvement of eight people and a minimum of 70 decision points (action steps) and a maximum of 104 per patient per course of therapy. There was significant variation observed within and between hospitals in the daily administration process.

CONCLUSIONS: This study document the complexity of IV PCA logistics and identified 28 major and 34 catastrophic potential error points associated with the process. When applied the concept of providing patient demand dose and patient-controlled delivery of analgesia, these results highlight the need to develop improved methods of reducing medication errors and adverse events related to IV PCA.

134. Clinical utility of pharmacist medication intervention documentation data. Laura C. Hobbs, Pharm.D., Elizabeth C. Udeh, Pharm.D., Robert A. Quercia, M.S.; RPh., Lisa Allen, Ph.D., Michael E. Dziek, B.S.; Hartford Hospital, Hartford, CT.

PURPOSE: Our goal is to effectively use data collected from our pharmacist medication intervention documentation program. At our institution, intervention data is used for three clinical functions. The first function is to focus education and training for prescribers, nurses, and pharmacists. Second is to help improve computer prescriber order entry (CPOE) processes, and third is to supplement the medication event reporting system.

METHODS: A new pharmacist intervention documentation program was implemented at our institution summer of 2004 in collaboration with the quality management department. Reports about the interventions were developed and shared with pharmacy clinical support team, Therapeutics Committee, Medication Error Reduction Group, and Hospital Quality Council. These forums suggested effective uses of this information for providing education to different disciplines. Reports from the intervention database were being used to tailor alerts in the CPOE system. The intervention program was then designed to provide automation of the hospital medication event reporting system without duplicate documentation by the pharmacists.

RESULTS: To provide feedback to the prescribers, department specific reports with clinical vignettes about high-risk orders on which pharmacists intervened were developed and shared at well-attended monthly meetings. In addition, department-specific interventions are used to supplement nursing in-service material. Interventions are shared periodically at pharmacist in-services to provide examples of excellent patient care. A report on the medications most frequently intervened on for renal dose adjustment is being used for additional alerts in our CPOE system. Capturing of selected interventions significantly increased the number of medication errors submitted by pharmacists into the hospital medication event reporting system.

CONCLUSION: Our intervention program has been well received by administration, pharmacy, medical, and nursing staff. Data from our intervention reports have been used successfully in educating pharmacy, medical, and nursing staff. This program has also been valuable in enhancing our CPOE system and hospital event reporting system.

135. Assessment of the impact of pharmacist-provided medication reconciliation services in the emergency department of a teaching institution. Lyle Kubik, Pharm.D., Stacey Mayes, Pharm.D., M.S.; St. Luke's Hospital/Mayo Clinic Jacksonville, Jacksonville, FL.

INTRODUCTION: The Joint Commission on Accreditation of Healthcare Organizations has listed medication reconciliation as one of the National Patient Safety Goals of 2003-2006. Medication reconciliation is a method by which healthcare practitioners ensure the completeness of a patient's
medication profile from admission to discharge. Presently, pharmacist-driven medication reconciliation programs are limited in hospitals throughout the country. This study will explore this opportunity by assessing the impact of pharmacist-provided medication reconciliation services in the Emergency Department of a teaching institution.

METHODS: This two-armed study will be conducted prospectively for 3 months during which the pharmacist will be responsible for obtaining medication histories, reconciling medications, differentiating medication allergies from side effects, and identifying drug interactions. This evaluation will be quantified by comparing the total number of order medication clarifications required prior to order entry after nursing/physician-completed medication histories versus pharmacist-completed medication histories. A completely reconciled medication profile contains a comparison of outpatient medications, admission medication history, and inpatient admission orders, and includes an explanation of omitted medications.

RESULTS: The results of both phases will then be analyzed in order to compare consistency and ascertain the impact of pharmacist-provided medication reconciliation services in the ED as it relates to patient safety. A cost savings analysis will be completed to assess potential savings based upon the average cost of an injury resulting from an adverse drug event.

CONCLUSION: Study in progress.

136. Allergy misclassification in three urban academic medical centers. Michael Gonyeau, Pharm.D., BCPS; Margarita DiVall, Pharm.D., BCPS; Jennifer Trujillo, Pharm.D., BCPS; Northeastern University School of Pharmacy, Boston, MA.

BACKGROUND: Healthcare workers who obtain medication histories from hospitalized patients frequently do not ascertain the nature of reported drug allergies and reactions nor record such in the medical record. Inaccurate allergy documentation may then be automatically transmitted from record to record without verification. This inappropriate information may result in alterations in prescribing patterns and the use of sub-optimal therapy if the unclarified drug allergy is the gold standard or most effective therapy.

Objectives: To determine the nature of drug allergies in a group of medical inpatients, and to evaluate the accuracy and completeness of allergy documentation by healthcare workers.

METHODS: Patients on medical wards were interviewed by a clinical pharmacist or pharmacy student using a pre-specified interview form to ascertain patient perceived allergies and reactions. This information was then compared with allergies listed in the hospital computer system and the patient’s medical record.

RESULTS: Five hundred twenty seven patients were interviewed. The average age of patients was 66 ± 27 years and 43% were men. 238 (45%) patients had ≥1 allergy documented in the medical record, while 232 (48%) had ≥1 allergy documented in the hospital computer system. However, allergy reactions were listed in only 7% and 5% respectively. One hundred sixty seven patients stated a medication allergy upon interview (p<0.001 vs. medical record and p<0.001 vs. hospital computer system). Upon further questioning, pharmacists determined that only 67 (40%) of the stated reactions were true allergies (p<0.001). There were 104 instances of treatment alteration based on documented patient allergy, with the most common alterations in antibiotic therapy.

CONCLUSION: Medication allergy documentation in patients on medical wards is inaccurate. Patient interview by a clinical pharmacist with pre-specified interview questions resulted in a more accurate patient allergy history. This may translate into decreased medication errors and preserve drug treatment options.

137E. Zonisamide disposition and dosage adjustment when given with phenytoin. Wesley J. Payne, Ph.D., William R. Garnett, Pharm.D., F.CCP; Virginia Commonwealth University Medical Center, Box 980353, Richmond, VA.

PURPOSE: Zonisamide (ZNS) is a broad spectrum antiepileptic drug that exhibits a significant interaction with phenytoin (PHT): the half-life of ZNS is decreased by 60% (from 69 hours to 28 hours) due to the induction of enzymatic metabolic activity by PHT. We explored this interaction and the withdrawal of PHT therapy and its clinical implications for ZNS dosing.

METHODS: Using a pharmacokinetic multiple-dosing model, we simulated the withdrawal of PHT to ZNS monotherapy. We also simulated the withdrawal of PHT from binary therapy. We made reasonable assumptions about the time course of PHT elimination and de-induction of oxidative enzyme activity.

RESULTS: The decline in ZNS plasma levels upon adding PHT was 60%; perhaps more significantly, the ZNS plasma levels seen on monotherapy were more than double those seen with PHT co-therapy. We note that in co-therapy with PHT, ZNS dosing levels could easily be pushed from 200 mg BID to as high as 400 mg BID and still have plasma levels in the therapeutic range of 15–30 µg/ml. After withdrawing PHT, the ZNS dose must be decreased to a target level of 200 mg BID. We made reasonable assumptions about the time course of PHT elimination and de-induction of oxidative enzyme activity on decreasing the ZNS dose in a stepwise fashion beginning 7 days after discontinuing PHT therapy.

CONCLUSIONS: ZNS dosing when given with PHT can be rationally elevated from the monotherapy dose recommendation of 200 mg BID up to a 400 mg BID level. The adherence to a 200 mg BID dose in co-therapy with PHT may explain apparent failure to achieve additional antiepileptic activity when adding ZNS. The reverse drug interaction occurs when PHT is withdrawn from ZNS therapy. Because of the dramatic effect of PHT on ZNS half-life, dose adjustments are necessary when PHT is withdrawn.


138. Medication use evaluation and pharmacoeconomic impact of zolendronic acid formulary restriction policy. Carissa J. Masek, Pharm.D., Erin J. Iselin, Pharm.D., Lisa J. Killam-Worrall, Pharm.D., BCPS, The Nebraska Medical Center, Omaha, NE.

PURPOSE: This medication use evaluation (MUE) examined the impact of a Medical Staff/Pharmacy and Therapeutics restriction policy designed to 1) manage the location of administration of intravenous zolendronic acid, 2) monitor adverse events occurring as a result of zolendronic acid administration, 3) evaluate the therapeutic recommendations resulting from the MUE, and 4) evaluate the potential pharmacoeconomic impact of the administration policy.

METHODS: Medical records of patients that received intravenous zolendronic acid in an outpatient cancer care center or the hospital between June 1, 2004, and June 30, 2005, were reviewed. Indications for use of zoledronic acid location of infusion, dose, dosage schedule, baseline and consequent serum creatinine and serum calcium levels, and presence of adverse events were collected and evaluated.

RESULTS: During the 13-month study period, 98 patients received zolendronic acid. All of the zolendronic acid doses were administered in the outpatient cancer care center. A majority of the patients received zolendronic acid for bone metastases (53%), followed by a diagnosis of multiple myeloma (30%), and hypercalcemia of malignancy (9%). Out of the 419 doses given, 13% required a renal adjustment, and of these 48% were not renally adjusted. For the 9 patients that received zolendronic acid for hypercalcemia of malignancy, 78% experienced a normalization of serum calcium level. Out of the 98 patients receiving zolendronic acid, 2% experienced a rise in serum creatinine, and 30% of patients experienced hypocalcemia. Four patients were switched to pamidronate upon hospital admission, resulting in a potential cost-savings of approximately $3000.

CONCLUSION: The results of the MUE show that the zolendronic acid formulary restriction policy was effective in managing the use of zolendronic acid in the outpatient cancer care center and inpatient setting. The results highlighted areas of education for pharmacy and medical staff. The policy resulted in a potential cost-savings for the institution.

139. Evaluating the safety and cost of bevacizumab use. Jacqueline K. Schneider, Pharm.D., Erin J. Iselin, Pharm.D., Lisa Killam-Worrall, Pharm.D., BCPS, The Nebraska Medical Center, Omaha, NE.

PURPOSE: A Medication Use Evaluation (MUE) was conducted at The Nebraska Medical Center to monitor the use of bevacizumab (Avastin) across the infusion centers since its addition to the formulary in September of 2004.

METHODS: Medical records of 13 patients who received at least one dose of bevacizumab between September 2004 and August 2005 were reviewed to determine appropriateness of use, safety, and cost. Each chart was reviewed for source of malignancy, administration, monitoring, and adverse drug events associated with bevacizumab, as well as patient history of thromboembolism and hypertension.

RESULTS: The majority of patients received bevacizumab for the approved indication of metastatic colorectal cancer treatment (85%). An adverse drug event was noted in seven patients receiving bevacizumab: an increase in blood pressure (2), proteinuria (2), and thromboembolic event(s) (3). The thromboembolic events were deep venous thromboses with one patient developing a pulmonary embolism as well. One of the two patients who developed hypertension was placed on antihypertensive therapy. During this monitoring period, 3 patients discontinued therapy due to an adverse effect they experienced (thromboembolism (2), proteinuria (1)). The cost of the 81 doses administered during the study time frame was $162,000.

CONCLUSION: The overall use of bevacizumab was appropriate. Due to the high percentage of patients (34%) who experienced an adverse event, monitoring of bevacizumab’s use will continue. Another medication use evaluation is scheduled to be conducted in approximately 12 months at The Nebraska Medical Center.

140E. Randomized, double-blind, placebo-controlled study of darbeptoin alfa every 3 weeks for the treatment of chemotherapy-induced anemia. Kerry Taylor, M.D., Peter Ganly, B.M.B.Ch., Ph.D., F.R.C.Path., F.R.C.P.Edin., Veena Chari, M.D., Joseph Dillenendetto Jr., M.D.,* Karolyn Kracht, Ph.D., Thomas Lillie, M.D., Ph.D.,* Enrique Hernandez, M.D., FACOG, FACS;
BACKGROUND: The ability to administer darbepoetin alfa (DA) every 3 weeks (Q3W) (coincident with chemotherapy) would simplify the treatment of chemotherapy-induced anemia (CIA). We report results from the first multi-center, randomized, double-blind, placebo-controlled, phase 3 clinical trial evaluating efficacy and safety of fixed-dose DA Q3W.

METHODS: This study enrolled patients ≥18 years old, anemic (hemoglobin (Hb) ≥11 g/dL), diagnosed with a nonmyeloid malignancy, and scheduled to receive ≥12 weeks of chemotherapy. Patients (N=391) were randomized 1:1 to receive DA 300 µg or placebo Q3W for 15 weeks. DA dose could have been increased or decreased depending on response. Efficacy assessment included incidence of red blood cell transfusions and achievement of target HB of ≥11 g/dL, notch ≥13 g/dL, consistent with evidence-based practice guidelines.

RESULTS: 386 randomized patients were included. Demographic characteristics were similar between the 2 groups. Mean (SD) baseline Hb was 10.03 (0.86) and 10.05 (0.92) g/dL in the placebo and DA groups, respectively. Most common tumor types were breast (23%), colon (11%), nonsmall-cell-lung cancer (10%), and hematologic malignancies (11%). Incidence of RBC transfusions (week 3 to end of treatment phase [EOTP]) was significantly lower with DA (24%, 95% CI: 18-30%) than with placebo (41%, 95% CI: 34-49%) (P<0.001). Hb rose steadily in the DA group through approximately week 9, increasing by a mean (SD) of 1.08 (1.28) g/dL from baseline, and remained relatively stable. The proportion of patients achieving target HB from week 5 to EOTP was significantly higher with DA (82%, 95% CI: 76-88%) than with placebo (48%, 95% CI: 41-56%) (P<0.001). Dose adjustment rules helped to maintain HB levels within target range. The safety profile of DA was consistent with that observed in previous studies. Rapid increases in HB concentration or increases to ≥13 g/dL were not associated with adverse events.

CONCLUSIONS: Fixed Q3W administration of DA is well tolerated and effective for the treatment of CIA.

141E. Synchronicity: evaluating darbepoetin alfa administered at 300 µg every 3 weeks to treat chemotherapy-induced anemia in breast cancer patients. Peter Silberstein, M.D.1, Ralph Boccia, M.D.2, Delong Liu, M.D.3, N. Simon Tchekmedyian, M.D.4, Charles Holladay, M.D.2, Dianne Tomita, M.S.S, Thomas Lillie, M.D. Ph.D.5, Gregory A. Otterson, M.D.6. 1Creghton Cancer Center, Omaha, NE; 2Center for Cancer and Blood Disorders, Bethesda, MD; 3New York Medical College, Valhalla, NY; 4Pacific Shores Medical Group, Long Beach, CA; 5Charleston Cancer Center, Charleston, SC; 6Amgen Inc., Thousand Oaks, CA. (7)Ohio State University, Columbus, OH.

BACKGROUND: Breast cancer chemotherapies are highly myelosuppressive, often resulting in anemia and reduced quality of life. Darbepoetin alfa (DA) can effectively treat chemotherapy-induced anemia in breast cancer patients (Schwartzberg et al., 2004). DA can be administered at extended intervals, allowing the possibility of synchronizing DA therapy with common chemotherapy regimens. Randomized controlled trials have demonstrated that DA 300 µg Q3W can increase hemoglobin concentrations, thereby reducing transfusion requirements.

METHODS: This 16-week, open label, single-arm study evaluated DA 300 µg Q3W chemotherapy schedule.

RESULTS: Data from the breast cancer subset are presented (n=354; 29% of the overall study). Demographic characteristics were similar between the 2 groups. Mean (SD) baseline Hb was 10.03 (0.86) and 10.05 (0.92) g/dL in the placebo and DA groups, respectively. Most common tumor types were breast (23%), colon (11%), nonsmall-cell-lung cancer (10%), and hematologic malignancies (11%). Incidence of RBC transfusions (week 3 to end of treatment phase [EOTP]) was significantly lower with DA (24%, 95% CI: 18-30%) than with placebo (41%, 95% CI: 34-49%) (P<0.001). Hb rose steadily in the DA group through approximately week 9, increasing by a mean (SD) of 1.08 (1.28) g/dL from baseline, and remained relatively stable. The proportion of patients achieving target HB from week 5 to EOTP was significantly higher with DA (82%, 95% CI: 76-88%) than with placebo (48%, 95% CI: 41-56%) (P<0.001). Dose adjustment rules helped to maintain HB levels within target range. The safety profile of DA was consistent with that observed in previous studies. Rapid increases in HB concentration or increases to ≥13 g/dL were not associated with adverse events.

CONCLUSIONS: Fixed Q3W administration of DA is well tolerated and effective for the treatment of CIA.

141E. Synchronicity: evaluating darbepoetin alfa administered at 300 µg every 3 weeks to treat chemotherapy-induced anemia in breast cancer patients. Peter Silberstein, M.D.1, Ralph Boccia, M.D.2, Delong Liu, M.D.3, N. Simon Tchekmedyian, M.D.4, Charles Holladay, M.D.2, Dianne Tomita, M.S.S, Thomas Lillie, M.D. Ph.D.5, Gregory A. Otterson, M.D.6. 1Cregトン Cancer Center, Omaha, NE; 2Center for Cancer and Blood Disorders, Bethesda, MD; 3New York Medical College, Valhalla, NY; 4Pacific Shores Medical Group, Long Beach, CA; 5Charleston Cancer Center, Charleston, SC; 6Amgen Inc., Thousand Oaks, CA. (7)Ohio State University, Columbus, OH.
145. Economic impact of pharmaceutical intervention in the care of human immunodeficiency virus patients. Branca S. Teixeira, Dr.; Barbara G. Santos, Dr.; Teresa Cunha, Dr.; Gustavo Dias, Dr.; Jose Neves, Dr.; Jorge Brochado, Dr.; Pharmacy Department St Antonio General Hospital, Porto, Portugal.

PURPOSE: Determine the adherence of human immunodeficiency virus (HIV) patients to the antiretroviral regimens treated in St. Antonio General Hospital during 2004 and the direct costs of the non-adherence. Identify the possible causes of non-adherence to antiretroviral treatment. Establish guidelines on the pharmacist's role in the care of patients with HIV infection.

METHODS: Retrospective analysis of HIV patients' pharmaceutical records. Literature review.

RESULTS: HIV patient records (316 records) were analysed between January and December 2004. 35.74 % of these were non-compliant, which directly implied a cost of 557,147.12 Euros. We were able to identify the following possible factors associated with non-adherence to antiretroviral therapies: mental illness, unstable housing, active substance abuse, antiretroviral adverse effects, dietary, pill burden, and inconvenient frequency of drug administration.

CONCLUSIONS: Pharmacists have a role in the care of HIV patients. Clinical pharmacists who provide these services are responsible for the quality of care, the satisfaction of patients and the efficient use of resources. The potential benefits to patients include access to medication information, the prevention and resolution of medication-related problems, improved outcomes and increased satisfaction. This study demonstrates the importance and effectiveness with respect to disease outcomes of the pharmacist's role in the institution. We recommend that the pharmacist is educating the patient about his or her disease and medications and the economic and professional credit for value-added services.

146. Evaluating the efficacy and tolerability of ketolide and macrolide antibiotics and notices of the managed care organization. David Feng, Pharm., D.; Saia Jan, Pharm., D.; Daniel Flores, Pharm., D.; (1) Horizon Blue Cross Blue Shield of New Jersey, Newark, NJ; (2) Pfizer Inc., Morris Plains, NJ.

PURPOSE: Microbiologically are commonly prescribed antibiotics, often used in the outpatient treatment of upper respiratory infections (URI). 1, 2 Telithromycin is the first of a new class of antibiotics, the ketolides, which are structurally similar to the macrolides. The FDA has approved telithromycin for the treatment of community acquired pneumonia (CAP), acute exacerbation of chronic bronchitis (AECB), and acute bacterial sinusitis (ABS) in adults. In vivo studies demonstrate efficacy of telithromycin equal to other commonly prescribed outpatient antibiotics; however, in vitro studies have shown improved effectiveness in eradicating strains of penicillin-resistant streptococcus pneumoniae (PRSP), a common URI pathogen. The purpose of this analysis is to compare telithromycin to macrolide antibiotics and to determine whether differences in the efficacy and/or tolerability can be identified in the setting of a large Managed Care Organization (MCO).

METHODS: A retrospective pharmacy claims analysis of MCO plan members receiving a prescription for a macrolide, ketolide, or fluoroquinolone during the 2004-05 flu season. Patients were included if they had a corresponding diagnosis code for CAP, ABS, or AECB within ±15 days of the index prescription. Treatment failures were defined as the filling of a second oral antibiotic (ketolide, macrolide, fluoroquinolone, or beta-lactam antibiotic) prior to the anticipated completion, or within 10 days of the anticipated end of therapy of the index treatment. Statistical analysis was performed using a Chi-Square test of independence.

RESULTS: A total of 13,709 patients were included in the study, with the majority receiving a macrolide antibiotic (90.3% vs. 9.5%). Overall failure rates were highest in the telithromycin group (13.11%), compared with either clarithromycin (11.96%) or azithromycin (9.65%). Higher telithromycin failure rates were evident, both for failures due to lack of efficacy or tolerability. The Rochebus VA Medical Center has multiple inhaled corticosteroids as well as two long-acting beta-2 agonists on formulary. Although the preferred formulary agents have been the fluticasone and formoterol inhalers, the fluticasone and salmeterol combination inhaler has been the most frequently used at a significantly higher cost to the institution. The objective of this analysis is to determine whether the two treatment options are similar in efficacy as well as patient compliance in order to aid in the selection of a preferred regimen. Patients with a diagnosis of COPD, who were prescribed a combination of fluticasone and formoterol inhalers or a fluticasone/salmeterol inhaler within the past two fiscal years, have been selected via a computerized database. In addition to baseline characteristics, charts will be reviewed and data collected to determine the number of COPD exacerbations, refill history, and adverse drug reactions. Finally a cost-effectiveness analysis will be performed to determine the most appropriate regimen based on the information collected. Upon final analysis, a recommendation of the most cost-effective corticosteroid and long-acting beta-2 agonist combination will be made to the Pharmacy, Nutrition and Therapeutics committee of the institution for preferred status on the formulary.

147. Implementation of a clinical documentation system with PDA capability at a large academic medical center. Morton P. Goldman, Pharm.D., BCPS, Michael A. Militello, Pharm.D., Michael Adams, B.S., Brad Main, R.Ph.; The Cleveland Clinic Foundation, Cleveland, OH.

PURPOSE: Documenting interventions is important for justification of clinical pharmacy services. A commercial documentation system that had been utilized at our institution was upgraded in a manner that was not compatible with our existing hardware. It was determined that it would be most cost effective to develop an institution-specific documentation system that could be customized to our specifications and incorporate PDA technology.

METHODS: A committee was convened to determine the key components for an effective system. These included speed and ease of use, complete array of intervention and outcomes choices with drop-down boxes to minimize text entry, patient information from our formulary system, the ability to document costs, ability to calculate direct cost savings, data entry via desktop or PDA, and flexible report-generating capability.

RESULTS: The internally developed Clinical Documentation System was implemented in the fall of 2003. Fifteen different types of interventions can be documented including drug information, discontinuation of drug, changing dose or drug, drug interactions, initiating therapy, IV to PO, etc. Clinical impact is documented as preventing toxicity or side effect, improved efficacy, unnecessary therapy, facilitating continuity of care, cost effectiveness, and improved compliance. Direct cost savings is automatically calculated utilizing both AW and institution specific data. Activities outside and within the institution such as presentations, publications, etc., are also documented. Clinical Specialists use both desktop and PDA applications and are satisfied with the speed and ease of data entry. More than 19,000 interventions were documented in this system in 2004.

CONCLUSION: The implementation of an internally developed Clinical Documentation System allowed us the flexibility to establish a method of documentation that is customized to our exact specifications. A number of changes will be implemented by the end of 2003 to upgrade the system. Overall satisfaction among users is excellent.


PURPOSE: Hospital pharmacists have demonstrated their importance in improving patient care by intervening in the medication use process and educating health care professionals and patients. In this era of fiscal constraints, documentation of clinical interventions and activities is essential to the practice of pharmacy. Objective is to document the clinical interventions, activities, cost savings and revenue-generating services of pharmacists and residents in a psychiatric facility.

METHODS: All clinical interventions and activities performed in a 1-year period by pharmacists and residents were documented in HealthProLink®E, a commercially available, Web-based documentation software. Documentation involved the following global categories: automatic therapeutic substitutions (ATS), committee work, order clarification, education, laboratory analysis, quality assurance, renal dose adjustment, inpatient and outpatient group counseling, therapeutic interventions, and pain consultations. Associated cost savings for each intervention was determined using actual contract pricing. Each pharmacist-managed pain consultation resulted in a cost savings of $100 per patient, which would have been charged to the facility as a physician-managed consult. Revenue generation for outpatient group counseling ranged between $120 and $180 per patient per session.

RESULTS: A total of 4,292 interventions and activities with a corresponding cost savings and revenue generation of $88,388 were documented in the study period for a macrolide clinical intervention and activities by global categories were: ATS ($6,156), committee work ($13,310), order clarification ($984), laboratory analysis ($724), quality assurance ($570), renal dose adjustment ($542), education ($595), group counseling ($508), therapeutic interventions ($484), and pain consultations ($13,300). The revenue generated by outpatient group counseling was $60,960.
CONCLUSIONS: This tool serves as an effective method for documenting clinical activities and interventions in real time with corresponding cost savings.

149. Enhancements of the physician-directed, pharmacy-managed intravenous to oral conversion program at a large metropolitan teaching hospital. Erin J. Iselin, Pharm.D., James Fuller, Pharm.D., Steven R. Abel, Pharm.D., Sharon M. Erdman, Pharm.D.; Wishard Health Services and Indianapolis.

PURPOSE: Recent enhancements to an existing intravenous (IV) to oral (PO) program include expansion of the program to all inpatient populations, including neonatal and pediatric populations, and implementation of documentation of IV to PO interventions in a clinical pharmacy database. The clinical tool was designed to help 1) establish an accurate conversion rate, 2) obtain cost savings information, and 3) show possible barriers to the conversion process.

METHODS: The clinical tool was queried for data collected between April 1, 2005, and September 30, 2005, at one large metropolitan teaching hospital. Data queried for analysis was the date a specified IV medication was initiated, date criteria was met for conversion to PO medication, physician acceptance of the conversion, length of therapy, and the specified hospital unit.

RESULTS: Sixteen approved IV medications were analyzed for conversion to a therapeutic PO alternative medication for two quarters. The IV eligible for conversion during the reported period were 2,238 and 2,492 respectively. These opportunities produced conversion rates of 35% and 28.5% respectively. Declination of the conversion by a physician did not play a significant role in the conversion process included IV medications being discontinued before the patient was identified as meeting criteria and absent pursuits to identify medications to convert. Cost savings with oral therapy for the reported period was estimated at $67,000.

CONCLUSION: The analysis of the intravenous to oral program illustrated that the conversion rate was below the desired goal of 80%, but was making better strides than the previous program. The enhancements to the program documented all possible opportunities and successful conversions in addition to enabling cost savings to be calculated. Barriers to the conversion process have been identified and are being assessed to ultimately increase future conversion rates and subsequently increase cost savings and produce a positive patient outcome.

150. Use of a tablet personal computer to enhance patient care on patient care rounds on a bone marrow transplant unit. Michael Cockerham, M.S., Pharm.D., BCOP; ULM College of Pharmacy, Shreveport, LA.

PURPOSE: Clinical pharmacists have demonstrated a positive impact on patient care; however, critical to the effectiveness of the pharmacist is the ability to access patient and pharmaceutical databases in a timely manner. The purpose of this project was to demonstrate the usefulness of a light-weight, portable Tablet PC system to access hospital patient databases, pharmacy medication profiles, and Internet accessible pharmaceutical databases in addition to on patient care rounds and to demonstrate the feasibility of collecting data for clinical trials, medication use evaluations and adverse drug reaction reporting. METHODS: A Motion Computing LE1600 Tablet PC was purchased, with wireless and Bluetooth technology, Integrated Fingerprint Reader, and Microsoft Office 2003 Professional Edition software. The study consisted of two study periods. The first 2 months data were prior to use of the Tablet PC in clinical practice. The second 2-month period data will be collected using the Tablet PC on patient care rounds. Data were collected on the numbers of Adverse Drug Events reported, pharmacy orders processed, databases accessed, progress notes written, and an objective evaluation of the computer’s usefulness.

RESULTS: Data are still being collected, and the evaluation period will be completed in February 2006. Systems accessed via the Tablet PC include: NetAccess with multiple patient databases, MicroMedex, Lexi-Drugs Online, M.D. Consult, hospital formulary, and oncology clinical guidelines. The study concluded that the conversion rate was below the desired goal of 80%, but was making better strides than the previous program. The enhancements to the program included IV medications being discontinued before the patient was identified as meeting criteria and absent pursuits to identify medications to convert. Cost savings with oral therapy for the reported period was estimated at $67,000.

CONCLUSIONS: The analysis of the intravenous to oral program illustrated that the conversion rate was below the desired goal of 80%, but was making better strides than the previous program. The enhancements to the program documented all possible opportunities and successful conversions in addition to enabling cost savings to be calculated. Barriers to the conversion process have been identified and are being assessed to ultimately increase future conversion rates and subsequently increase cost savings and produce a positive patient outcome.

151. Impact of a pharmacy-managed medication reconciliation program. Sanjeev K. Bhanot, Pharm.D.; James Fuller, Pharm.D., Steven R. Abel, Pharm.D., Wishard Health Services and Purdue University School of Pharmacy, Indianapolis, IN.

PURPOSE: The Joint Commission on Accreditation of Healthcare Organizations has identified medication reconciliation as a 2006 national patient safety goal. The purpose of this study was to evaluate the impact of pharmacy-managed medication reconciliation at a county teaching hospital in Indianapolis.

METHODS: Fourth professional year pharmacy students conducted medication histories on hospitalized adult patients to identify medications taken prior to admission for comparison to admission medication orders. A pharmacist evaluated any identified discrepancies, and the pharmacy student communicated recommendations to the primary medical service. The frequency and nature of the pharmacy interventions were collected. Interventions were defined by type of error (omission, incorrect order, or duplicate therapy) or other therapeutic recommendation.

RESULTS: In a 4-month period, 1,753 medications were evaluated for reconciliation in 316 patients. Overall, 1,708 (97.4%) of the medications were reconciled. The remaining 45 (3.6%) medications were not reconciled as a result of patient discharge prior to follow up. Of the 1,753 medications, 97 (5.3%) required a pharmacist intervention to become reconciled. The types of interventions included: omission of an outpatient medication on admission orders (61.9%); incorrect medication order such as wrong dose or scheduled (26.8%); duplicate therapy (2.1%); and other therapeutic recommendation (10.3%). A pharmacist intervention was required in 46 (14.6%) patients in order to reconcile their medications.

CONCLUSIONS: A considerable number of pharmacist interventions were required to reconcile medications for hospitalized patients through a pharmacy-managed medication reconciliation program at a county teaching hospital.

152. Pharmacist-provided bone density screenings in the female population. Kimberly D. Mitchell, Pharm.D.¹, Kimberly M. Crosby, Pharm.D.², (1)Southwestern Oklahoma State University College of Pharmacy and May’s Drug Stores, Inc., Tulsa, OK, (2)The University of Oklahoma College of Pharmacy and May’s Drug Stores, Inc., Tulsa, OK.

PURPOSE: Pharmacist-provided community bone density screenings may help to target sub-populations at risk for premature bone loss. Current guidelines from the U.S. Preventive Services Task Force recommend that all women 65 years of age and older and women 60 years of age and older with one or more risk factors for osteoporosis receive bone density screening. Screening this guideline may especially benefit women who are at increased risk for osteopenia/osteoporosis, and 2) risk factors that are common among this younger population.

METHODS: Ultrasound bone density measurements were recorded from women 18 years of age and older participating in community health screening events. Each subject was asked to complete an osteoporosis questionnaire, which included questions regarding age, exercise habits, personal fracture history, dietary calcium intake, and other osteoporosis risk factors. Subjects received counseling regarding lifestyle and risk factor modification.

RESULTS: Between August 2004 and November 2005, 739 subjects received bone density screenings. Subject data were analyzed to identify sub-populations with reduced bone density as measured by T-score. Forty-five percent of smokers, 40% of women with a body weight less than 70 kilograms, and 26% of women who reported > 8 hours of exercise per week had an abnormal T-score less than -1.0.

CONCLUSIONS: Women with dietary and lifestyle risk factors related to osteoporosis often fall outside current recommended screening range by age. These women may benefit early in the disease process from pharmacist-provided education in the community setting.

RESIDENTS AND FELLOWS RESEARCH IN PROGRESS

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

153. Effect of antifibrinolytic prophylaxis on transfusion rates for on-pump cardiac surgeries. Evany Z. Raimondi, Pharm.D.¹, Wendell S. Akers, Pharm.D, Ph.D.², Douglas T. Steineke, Ph.D.³, Kelly M. Smith, Pharm.D.⁴, John A. Armistead, M.S., FASHIP⁵, Phillip C. Camp, M.D.⁶, Chandra Shekar Ramaiah, M.D.⁷, Victor Ferreris, M.D.⁸, Ph.D.⁹, Jeremy D. Flynn, Pharm.D.¹⁰, (1)University of Kentucky Chandler Medical Center, Lexington, KY, (2)University of Kentucky College of Pharmacy, Lexington, KY.

PURPOSE: Cardiac surgery is often accompanied by substantial coagulopathies secondary to the use of cardiopulmonary bypass (CPB), which can result in significant blood loss. Antifibrinolytic agents, such as aprotinin and e-aminocaproic acid, have been shown to decrease blood loss and transfusion requirements. The purpose of this study is to compare the outcomes associated with the use of aprotinin and e-aminocaproic acid in on-pump cardiac surgeries at our 473-bed teaching hospital.

[Date]: [Date]
A retrospective chart review was conducted to determine the incidence of CIN in patients receiving oral n-acetylcysteine plus IV hydration (Group I), IV sodium bicarbonate (Group II) or oral n-acetylcysteine plus IV sodium bicarbonate (Group III).

METHODS: Medical records of patients admitted to the coronary care unit that received one of the aforementioned preventive regimens and underwent cardiac catheterization between September 1, 2004 and July 31, 2005, were reviewed. Exclusion criteria selected were similar to other larger randomized controlled clinical trials evaluating CIN. Patients' demographics, risk factors for CIN, medications administered pre-catheterization, and preventive regimens were documented.

RESULTS: Medical records from 232 patients receiving one of the preventive regimens were reviewed. Fifty-two patients met inclusion criteria (30 Group I, 5 Group II, and 17 Group III). All patients received the isosmolar contrast media ioxithalamate. The average amount of ioxithalamate administered was 219 mL. Overall, 14 patients (27%) developed CIN following cardiac catheterization.

CONCLUSION: The incidence of CIN was similar. However, a larger prospective trial with equal numbers of patients is needed to confirm these results. It was also found that the combination of oral n-acetylcysteine plus IV sodium bicarbonate was frequently used. It is unknown whether or not this combination has additional protection against the development of CIN.

157. Assessment of relationships between antibiotic use and susceptibility of microorganisms in a surgical trauma intensive care unit. Brian P. Anger, Pharm.D., Cathy L. Worrell, Pharm.D., BCPS, BCN; FAPA, Nicole A. Weimer, Pharm.D., John A. Bosso, Pharm.D., BCPS, FCCP; Medical University of South Carolina, PO Box 230132, Charleston, SC.

PURPOSE: A relationship between antibiotic use and bacterial susceptibility is thought to exist. Realizing that unit-specific susceptibility and prescribing patterns may vary from hospital-wide data, we began tracking these data in our surgical trauma intensive care unit (STICU) in 2002. Over time, this information may affect empiric antimicrobial therapy decisions.

METHODS: Census, antibiotic usage, and microbiology data were obtained from the admissions, pharmacy, and microbiology departments, respectively. Defined daily dose per 1000 patient days (DDD/1000 PD) for organisms with at least 10 isolates per year after duplicate isolates were eliminated. Duplicate negative organisms was considered versus DDD/1000 PD for organisms with at least 1 isolates per year after duplicate isolates were eliminated. Duplicate isolates were defined as any organism with the same susceptibility pattern from the same site in the same patient.

RESULTS: Among 20 genera of organisms isolated, six met our criterion for inclusion: Pseudomonas aeruginosa, Acinetobacter spp., Enterobacter spp., coagulase(-) staphylococci, methicillin-susceptible Staphylococcus aureus, and methicillin-resistant S. aureus. Of these, 231 resistant Enterobacter and Acinetobacter species occurred in 2004 that did not appear to be related to antibiotic usage patterns. For P aeruginosa, the expected inverse relationship between drug usage and susceptibility occurred for certain antibiotics. For example, our unit-specific cephalosporin and ciprofloxacin susceptibilities have increased to 66% and 82% with declining drug use compared to susceptibilities of 33% and 64% institution-wide, respectively. In contrast, piperacillin/tazobactam susceptibility has not changed despite increased empiric use in our unit. Tobramycin displayed an unexpected increase in susceptibility from 83% to 100% with increased drug usage.

CONCLUSIONS: Further data are needed to determine the statistical and clinical significance of drug prescribing and antimicrobial susceptibility patterns in our STICU. The 2005 data will be added to the database in early 2006.


PURPOSE: This retrospective study was conducted to determine the incidence of CIN in patients receiving oral n-acetylcysteine plus IV hydration (Group I), IV sodium bicarbonate (Group II) or oral n-acetylcysteine plus IV sodium bicarbonate (Group III).

METHODS: Medical records of patients admitted to the coronary care unit that received one of the aforementioned preventive regimens and underwent cardiac catheterization between September 1, 2004 and July 31, 2005, were reviewed. Exclusion criteria selected were similar to other larger randomized controlled clinical trials evaluating CIN. Patients' demographics, risk factors for CIN, medications administered pre-catheterization, and preventive regimens were documented.

RESULTS: Medical records from 232 patients receiving one of the preventive regimens were reviewed. Fifty-two patients met inclusion criteria (30 Group I, 5 Group II, and 17 Group III). All patients received the isosmolar contrast media ioxithalamate. The average amount of ioxithalamate administered was 219 mL. Overall, 14 patients (27%) developed CIN following cardiac catheterization.

CONCLUSION: The incidence of CIN was similar. However, a larger prospective trial with equal numbers of patients is needed to confirm these results. It was also found that the combination of oral n-acetylcysteine plus IV sodium bicarbonate was frequently used. It is unknown whether or not this combination has additional protection against the development of CIN.

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159. Pharmacy resident attitudes toward pharmaceutical promotion. Sumer L. Huber, PharmD, Jill S. Burkiewicz, PharmD; Midwestern University Chicago College of Pharmacy, Downers Grove, IL.

PURPOSE: Pharmaceutical industry promotional activities involving healthcare professionals are extremely prevalent. Research shows that pharmacy residents may help to determine whether educational intervention is necessary during pharmacy residency programs.

METHODS: An electronic, anonymous, multiple choice survey will be distributed to 500 general and specialty pharmacy residents via electronic mail. Questions will investigate opinions regarding ethics and appropriateness of pharmaceutical industry promotion. They will also investigate opinions regarding industry-sponsored meals, educational events, gifts, and pharmaceutical sales representatives. In addition, questions will investigate the perceived influence that pharmaceutical promotion has on the professional knowledge and practice of pharmacy residents. Other questions will inquire whether pharmacy residency programs have policies or offer training regarding resident-industry interactions. Descriptive statistics and the Mann-Whitney U test will be used to report results.

RESULTS: Results are pending.

CONCLUSIONS: Information regarding pharmaceutical industry influence on pharmacy residents’ opinions will help to determine whether educational intervention is necessary during pharmacy residency programs.

160. Effects on the lipid profile after conversion from rosiglitazone to pioglitazone in Native American, type 2 diabetic patients. Jodi N. Sparkman, Pharm.D.; Midwestern University Chicago College of Pharmacy, Downers Grove, IL.

OBJECTIVE: Thiazolidinediones regulate the body’s response by altering the transcription of genes controlling glucose and lipid metabolism. Recent literature has shown a more favorable lipid profile with the use of pioglitazone versus rosiglitazone, resulting in an increase in HDL-C, decrease in triglycerides, and no change in LDL-C. The objective of this study is to identify whether there is a difference in the lipid profile in the Native American population, when rosiglitazone is replaced with pioglitazone.

METHODOLOGY: The conversion of rosiglitazone to pioglitazone is as follows per P&T committee: 2 mg rosi daily to 15 mg pio daily (group 1), 4 mg rosi daily to 13 mg pio daily (group 2), 8 mg rosi daily to 30 mg pio daily (group 3), and 4 mg rosi twice daily to 45 mg pio daily (group 4). Electronic chart review will identify patients diagnosed with type 2 diabetes currently treated with pioglitazone. The primary outcome will be change in the fasting lipid panel. The following data will be collected: lipid levels including total cholesterol (TC), LDL-C, HDL-C, and triglycerides (TG) while taking rosiglitazone and after a minimum of 12 weeks of pioglitazone therapy. Secondary outcomes measured will be change in weight, BMI, ALT, AST, and HbA1c.

RESULTS: Baseline data as mean (mg/dL) as follows: Group 1 TC = 163.95, LDL-C = 87.98, HDL-C = 38.53, TG = 187.13; Group 2 TC = 175.20, LDL-C = 99.76, HDL-C = 34.70, TG = 205.10; Group 3 TC = 185.83, LDL-C = 104.78, HDL-C = 38.52, TG = 232.40; Group 4 TC = 182.17, LDL-C = 99.73, HDL-C = 36.79, TG = 223.19.

161. Pharmacy resident participation in cardiopulmonary resuscitation events. Meredith B. Toma, Pharm D.1, P. Shane Winstead, Pharm D.2, Kelly M. Smith, Pharm D.1, Daniel A. Lewis, Pharm D.1, Timothy Clifford, Pharm D.1

(1)University of Kentucky Chandler Medical Center, Lexington, KY; (2)University of Kentucky College of Pharmacy, Lexington, KY.

PURPOSE: Little data are available describing the role of pharmacists in cardiopulmonary resuscitation (CPR) events. Most publications indicate that pharmacists are responsible for drug admixture and provision of drug information. However, there are no data specifically describing pharmacy resident participation in CPR events. A survey of accredited pharmacy residency programs was conducted to determine the participation of pharmacy residents in CPR situations. Secondary objectives include identification of pharmacy staff responsibilities, educational methods used to train pharmacy staff and residents, and evaluation methods used to assess competency for personnel that respond to CPR events.

METHODS: A 46-question survey was developed, and IRB approval obtained. The survey was tested internally and externally prior to final distribution. The survey was sent to all residency program directors at ASHP-accredited residency programs via Survey Monkey, a Web-based distribution tool. A total of 720 residency program directors were contacted via e-mail, as listed in the ASHP online residency directory. Respondents were asked to complete the survey within 3 weeks of the invitation, with two electronic reminders sent to prompt response.

RESULTS: Survey response is ongoing. Currently, 15% of program directors have responded (108/720). Approximately 30% of survey respondents require resident participation in CPR events, while roughly 40% state that resident response to CPR events is optional and dependent on rotation. Eighty-two percent of respondents indicate that there is a formal CPR team at their institution, with pharmacy staff included 84% of the time. The primary duties of responding pharmacy personnel have been listed as drug admixture (89%) and provision of drug information (94%).

CONCLUSIONS: Final results of this survey will help to categorize the level of involvement of pharmacy residents in CPR events, describe their assigned roles, ascertain training methods, and determine assessment methods for pharmacy staff that respond to CPR events.

162. Antiretroviral resistance patterns in a rural southern state. Molly E. Kent, Pharm. D.1, David J. Feola, Pharm. D., Ph.D., BCPS1, Kelly M. Smith, Pharm. D.2, Ardis Hoven, M.D.1, Frank Romanelli, Pharm. D., BCPS2
(1)University of Kentucky Chandler Medical Center, Lexington, KY; (2)University of Kentucky College of Pharmacy, Lexington, KY.

PURPOSE: To document the rate of antiretroviral resistance at an infectious diseases clinic in a rural southern state in order to (1) establish baseline antiretroviral resistance rates and (2) compare resistance rates for the time periods of January 1, 2003, to December 31, 2003, and January 1, 2004, to June 30, 2005.

METHODS: Medical records of therapy-naïve and treatment-experienced patients (n=200) with human immunodeficiency virus (HIV) who underwent genotypic or phenotypic resistance testing between January 1, 2003, and June 30, 2005, at an infectious diseases clinic of a academic medical institution were identified for review. Demographic data, viral load, CD4 cell count, and genotypic (mutations) and phenotypic (IC50) resistance testing results are being collected. Data stratified by patient treatment type (treatment-experienced vs. therapy-naïve) and by resistance testing modality (genotypic vs. phenotypic) will be analyzed using the chi-square test to compare mean rates of resistance between the two cohorts (2003 vs. 2004 to June 30, 2005). It is anticipated that final research results will be completed by March of 2005.

RESULTS: To date, medical records were analyzed from treatment-experienced patients (n=21) in the January 1, 2004, to June 30, 2005, cohort.
only. Phenotypic resistance (defined as resistance to one or more agents within a drug class) for nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs) was 71% (15/21), 76% (16/21), and 67% (14/21), respectively. Phenotypic multi-drug resistance (defined as resistance to three or more drug classes) occurred in 43% (9/21) of treatment-experienced patients.

CONCLUSION: Knowledge of local antiretroviral resistance patterns may enhance antiretroviral drug selection and improve patient care.

163. The development of a pharmacy-based infectious disease Web site and its impact on patient care. Jason J. Schafer, Pharm.D., Debra A. Gold, Pharm.D., Kurt B. Stevenson, M.D., M.P.H., Julie E. Mangano, M.D., Kim D. Hawksworth, R.Ph.; The Ohio State University Medical Center, Columbus, OH.

PURPOSE: Evaluate a new pharmacy-based infectious diseases (ID) Web site’s impact on patient care and the exchange of ID knowledge among pharmacists. METHODS: A custom-made ID Web site was designed for the inpatient pharmacy department in a large academic teaching hospital employing 106 pharmacists who provide uninterrupted pharmacy services. 2 ID pharmacists, 2 ID physicians, and 1 information technology pharmacist created the Web site. Three pharmacists were randomly selected to pilot the Web site for 3 weeks. They could post questions as patient specific with a medical record number or as general infectious diseases inquiries. Questions were answered by the ID specialists who received e-mail notification each time a question was posted. They then informed the patient care team of the relevant questions. Data collected from the posted questions included the medical record number and whether an ID consult was present or recommended. Electronic charts were reviewed to determine whether the ID Web site recommendations were followed and how it changed patient care. Questions were answered using evidence-based medical literature linked as PDF articles. The impact of general knowledge questions is assessed by monitoring Web site viewing frequency and evaluating satisfaction surveys designed to measure ID knowledge enhancement.

RESULTS: During the 3-week pilot, 10 questions were submitted by 3 pharmacists. 3 questions were patient specific: 1 had an ID consult, and 2 had recommendations to change therapy for which both were subsequently followed. The satisfaction survey for the 7 general knowledge questions confirmed that all 3 pharmacists increased their ID knowledge.

CONCLUSION: This pilot study demonstrates that a pharmacy-based ID Web site has the potential to affect patient care and improve the efficiency of ID knowledge distribution in a large pharmacy department. Full implementation by the pharmacy department is under way, and its impact will continue to be measured.

164. Does prescriber compliance with a prospective approval procedure of an antibiotic management program affect medication-ordering process time? Patricia L. Saunders, Pharm.D., Blair Capitano, Pharm.D., David L. Paterson, M.D., Ph.D., Brian A. Potoski, Pharm.D., University of Pittsburgh Medical Center, Pittsburgh, PA.

PURPOSE: A criticism of antibiotic management programs that require prospective antibiotic approval is that they delay the patients’ receipt of antibiotic therapy through impedance of the medication ordering process. However, it can be postulated that such a delay occurs only when the prescriber is non-compliant with the procedure, thus necessitating an additional pharmacist intervention. The objective of this study was to determine the impact of prescriber non-compliance with the antibiotic management program (AMP) procedure on the medication ordering process time.

METHODS: Antibiotic orders will be collected in the central pharmacies of the two academic medical centers where the AMP currently operates. Orders should be received by the pharmacy with an approval number to indicate prescriber compliance. Orders received without an approval number denote prescriber non-compliance with the procedure. The medication-ordering process time will be measured based on the following: the time the medication order is received by the pharmacy, the time needed to contact the physician regarding antibiotic approval, the time needed for the AMP approval call, and the time the antibiotic is entered into the pharmacy system. The average time of the medication-ordering process for antibiotics ordered by complaint prescribers will be compared to that ordered by non-compliant prescribers. These times will then be compared to the average time of the medication-ordering process of a random sample of orders for unrestricted antibiotics, which will serve as a control group. The student’s t-test will be used to assess for differences of medication-ordering process time between groups.

RESULTS: Data collection is currently ongoing.

165. Pharmacist’s impact on the adherence to JCAHO medication management standards. Kimberly Zullian, Pharm.D., Joyce Levag, Pharm.D.; University of California, San Diego Medical Center, San Diego, CA.

BACKGROUND: The medication management standards are a new chapter introduced by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 2004. These medication management activities involve systems and processes that an organization uses to provide medication-related therapies to patients, which are critical to the safety and care of these patients. As part of the JCAHO’s new continued readiness accreditation process, the tracer methodology is used to look at performance with respect to services provided as viewed by the patient.

PURPOSE: To assess whether the spot tracer methodology conducted by pharmacists on high-risk medications was able to identify opportunities for improvement and provide a valid mechanism to track compliance with the medication management standards over time.

METHOD: This was a retrospective study conducted in the inpatient setting between August 2004 and April 2005. Spot tracers were conducted by the pharmacist on high-risk medications, which focused on medication management standards related to prescribing, ordering, preparation, dispensing, and administration.

RESULTS: Fifty-two high-risk medication spot tracers were completed (chemotherapy (n=4), heparin (n=13), insulin (n=9), narcotic (n=15), anticoagulant (n=7), vasoactive agent (n=2)). Compliance in legibility, indication, and signature were found. Improvement in correct order written (80% vs. 96%), pump settings (95% vs. 100%), and MAR documentation (84% vs. 93%) were seen. Lack of compliance with double checks of high risk medications (90% vs. 35%) prompted an educational effort and biweekly audits. This intervention provided nurses with a greater awareness of the standard and showed that the compliance level surpassed the baseline level when reassessed.

CONCLUSIONS: Spot tracers conducted by pharmacists can identify areas of non-compliance with the JCAHO medication standards. These areas of non-compliance can be used as opportunities for improvement to not only positively affect patient safety but also build important new collaborative relationships between pharmacists and nurses at the bedside.

166. Clinical efficacy of darbepoetin versus erythropoietin in adult end-stage renal disease. Theresa Breithaupt, Pharm.D., Julie Barnes, Pharm.D., BCPS; Medical University of South Carolina, P.O. Box 250132, Charleston, SC.

BACKGROUND: End-stage renal disease (ESRD) is associated with anemia due to decreased erythropoiesis. Treatment with erythropoietin has been used to increase the production of erythrocytes and improve hemoglobin levels, which in turn improves quality of life and overall health. On an outpatient basis, treatment with erythropoietin is given 3 times/week as maintenance therapy, and prior to the initiation of the darbepoetin protocol, this therapy was continued at our institution on an inpatient basis.

PURPOSE: Due to contractual issues, darbepoetin is less expensive for our institution to procure. Therefore, a protocol was developed to convert patients from 3 times/week erythropoietin to once-weekly darbepoetin on an inpatient basis. Previous studies have shown effectiveness when using darbepoetin to increase hemoglobin. However, ensuring the clinical effectiveness of using darbepoetin over erythropoietin in the inpatient setting needs further investigation.

METHODS: This will be a retrospective chart review assessing the efficacy of darbepoetin compared to erythropoietin in maintaining hemoglobin levels. All patients with ESRD admitted to the nephrology service and receiving echrythropoietin between October and November 2004 or receiving darbepoetin between August and September 2005 will be included. The primary outcome will be the difference in hemoglobin between admission and discharge. Secondary outcomes include cost savings, FDA-approved dosing conversion from erythropoietin to darbepoetin, admission diagnosis, and incidence of transfusion.

RESULTS: Initial analysis of the erythropoietin arm included 11 patients with ESRD. The mean length of stay was 4.95 days, the mean admission hemoglobin was 10.2 mg/dL, and the mean discharge hemoglobin was 10.3 mg/dL.

CONCLUSION: Complete results will be presented at the ACCP Spring meeting, Monterey, CA.

167. Impact of permissive underfeeding on outcomes in surgical-trauma patients. Kelly M. Goodson, Pharm.D., Cathy Worrall, Pharm.D., BCPS, BCNSP, FAPhA; English F. Barhour, R.D., CNSD, Kit N. Simpson, D.F.P.H., Mark H. DeLegge, M.D., Medical University of South Carolina, Charleston, SC.

PURPOSE: Intensive glycemic control in critically ill patients improves clinical outcomes by reducing morbidity and mortality. Studies are beginning to suggest that hypocaloric feeds improve mortality at discharge, shorten both hospital and intensive care unit lengths of stay, and decrease need for mechanical ventilation by improving glycemic control. The primary objective of this study is optimal blood glucose control. Secondary objectives include reduction in hospital and intensive care unit length of stays of mechanical ventilation, infectious complications, and all-cause mortality.
METHODS: Patients > 18 years of age admitted to the surgical trauma intensive care unit will be candidates for the permissive underfeeding protocol. Patients receiving specialized nutrition support who have < 2 blood glucose measurements > 150 mg/dl will be eligible for study enrollment. After collecting data for 30 patients in the control group, study patients will be initiated on the permissive underfeeding protocol. The primary end point is mean blood glucose control score for the four worst measures daily for the first five days. The expected range for the glucose control score is 20-80. The expected range is 26-52 with an expected standard deviation of 4. The criteria for scoring are provided in the table below.

<table>
<thead>
<tr>
<th>Glucose Levels</th>
<th>Control</th>
<th>Score</th>
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<tbody>
<tr>
<td>&gt;181 mg/dl</td>
<td>Very Hyperglycemic</td>
<td>4</td>
</tr>
<tr>
<td>151-180 mg/dl</td>
<td>Hyperglycemic</td>
<td>3</td>
</tr>
<tr>
<td>121-150 mg/dl</td>
<td>High Control</td>
<td>2</td>
</tr>
<tr>
<td>101-120 mg/dl</td>
<td>In Control</td>
<td>1</td>
</tr>
<tr>
<td>71-100 mg/dl</td>
<td>Low Control</td>
<td>2</td>
</tr>
<tr>
<td>51- 70 mg/dl</td>
<td>Hypoglycemic</td>
<td>3</td>
</tr>
<tr>
<td>&lt; 50 mg/dl</td>
<td>Very Hypoglycemic</td>
<td>4</td>
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RESULTS: To date, nine patients have been enrolled in the control arm. The mean baseline blood glucose was 160 mg/dL, with all patients requiring insulin therapy at baseline according to the institutional standards for treatment of hyperglycemia. The mean blood glucose control score was 50.7. CONCLUSION: Complete results will be presented at the ACCP Spring meeting, Monterey, CA.


PURPOSE: A significant amount of time and money is spent at many institutions analyzing blood samples for ionized magnesium levels. Tremendous cost savings are possible if a clinician could recognize the appropriate circumstance under which an ionized magnesium level should be obtained to accurately evaluate the magnesium stores of a patient. Incidental reports in the literature have also suggested a potential link of ionized magnesium levels to that of other regularly measured serum values. The primary objective of this study is to describe the correlation of serum total and ionized magnesium levels in relationship to serum pH, albumin, triglycerides, and total cholesterol concentrations.

METHODS: Medical records from approximately 403 total parenteral nutrition patients between January 2004 and December 2003 were reviewed for availability of concomitant measurements of serum total and ionized magnesium, pH, albumin, triglycerides and total cholesterol concentrations. Those patients possessing this complete set of serum values will be included for analysis. A scatter plot will be created to informally explore the correlation between ionized and total magnesium values and their relationship to the other serum measurements. Linear regression will then be used to further explore the relationship between the two magnesia values. Significant correlations will be further explored for analysis.

CONCLUSION: Initial results from the data obtained indicate a weak correlation between ionized and total serum magnesium values. Further analysis of the data with respect to the other measured serum variables will follow and be available at the time of presentation.

169. Collaborative anemia management in an outpatient oncology clinic. Deborah M. McNutt, Pharm.D., James A. Trovato, Pharm.D., M.B.A., BCOP, University of Maryland School of Pharmacy, Baltimore, M.D.

PURPOSE: The intent of this study is to prospectively evaluate the role of the clinical pharmacist in treating breast cancer patients with anemia compared with a retrospective control and establish pharmacist-provided anemia management services in our oncology clinic. We hypothesize that collaboration between the physician and pharmacist in the management of anemia results in optimal darbepoetin alfa utilization and decreased drug cost. The primary objective of this study is to measure the change in patient’s hematoglobin from baseline and the number of blood transfusions required compared to a retrospective control. The secondary objectives include documenting the potential cost savings in terms of drug cost and describing the dose and schedule of darbepoetin alfa compared with the retrospective control.

METHODS: A retrospective review of breast cancer patients who received darbepoetin alfa for the treatment of their anemia in our outpatient clinic during the time period of 06/01/04 to 05/31/05 will be conducted. These patients will be compared to a prospective group of breast cancer patients who have been diagnosed with anemia and are candidates to receive darbepoetin alfa. Patients will be excluded if they have received prior erythropoietin therapy within two weeks of screening, uncontrolled hypertension, or an active gastrointestinal bleed. Informed consent will be obtained from patients who meet the eligibility criteria for study entry. In collaboration with the physician, the pharmacist(s) will initiate, monitor, and adjust darbepoetin alfa therapy according to laboratory findings. We will document and describe the usage, monitoring parameters, response, and drug cost associated with darbepoetin alfa first 12 weeks of therapy. RESULTS: Pending results of the retrospective control arm will be reported at the 2006 ACCP Spring Practice and Research Forum. In addition, descriptive preliminary data from the prospective arm is anticipated.

170. Adverse events associated with vaccination of infants in the neonatal intensive care unit at sixty days of life. Jacques Y. Damm, Pharm.D., Debra K. Gardner, Pharm.D., The Ohio State University Medical Center, Columbus, OH.

PURPOSE: The administration of diphtheria-tetanus-acellular pertussis-inactivated polio-Haemophilus influenzae type B (DTaP-IPV-HIB) to preterm infants has been associated with an increase in cardiorespiratory events (apnea, bradycardia, and/or desaturation). The purpose of this study is to assess whether treatment changes made near the time of vaccine administration contribute to these adverse events.

METHODS: A retrospective chart review of 70 preterm infants who received DTaP-IPV-HIB while hospitalized between January 1, 2004, and October 31, 2005, was conducted. Adverse events defined as apnea, bradycardia, and desaturation measured pre and post DTaP-IPV-HIB administration were documented. Recent changes in medical management with regard to oxygen requirement, caffeine administration, formula or feeding route, and environment (open crib versus heated isolate) were recorded. The infants were divided into two groups: those who exhibited an increase in cardiorespiratory events and those who did not. Statistical analysis was performed using Fisher’s Exact Test to compare the frequency of changes in medical management between the two groups.

RESULTS: Thirty-nine medical records have been reviewed. Thirteen of the 39 infants (33%) had an increase in apnea, bradycardia, and/or desaturation. Of those 13 subjects, 11 had at least one recent change in medical management (85%). In the group that did not have an increase in cardiorespiratory events, 18 of 26 patients had at least one recent change to therapy (69%), p=0.45. CONCLUSION: Interim results indicate there is not a statistically significant difference of change in medical management between infants who experienced an increase in cardiorespiratory events versus those that did not after DTaP-IPV-HIB administration.

171. Caspofungin use at an urban tertiary-care center: outcomes and opportunities for cost reduction. Nadiu Z. Haque, Pharm.D., Susan L. Davis, Pharm.D., (1)Henry Ford Hospital, Detroit, MI; (2)Henry Ford Hospital and Wayne State University, Detroit, MI.

PURPOSE: We conducted a retrospective review of caspofungin use at an inner-city tertiary-care teaching hospital in Detroit, Michigan.

METHODS: All patients receiving caspofungin were evaluated for indication, clinical and microbiological characteristics, outcomes, and cost. RESULTS: 118 orders were written for caspofungin in 2005, 56% approved by Infectious Diseases, average duration 10.2 days (95%CI 7.2–13.3). Services prescribing caspofungin were medical intensive care unit (ICU) (33%), transplant (19%), internal medicine (19%), hematology/oncology/BMT (9%), and surgery (11%). Characteristics of 90 clinically evaluable patients (initial course of caspofungin, receiving ≥ 3 days): 33% male, APACHE II score 12.4 (95%CI 10.5–14.3), 88% hospitalized ≥ 72 hours, 42% prior ICU admission; 84% prior antibiotic usage, 43% prior antifungal use, and 19% recent surgery. Comorbid conditions included: 16% transplant, 19% diabetes, 42% central venous catheters, and 53% immunosuppressed (including HIV, malignancy, or medications). Indications: 34% empiric therapy in sepsis, 23.4% documented candidemia, 14% febrile neutropenia, 8% documented aspergillosis, 6% esophageal candidiasis, and 14% other. Microbiology: 46% no fungal organisms isolated, 21% C. albicans, 14% C. glabrata, 12% multiple Candida spp, 7% moulds. Five cases of C. glabrata demonstrated resistance to fluconazole. 9% of patients had their therapy de-escalated after cultures reported, and 9% had oral steroid therapy to azoles. Clinical success was achieved in 73% of empiric uses and 62% of definitive therapy; 9% of patients had infection-related readmissions. Crude mortality was 27%. Overall caspofungin cost was $614,000/12 months. Average cost/patient was $2600 for empiric and $4900 for definitive therapy, highest cost observed in mould infections (e.g. aspergillosis). A broad prospective restriction program would potentially avoid 16% of doses, saving $98,000 annually. CONCLUSION: Use of caspofungin requires prospective monitoring for appropriate indication and duration. Additional outcomes and cases from 2004 will also be presented.
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172. Gestational diabetes in a Medicaid population: 10-year trends in incidence and control usage. Brooks Pugmire, Pharm.D., Rex W. Force, Pharm.D., FCCP BCPS; Departments of Family Medicine and Pharmacy Practice, Idaho State University, Pocatello, ID.

PURPOSE: The goal of this study was to examine Medicaid claims data to describe the incidence of and evaluate prescribing trends in gestational diabetes mellitus (GDM).

METHODS: This retrospective, observational study reviewed Medicaid claims among pregnant women between January 1, 1995, and September 30, 2005, to identify those with GDM and describe the yearly incidence. Ethnicity and age were determined. The prescription claims database was queried to evaluate hypoglycemic drug utilization by obtaining yearly counts of claims for these agents and number of patients using them. Diagnoses of diabetes after delivery and gestational diabetes in subsequent pregnancies were determined.

Rates of maternal complications including hypertensive disorders and cesarean deliveries were also assessed.

RESULTS: Preliminary results indicate that during the study period 87,946 pregnancies were identified in 61,553 women. The number of pregnancies complicated by GDM was 4,639 (5.3%) in 4,233 women. The incidence of GDM was 3.87% in 1995 and 7.25% in 2005. The average age was 27 and 24 in the pregnancy groups with and without GDM, respectively. Of the pregnancies complicated by GDM, 762 (16%) were treated with a hypoglycemic agent. There were 4,112 prescription claims among the 762 pregnancies treated with hypoglycemic agents. Insulins accounted for 84% of these claims. Metformin, sulfonylureas, glitazones, and combination drugs accounted for 8.8%, 3.2%, 1.6%, and 0.4% of claims, respectively. Claims for oral agents indicate increasing rates of use during the study period.

CONCLUSIONS: These data indicate increasing rates of GDM and use of oral hypoglycemic agents in a Medicaid population. Completed analysis of the data will be available at the time of presentation.

173. Examining the incidence of fungal infections in heart and lung transplant recipients receiving itraconazole prophylaxis. Amanda M. Ball, Pharm.D., Craig A. Martin, Pharm.D., Kelly M. Smith, Pharm.D., Phillip C. Camp, M.D., Timothy Mullert, M.D., Jeremy D. Flynn, Pharm.D., University of Kentucky Chandler Medical Center, Lexington, KY.

PURPOSE: Invasive fungal infections are a significant source of morbidity and mortality in heart and lung transplant recipients. Antifungal prophylaxis is common practice, but antifungal management strategies vary among institutions. At our institution oral itraconazole is the prophylactic antifungal of choice. The study objective is to examine the incidence of fungal infections in heart and lung transplant recipients receiving itraconazole prophylaxis at our institution. This incidence will be compared to those reported in the literature to gain insight into the efficacy of our antifungal management strategy. We hypothesize that our fungal infection incidence is similar to those reported in current literature.

METHODS: Observational, retrospective chart review of adults receiving a heart or lung transplant, from January 2001 until May 2005, who received itraconazole for prophylaxis. The study protocol was approved by the Institutional Review Board. Transplant databases were utilized to screen all heart or lung transplant patients meeting inclusion criteria. The medical records of all eligible patients were reviewed for demographics, risk factors for fungal infections, duration of antifungal prophylaxis, rejection episodes, bacterial/viral infections, and mortality. Pharmacy and microbiology databases were reviewed for patients meeting inclusion criteria who also received an antifungal agent for treatment of documented or suspected infection, or positive fungal cultures. The medical records of patients with a possible, probable, or proven fungal infection were further evaluated for causative pathogen, site of infection, treatment, and outcome.

RESULTS: 87 patients met inclusion criteria, 44 heart and 43 lung transplants. To date 14 patients (16.3%) have a documented fungal infection, 11 (7.8%) of which are lung transplant recipients. Aspergillus spp. account for 73% of these infections and 82% of those were lung transplant recipients. Candida spp. account for 13% of infections. Final study results will be utilized by our Transplant Steering Committee to reassess current antifungal prophylaxis regimen.

174. Involvement of a clinical pharmacist in a post-transplant outpatient clinic. Erin M. Megerle, Pharm.D., Rex W. Force, Pharm.D., FCCP BCPS; Departments of Family Medicine and Pharmacy Practice, Idaho State University, Pocatello, ID.

PURPOSE: Clinical pharmacy services have been shown to greatly affect patient care in many areas of medicine such as transplantation. Transplant patients are often maintained on complex medication regimens that put them at risk for adverse drug reactions and harmful drug interactions. The purpose of this study is to report the types of drug therapy interventions made by a clinical pharmacist in a post-transplant clinic.

METHODS: An observational study of all solid organ transplant patients followed by a clinical pharmacist in an outpatient transplant clinic from July 2004 to March 2006. Data were taken from pharmacy monitoring forms. All pharmacy recommendations and interventions were documented, including medication and allergy list reconciliation, potential drug-drug interaction recognition, dosage adjustment recommendations, and patient counseling.

RESULTS: Fifty-seven transplant patients (45 kidney and 12 kidney/pancreas) have been analyzed to date. Preliminary results show that 19% of the patients had medical records containing incomplete or incorrect allergy lists. Eighty-one percent of the patient medication profiles required reconciliation by the clinical pharmacist. A major drug interaction was identified in over half (52%) of the patients. Ninety-three percent of the drug interactions involved one of the patient’s immunosuppressive medications. A potential adverse drug reaction was recognized in 44% of the patients. A recommendation to the physician was made for 63% of the patients. The most common recommendations included the adjustment of antihypertensive medications, suggestions for over-the-counter products, laboratory monitoring of side effects, bone density surveillance, and lipid management. Following the initial medication history interview with the clinical pharmacist, 28% of patients were revisited for patient counseling.

CONCLUSION: A clinical pharmacist is an integral member of the outpatient transplant team. Clinical pharmacy involvement in a post-transplant clinic improves the quality, accuracy, and safety of patient care.

STUDENT SUBMISSIONS

These papers describe original research by students in therapeutics, pharmacokinetics, pharmacodynamics, pharmacoeconomics, and pharmacoepidemiology. The abstract titles and authors are published in Pharmacotherapy online; the full abstract will be published in the meeting program book.

175. Gender differences in blood pressure control in an outpatient family medicine clinic. Michelle Kender, Pharm.D., Candidate, Patricia Wigle, Pharm.D., University of Cincinnati College of Pharmacy, Cincinnati, OH.

PURPOSE: This study was conducted to evaluate the level of blood pressure control in male and female patients in an outpatient family medicine clinic.

METHODS: A retrospective chart review of 40 patients was performed.

RESULTS: Forty percent of the patients had Stage 2 hypertension. Fifty-three percent of patients (38% female, 62% male) were at their blood pressure goal at the last clinic visit. Forty-seven percent of the patients (74% female, 26% male) were not at their goal blood pressure. Other parameters assessed included social history, current drug therapy, and whether the blood pressure was stable or recently controlled.

CONCLUSIONS: In this sample of patients, there was a difference in blood pressure control between male and female patients.

176. Methods for dosing digoxin in heart failure in the modern era. Melissa Fitch, BS, Robert J. DiDomenico, Pharm.D., Marlos Viana, Ph.D., Jerry Bauman, Pharm.D., University of Illinois at Chicago, Chicago, IL.

PURPOSE: The therapeutic range of digoxin (Dig) for heart failure (HF) has changed to become more narrow but older dosing methods have not been modified to reflect this change. We sought to compare the Jelliffe and Jusko-Koup methods of choosing an initial dose of Dig using the newer therapeutic range in order to offer simple dosing guidelines for patients (pts) with HF in the modern era.

METHODS: Laboratory records over a 6-month period were screened for hospitalized pts who had Dig levels. Pt medical records were then reviewed for those who had post-distributive, steady-state levels for inclusion into the study (N=54 pts). Pts with drug interactions (e.g., amiodarone) were excluded. Pt-specific data was collected and used to calculate expected Dig level by both the Jelliffe and Jusko-Koup methods.

RESULTS: Of the 54 pts, 30 were male and 24 were female, aged 68+15yrs. Dig levels ranged from 0.4 to 2.4 ng/ml and creatinine clearance (Clcr, Cockcroft and Gault) ranged from 8 to 132 ml/min. Using the Jelliffe method, there was a significant correlation between expected and observed Dig levels (r2=0.23, p<0.01). Using the Jusko-Koup method there was a similar significant correlation (r2=0.24, p<0.01). However, measurement of agreement between expected and observed Dig levels as described by the root mean square error (MSE) revealed more accurate performance for the Jusko-Koup method (MSE=0.40) compared with the Jelliffe method (MSE=0.81).

CONCLUSION: The Jusko-Koup method is a more accurate method to estimate the initial dose of Dig using the newer therapeutic range in order to offer simple dosing guidelines for patients (pts) with HF in the modern era.
177. Exploring patients' knowledge about therapeutic lifestyle changes for hypertension. Bryan Mierwether, Pharm.D., candidate; Kristal L. Williams, Pharm.D.; Butler University College of Pharmacy and Health Sciences; Methodist Family Practice Center, Indianapolis, IN.

PURPOSE: The objective of this study is 1) to evaluate the level of knowledge about specific therapeutic lifestyle changes and the DASH diet among patients with hypertension and 2) to increase the awareness among healthcare professionals of the need to provide patient education on lifestyle modifications for hypertension.

METHODS: A 9-item questionnaire about the DASH diet and JNC-VII recommendations was designed by the principal investigators. The questionnaire will be randomly administered to consenting, English-speaking and English-reading, adult (18 years or older) patients with hypertension identified by ICD-9 code 401, who present to the family medicine center for primary healthcare services between December 2005 and March 2006. Patient responses will be stratified based on demographics to explore relationships between questionnaire scores and demographic information. Results will be presented to the family practitioners, and a patient counseling training session on lifestyle modifications for hypertension will be given.

RESULTS: In progress. To date, 13 patients have completed the questionnaire. The average age of the participants was 55.7 years. Eighty percent of the participants were female. Sixty-six percent were Caucasian. All patients reported completing some college courses. All patients reported having hypertension for more than 5 years, and all had at least one co-morbid condition. Sixty percent of the participants stated they had some form of nutritional and lifestyle counseling by a healthcare professional. Only 2 participants reported previously hearing of the DASH diet. The most commonly incorrectly answered questions were related to recommendations on daily intake of fruits and vegetables, definition of low sodium, the allotted daily sodium intake for patients with hypertension, and the recommendation for physical activity.

CONCLUSION: More emphasis is needed to be given to providing specific lifestyle and dietary recommendations to patients with hypertension. Pharmacists have a vital role in providing counseling on the DASH diet and JNC guidelines.

178. Comparing two methods for assessment of adrenal function in critically ill patients. Mallika P. Patel, Pharm.D., candidate; Kristal L. Williams, Pharm.D.; Butler University College of Pharmacy and Health Sciences; Methodist Family Practice Center, Indianapolis, IN.

PURPOSE: Currently, the most common method at our institution to determine appropriateness of steroid treatment in the critically ill adult patient population is to perform a corticocortisol stimulation test to assess patient's response. An alternative method of using a baseline cortisol level < 25 µg/dL may indicate patients with adrenal insufficiency, and therefore those who would benefit from treatment with steroids. The purpose of this study is to determine if the rate in which patients that had a baseline cortisol level < 25 µg/dL could be diagnosed with adrenal insufficiency without having a stimulation test performed for the diagnosis.

METHODS: Medical records of 58 adult patients admitted to the Intensive Care Units at the University of Kentucky Chandler Medical Center who were administered a dose of cosyntropin were reviewed. Patient's baseline cortisol levels, results of corticocortisol stimulation test, and date of steroid initiation were documented as primary endpoints. Secondary data obtained included length of steroid treatment, appropriateness of steroid taper, duration of vasopressor therapy, length of stay (hospital and ICU), survival data, and use of drotrecogin alfa.

RESULTS: Data will be reported based on the patient population identified between the time period of July 1, 2004 and June 30, 2005 who were administered a dose of cosyntropin for use in diagnosis of cortical response. The retrospective data collection and analysis will be completed by April.

CONCLUSION: This data may provide rationale to support using a single baseline cortisol level to predict adrenal insufficiency and responsiveness to corticosteroids in critically ill adult patients.

179. Antibiotic administration times in a septic population from a multidisciplinary perspective. Jeffrey G. Biermann, B.S., Pharm; Midwestern University, Downers Grove, IL.

PURPOSE: Severe sepsis, with an incidence of 300 cases per 100,000 in the United States, will become an ever increasing dynamic problem. Appropriate treatment with and early initiation of antibiotics has been shown to decrease death rate among patients admitted for severe infections. Appropriate initiation of antibiotics has been defined as treatment initiated within 24 hours of established sepsis onset. To our knowledge, no study has been published which examines the interacting role of physician ordering, pharmacy data entry, and drug availability in the administration of antibiotics to the septic population. This study will examine various processes in the continuum of ordering to administration of antibiotics from a physician, nursing, and pharmacy perspective in a population of severe sepsis and septic shock patients.

METHODS: Retrospective chart review will be conducted on 100 patients (planned) at Northwest Community Hospital admitted with sepsis who are enrolled as part of the CHASE (Community Hospitals Against the Sepsis Epidemic) study.

RESULTS: The results of this study will primarily be descriptive in nature. Various analyses are planned, including time to first dose of antibiotic based on location of order (e.g., ER, ICU, floor), time for pharmacy data entry and subsequent delivery to nursing staff, time the antibiotic was actually administered by nursing staff, and time of the day and week the order was written (to find a correlation/discordance between pharmacy services operating under higher staff volumes during the day versus lower volumes during evening and weekend hours).

CONCLUSIONS: Physicians, pharmacists, and nursing staff all play a critical role in the early administration of antibiotics in the septic population. Pharmacy order entry times have a direct effect on nursing administration times and may improve patient outcomes.

180. The prevalence and mechanism of ceftazidime resistance in Pseudomonas aeruginosa. Amy N. Schilling, B.S.1, Kevin W. Gary, Pharm.D.1, Mark T. L. Rocco, Ph.D.2, Vincent H. Tam, Pharm.D.1, (1)University of Houston College of Pharmacy, Houston, TX, (2)St. Luke's Episcopal Hospital, Houston, TX.

PURPOSE: Pseudomonas aeruginosa (PA) is a common cause of nosocomial infections, and ceftazidime (CAZ) is often used to treat these infections. PA resistance to CAZ is an increasing problem which could be due to multiple mechanisms of resistance. The purpose of our study was to determine the predominant mechanism of CAZ resistance in our institution.

METHODS: Bloodstream PA isolates from 2003 were obtained from St. Luke’s Episcopal Hospital. The susceptibility to CAZ, ceftazidime (CLA) was determined using Etest, to assess the presence of plasmid mediated extended spectrum β-lactamase (ESBL). A spectrophotometric assay was performed using nitrocefin as the substrate to confirm β-lactamase overproduction in the PA resistant isolates. The pI of the cell lysate was assessed using isoelectric focusing with/without claxolin (CLX). Point mutations in ampC and ampR (negative regulatory gene for AmpC production) genes of the CAZ resistant isolates were screened using polymerase chain reaction. RESULTS: Of the 76 PA isolates collected, 14 were found to be resistant to CAZ, and the susceptibility was not reversed in the presence of CLA. The spectrophotometric assay established a greater than 10-fold increase in enzymatic activity compared with a microbiological wild-type standard (ATCC 27853) which was most likely AmpC. (pI=8.7, inhibited by CLX). Point mutations in ampC and ampR genes were detected 12 and 9 out of the 14 CAZ-resistant isolates, respectively.

CONCLUSION: The prevalence of CAZ resistance in PA isolates was found to be 18%. The predominant mechanism of CAZ resistance was due to an overproduction of AmpC.
submitted substantially decreased the amount of time and costs absorbed by the medical clinic. By limiting the cost associated with providing this program, there is a greater chance that medical clinics will include this service in their care to the medically indigent population.

182. Changes in lipid lowering and heart failure medications associated with thiazolidinedione (TZD) use in a Medicaid population. Stacia Topham, Pharm.D., Candidate, Christopher T. Owens, Pharm.D., Rex W. Force, Pharm.D., BCPS; Idaho State University College of Pharmacy, Pocatello, ID.

PURPOSE: Available evidence suggests equivalent glycemic control and propensity to induce fluid retention with both pioglitazone and rosiglitazone. However, recent data suggest differences in lipid effects. The purpose of this study was to evaluate changes in drug therapy reflecting potential adverse effects of TZDs on fluid retention and lipids.

METHODS: Retrospective review of Medicaid claims was performed identifying Type 2 diabetics, aged greater than or equal to 50, who received greater than or equal to 10 of 12 months of therapy with pioglitazone or rosiglitazone from 3/1999-11/2004. TZD patients were matched to diabetic controls not receiving a TZD. An index date (ID) was defined as the start date of TZD. CHF and lipid medication dosages were assessed for 12 months following ID by calculating mean daily dose per member per month (PMPM) for each medication (furosemide, ACE inhibitors, statins, fibrates). Mean percent of patients receiving these drugs was also analyzed.

RESULTS: Four hundred seventy-two pioglitazone and 331 rosiglitazone patients were matched with 419 control patients. The mean change in percent of patients on furosemide over 12 months was +4.6%, +3.7%, and -1.3% for pioglitazone, rosiglitazone, and control, respectively. The mean change in furosemide dose over 12 months was +3.20 mg, +2.25 mg, and -1.21 mg PMPM for pioglitazone, rosiglitazone, and control, respectively. Statistical analysis and results for lipid-lowering and ACE inhibitor therapy will be available at the time of poster presentation.

CONCLUSIONS: Preliminary analysis of this research in progress indicates that the chronic use of either TZD is associated with increased diuretic utilization. Data on the usage of ACE inhibitors and lipid lowering agents will be made available at the time of poster presentation.

183. New diagnosis of CHF/edema and dyslipidemia associated with thiazolidinedione (TZD) use in a Medicaid population. Stacia Topham, Pharm.D., Candidate, Christopher T. Owens, Pharm.D., Rex W. Force, Pharm.D., BCPS; Idaho State University College of Pharmacy, Pocatello, ID.

PURPOSE: Available evidence suggests equivalent glycemic control and propensity to induce fluid retention with pioglitazone and rosiglitazone. However, recent data suggest differences in lipid effects. The purpose of this study was to evaluate the number of patients with new diagnoses of CHF, edema, and dyslipidemia after starting a TZD.

METHODS: Retrospective review of Medicaid claims was performed identifying Type 2 diabetics, aged 50 and older, who received greater than 10 of 12 months of therapy with pioglitazone or rosiglitazone from 5/1999-11/2004. Patients were matched to diabetic controls not receiving a TZD. An index date (ID) was defined as the start date of TZD. New diagnoses of CHF, edema, and dyslipidemia were analyzed for 12 months following ID. Relative risks (with 95% CI) versus control and between TZDs were calculated.

RESULTS: Four hundred seventy-two pioglitazone and 331 rosiglitazone patients were matched with 419 control patients. At baseline, CHF and edema were more common in controls than TZD patients (p<0.05); dyslipidemia was less common in controls (p<0.05). There were no baseline differences between the TZDs. New CHF was identified for 5.72%, 4.90%, and 7.64%, of the pioglitazone, rosiglitazone, and control groups, respectively (p=0.05). New edema was identified for 4.45% (RR=1.33, 95% CI 1.09–1.80 vs. control), 6.97% (RR=1.47, 95% CI 1.18–1.84 vs. control), and 2.15% of the pioglitazone, rosiglitazone, and control groups, respectively (p=0.05). New dyslipidemia was identified for 11.23% (RR=1.92, 95% CI 1.13–1.70 vs. control), 12.05% (RR=1.39, 95% CI 1.17–1.66 vs. control), and 6.92% of the pioglitazone, rosiglitazone, and control groups, respectively. There were no statistically significant differences between pioglitazone and rosiglitazone with regard to the development of any diagnoses.

CONCLUSIONS: Compared with controls, TZD use was associated with an increased risk of developing edema and dyslipidemia. However, the risk of development of CHF was not increased in patients receiving a TZD.
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