and 2005-06 National Ambulatory Medical Care Survey and the outpatient department component of the National Hospital Ambulatory Medical Care Survey was conducted to examine maternal characteristics and physician characteristics associated with Category D and X prescriptions. Descriptive statistics and logistic regression analysis were performed to determine the time trend and predictors associated with prescribing category D and X drugs. **RESULTS:** Approximately 35 million visits were made by pregnant women annually during these years. Of these visits, 1.4% (95%Confidence Interval (CI):1.13-1.77%) of the visits involved prescription of Category D drugs and 1.1% (CI:0.6-1.4%) of the visits involved prescription of Category X drugs. A significant positive time trend was observed in prescribing of category D and X drugs in 2005-06 (OR-2.14, 95%CI:1.23-3.73) compared to 1997-98. Pregnant women above the age of 30 had greater odds (OR-1.62, 95%CI:1.08-2.44) of receiving these drugs than pregnant women below the age of 30. Pregnant women who received ≥2 medications had greater odds (OR-15.31,95%CI:9.02-26.01) of receiving these drugs than who received ≤1 medication. Significant differences across physician specialty and race were also observed. **CONCLUSIONS:** Both maternal and physician characteristics play a role in prescribing of Category D and X drugs. With increase in use of category D and X drugs, more research is needed to evaluate the clinical consequences of these prescribing practices.

Health Care Use & Policy Studies – Quality of Care

PHP91

ASSOCIATION BETWEEN QUALITY OF CARE AND SHORT TERM OUTCOMES FOR VERY OLD PATIENTS HOSPITALIZED FOR ACUTE ILLNESSES

Chong WF[1], Ding YY[2], Sun Y[1], Heng BH[1]
[1]*National Healthcare Group, Singapore,* [2]*Tan Tock Seng Hospital, Singapore*

OBJECTIVES: To determine the association between quality of hospital care, using selected Assessing Care of Vulnerable Elders (ACOVE) quality indicators, and short term outcomes for very old patients admitted for acute illnesses in a tertiary hospital. **METHODS:** This is a retrospective review of medical records of a random sample of all patients aged 80 years and above admitted to the Department of General Medicine and Department of Geriatric Medicine from 2005 to 2008, with an equal number of cases (750) selected for each year. The quality indicators selected were cognitive and functional assessment, discharge planning, delirium evaluation and treatment, mobilization, and aspiration precautions. If patients met the inclusion criteria for each specific quality indicator, they were assessed to determine if the process-of-care was carried out and documented. The outcomes of interest were inhospital mortality, 30-day mortality and hospital readmission within 15 days of discharge. **RESULTS:** From the review of 2,923 cases, the adherence for the quality indicators ranged from 33.8% for cognitive and functional assessment to 88.1% for discharge planning. In univariate analyses, adherence to delirium evaluation and treatment was associated with a reduction in inhospital (17.5% vs 26.1%, p=0.004) and 30-day mortality rates (22.6% vs 32.5%, p=0.002). Documentation of cognitive and functional assessment was associated with a reduction in inhospital (6.2% vs 16.2%, p<0.005) and 30-day mortality rates (10.3% vs 22.3%, p<0.005). The association between adherence to quality indicators and hospital readmission was not statistically significant. After adjustments using the biovariate probit regression, adherence to aspiration precautions was associated with lower inhospital mortality (rho=-0.128 (95% Confidence Interval: −0.233,-0.021). **CONCLUSIONS:** Adherence to selected process-of-care quality indicators was generally low. Adherence to aspiration precautions was the only quality indicator that had an impact on the short term outcome for elderly patients hospitalized for acute medical conditions.

PHP92

RESULTS OF A PHARMACY MANAGEMENT PROGRAM FOR IMPROVING MEDICATION ADHERENCE

Regine ML, Bunz TJ
CIGNA HealthCare, Bloomfield, CT, USA

OBJECTIVES: CIGNA's CoachRx pharmacy management program provides services to pharmacy customers with medication adherence and/or medication safety issues/concerns. In this study, telephonic engagement with a CoachRx pharmacist initiated the process. The aim of this analysis was to evaluate the effect of the CoachRx program on medication adherence; use of mail-order pharmacy services; utilization of generic, preferred, and non-preferred-brand medications; and ingredient costs. **METHODS:** A pre/post comparison spanning one year (6mo pre/6mo post) was conducted. Adherence was measured at the customer level. Continuously enrolled individuals were identified, and the following demographic information was collected: age, sex, and employer. Medication possession ratio was used to measure adherence for five classes of medications: asthma, depression, diabetes, dyslipidemia, and hypertension. Use of mail order pharmacy products, gaps-in-care measures, and patient-requested, targeted medication switches were evaluated at the medication level. **RESULTS:** Across the classes of medications, four of the five showed an increase in adherence following enrollment in CoachRx. Among the customer subgroup sub-optimally adherent (MPR < 80%) prior to enrolling in CoachRx, there was a statistically significant increase in adherence for all five medication classes. Compliance to adherence related gaps-in-care increased by 4% and the number of treatments filled solely through mail-order pharmacy increased by 11% following enrollment. There was a 14.4% decrease in the share of non-preferred brand medications, with no change in preferred brand medications and a 2.2% increase in generic medications. Among the study participants, there were 40 confirmed patient-requested switches from targeted medications, with an average ingredient cost savings of $661 per switch per year. **CONCLUSIONS:** The main goal of CoachRx, to drive appropriate use of pharmacotherapy, was achieved in the six-month, post-enrollment period. Improvement in care over such a short period is a positive finding. These improvements may have an even greater impact on future medical costs and may lead to continued reductions in medication costs.

PHP93

AN EXAMINATION OF HOSPITAL-ACQUIRED CONDITIONS BY AGE AND PAYER IN FIFTEEN STATES, 2008

Maeda JL[1], Parlato J[2], Levit K[1], Andrews RM[3], Jiang HJ[3]
[1]*Thomson Reuters, Washington, DC, USA,* [2]*Thomson Reuters, Cambridge, MA, USA,* [3]*Agency for Healthcare Research and Quality (AHRQ), Rockville, MD, USA*

OBJECTIVES: The Centers for Medicare and Medicaid Services (CMS) has identified several preventable adverse events, known as hospital-acquired conditions (HACs), that in most cases CMS will not allow additional reimbursement to hospitals. HACs are common or costly conditions that are acquired during the hospital stay and could have been prevented through the application of evidence-based guidelines. CMS has identified ten categories of HACs that are deemed to be preventable causes of morbidity and mortality. The objective of this study was to document the prevalence of HACs for all-payers and to differentiate the impact of HACs by payer and age group. **METHODS:** The study design was a retrospective cohort from the 2008 Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID) files. We used the CMS definition to identify HACs from the present-on-admission (POA) indicator associated with secondary diagnoses in the SID. The SID are the only multi-state all-payer data available that include the POA indicator needed to identify HACs. We studied adult, non-maternal, medical-surgical or selected surgical discharges, depending on the HAC, from community, non-rehabilitation hospitals in fifteen states that reported POA indicators to HCUP. **RESULTS:** Falls or trauma was the most prevalent HAC in our sample. For selected surgical procedures, deep vein thrombosis/pulmonary embolism had the highest rate of HACs (832 per 100,000 hip or knee replacement discharges). Medicaid discharges had about twice the rate of manifestations of poor glycemic control and more than twice the rate of selected surgical site infections relative to Medicare discharges. For the conditions of stage III and IV pressure ulcers, falls and trauma, catheter-associated urinary tract infection, and deep vein thrombosis/pulmonary embolism the relative risk of acquiring a HAC increased with age. **CONCLUSIONS:** The rate of HACs differed by payer and age group. Thus, it is important to consider examining HACs by all third-party payers.

Health Care Use & Policy Studies – Regulation of Health Care Sector

PHP94

THE ROLE OF HEALTH-RELATED QUALITY OF LIFE DATA IN THE DRUG APPROVAL PROCESSES IN THE UNITED STATES AND EUROPE: A REVIEW OF GUIDANCE DOCUMENTS AND AUTHORIZATIONS OF MEDICINAL PRODUCTS FROM 2006 TO 2010

Marquis P[1], Caron M[2], Emery MP[2], Scott J[3], Acquadro C[2]
[1]*MAPI Values, Boston, MA, USA,* [2]*MAPI Research Trust, Lyon, France,* [3]*MAPI Values, Macclesfield, UK*

OBJECTIVES: The objective of this research was to review the extent to which HRQL and other PROs have played a role in drug approval and labeling since the FDA issued its draft guidance on the use of PRO measures and the EMA, its reflection paper on HRQL in 2006. **METHODS:** This research was conducted through a systematic manual review of therapy area-specific regulatory guidelines (US and EU) and product labelings issued during the period of January 1, 2006 to November 16, 2010. **RESULTS:** Fifteen and 34 guidance documents were released by the FDA and the EMA respectively, containing recommendations for the inclusion of PRO endpoints in clinical trials. The FDA referred to HRQL (as a secondary endpoint) in three of the 15 (20%) guidance. The EMA recommended use of HRQL endpoints in 22 of the 34 (65%) guidance. The FDA approved 93 products with label claims that included PRO endpoints (out of 432 total approvals). Of those, 8 products (8.6% of all products with a PRO claim) documented treatment benefits characterized as HRQL. The EMA approved 54 products that included PRO endpoints (out of 248 total approvals), of which 16 products (29.62% of all products with a PRO claim) reflected HRQL data. **CONCLUSIONS:** Our review showed that patients' perspective in clinical research is important for the EMA and FDA, with HRQL endpoints still playing a minor role. Our analysis suggests that EMA's receptivity to HRQL endpoints is greater than FDA's, more sensitive to patient symptoms-based data. For the future, we believe that patients' involvement should be extended to get a more precise idea of the PROs relevant to them. Other key players involved in reimbursement and pricing decisions might have their say since financial health resources will become scarce and that assessing value for money will be more crucial.

PHP95

EXPECTED CHANGES IN HEALTH CARE UTILIZATION DUE TO PATIENT PROTECTION AND AFFORDABLE CARE ACT

Ghushchyan VH[1], Sullivan PW[2], Naim A[3], Nair KV[1]
[1]*University of Colorado, Denver, Aurora, CO, USA,* [2]*Regis University School of Pharmacy, Denver, CO, USA,* [3]*Centocor Ortho Biotech Services, LLC, Horsham, PA, USA*

OBJECTIVES: On March 23, 2010 the Patient Protection and Affordable Care Act (PPACA) was signed into a law providing health insurance coverage for approximately 32 million uninsured Americans. The objective is to determine the expected changes in health care utilization for the uninsured after 2014 when key provisions of PPACA law become effective. **METHODS:** Medical Expenditure Panel Survey data (2008) was used for the analysis. The differences in health care utilization between the uninsured and those with private or Medicaid coverage was estimated using a

negative binomial regression model, controlling for age, gender, race/ethnicity, income education, general physical and mental health and co-morbidity burden. In 2014 depending on family income and employment status, the uninsured will either obtain private or Medicaid insurance coverage, thus the analysis was restricted to individuals less than 65 years with 12 months of continuous private or Medicaid converge or uninsured for the whole year. Our study sample was nationally representative on behalf of 71.3% of US population. **RESULTS:** Five measures of health care utilization were used (emergency room (ER) visits, outpatient visits, office visit, inpatient visits, prescription use). Uninsured individuals had lower utilization for all health care services except ER visits. Holding everything else constant, the uninsured will have 1.98 (1.75-2.25) and 1.61 (1.24-2.1) times higher expected rate of office based visits, 2.39 (1.81-3.15) and 2.62 (1.41-4.86) times higher expected rate of outpatient visits, 2.17 (1.58-2.97) and 1.70 (1.11-2.62) times higher expected rate of inpatient visits, 1.70 (1.53-1.89) and 1.92 (1.57-2.34) times higher expected rate of prescribed medication use after obtaining private or Medicaid coverage, respectively. **CONCLUSIONS:** Health care reform will increase the demand for health services and prescribed medications, except ER use for the uninsured. These results may be used by various stakeholders to estimate expected changes in health care expenditures.

PHP96

REASONS FOR REJECTION OF PRO LABEL CLAIMS: AN ANALYSIS BASED ON A REVIEW OF PRO USE AMONG NEW MOLECULAR ENTITIES AND BIOLOGIC LICENSE APPLICATIONS 2006-2010

DeMuro C[1], Clark M[2], Mordin M[2], Evans E[1], Copley-Merriman K[2], Fehnel SE[1], Gnanasakthy A[3]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*RTI Health Solutions, Ann Arbor, MI, USA,* [3]*Novartis, East Hanover, NJ, USA*

OBJECTIVES: Previous analyses of PRO label claims concentrated only on successful label claims. The goal of this research was to explore the reasons why PRO label claims were either denied or not sought. **METHODS:** Using the FDA Drug Approval Report Webpage, all approved new molecular entities (NMEs) and biologic license applications (BLAs) between February 2006 and December 2010 were identified. For identified drug products, medical review sections from publicly available summary basis of approvals (SBAs) were reviewed to identify PRO endpoint status and any FDA Study Endpoints and Label Development comments. **RESULTS:** Out of the 116 NMEs/BLAs identified and accompanying SBAs reviewed, 44.8% of products included PROs as part of the pivotal studies; however, only 24.1% received PRO claims. Primary reasons for denial (where data available) included a lack of demonstration of content validity (inclusive of general measures such as the EQ5D and SF-36) as well as use of PROs to assess symptoms in an open-label setting, lack of consensus on clinically meaningful change, interpretation of or missing PRO data, lack of measurement of full constellation of symptoms, issues of multiplicity and concerns of "bias" in certain PRO measures. **CONCLUSIONS:** Nearly half (45%) of submissions included PROs yet this rate is not reflected by claims granted. Understanding the nature of PRO claims granted under the current regulatory guidance is important. Additionally, a clear understanding of claims denied yields valuable insight into where sponsors may improve implementation of PROs in clinical trials and the PRO evidence submitted in order to increase the likelihood of obtaining PRO label claims.

PHP97

PRO LABEL CLAIMS: AN ANALYSIS BASED ON A REVIEW OF PROS AMONG NEW MOLECULAR ENTITIES AND BIOLOGIC LICENSE APPLICATIONS 2006-2010

Mordin M[1], Clark M[1], DeMuro C[2], Evans E[2], Copley-Merriman K[1], Fehnel S[2], Gnanasakthy A[3]
[1]*RTI Health Solutions, Ann Arbor, MI, USA,* [2]*RTI Health Solutions, Research Triangle Park, NC, USA,* [3]*Novartis Pharmaceuticals, East Hanover, NJ, USA*

OBJECTIVES: Wilke and colleagues (2004) previously conducted a review of effectiveness endpoints reported in the labels of new drug products approved in the United States (US) between 1997-2002 to determine the extent and type of PRO endpoints utilized. They reported that 30% of product labels reviewed included PROs. Our study aimed to build upon this work by describing the current state of PRO label claims granted for new molecular entities (NMEs) and biologic license applications (BLAs) following release of the draft and final FDA PRO Guidance documents (i.e., since February 2006). **METHODS:** Using the FDA Drug Approval Reports webpage, all FDA approved NMEs and BLAs between February 2006 and December 2010 were identified. Generic products with tentative approvals granted in this period were excluded. For all identified drug products, medical review sections from publicly available summary basis of approvals (SBAs) were reviewed to identify PRO endpoint status. Product labels (indication, clinical trials sections) were reviewed to determine the number and type of PRO claims. **RESULTS:** Of the 116 NMEs/BLAs identified, 28 (24.1%) were granted PRO claims. The majority (n=24) were for signs and symptoms. Nine of the signs and symptom claims were pain-related. Of the 28 products with PRO claims, a PRO was a primary endpoint for 20 (71%). All 20 of these primary endpoints were symptom-related and the majority (12 of 20) were collected via diary. **CONCLUSIONS:** PRO claims continue to be approved by FDA, with 24% of NMEs and BLAs granted PRO claims. Successful PRO label claims over the past five years have been largely in support of treatment benefit for symptoms specified as primary endpoints. The proportion of NMEs with PRO label claims during the post-guidance period (24.1%) was lower than that of the pre-guidance period (30%).

PHP98

A TREND ANALYSIS OF NEW MOLECULAR ENTITIES WITHDRAWN FOR SAFETY REASONS FROM 1980 TO 2009 IN THE UNITED STATES

Seoane-Vazquez E[1], Rodriguez-Monguio R[2], Qureshi ZP[3], Szeinbach SL[4]
[1]*Massachusetts College of Pharmacy & Health Sciences, Boston, MA, USA,* [2]*University of Massachusetts, Amherst,, MA, USA,* [3]*University of South Carolina, Columbia, SC, USA,* [4]*Ohio State University, Columbus, OH, USA*

OBJECTIVES: Besides the influence of economic factors, prescribing patterns, and market dynamics, decisions to withdraw products from the market are driven by concerns over safety. This study evaluated new molecular entities (NMEs) approved by the FDA in the period 1980-2009 that were withdrawn from the market for safety reasons. **METHODS:** Data were obtained from the FDA and the US Federal Register. Descriptive analyses were used to classify product discontinuations by therapeutic category, year, and reason for discontinuation. **RESULTS:** There were 740 NMEs approved by the FDA during the study period. As of December 1, 2010, the number of drugs discontinued was 118 (15.9%). Safety was the reason for withdrawing 27 (3.6%) drugs from the market. Therapeutic categories with the most safety withdrawals as a percentage of approvals in the 1980s were respiratory (28.6%), musculo-skeletal (23.1%), and nervous system (7.4%). During the 1990s, classes with the most safety withdrawals as a percentage of approvals were musculoskeletal (18.8%), alimentary tract and metabolism (12.0%), and blood and blood forming organs (7.7%). Therapeutic categories affected by safety withdrawals as a percentage of approvals in the 2000s were musculo-skeletal (20.0%), alimentary tract and metabolism (4.2%), and antineoplastic and immunomodulating agents (3.2%). Major problems that spurred safety withdrawal were hepatic toxicity, severe cardiovascular effects, and gastrointestinal issues. Average time from approval to safety withdrawal was 5.9 (SD = 5.0) years, with a range of 0.3-18.2 years, and a 95% CI of 4.0-7.8 years. **CONCLUSIONS:** Approximately one in seven NMEs approved in the period 1980-2009 was discontinued from the market. Less than one-quarter of the discontinuations were attributed to safety reasons. Products remained in the market for an average of six years before safety withdrawal. An ongoing evaluation of new drugs through their product life cycle is important to determine their long-term safety and value to society.

PHP99

WILL BIOPHARMACEUTICAL INNOVATION STILL BE A PICTURE OF HEALTH AFTER IMPLEMENTATION OF HEALTH CARE REFORM?

Ross KD
University of Washington, Seattle, WA, USA

OBJECTIVES: To determine what impact shortening or lengthening the data exclusivity period (DEP) for biologic drugs has on innovation. As a part of this, the goal is to determine what effects on innovation the 12-year DEP included in healthcare reform will have. **METHODS:** A simulation model is developed to assess the profitability of candidate drugs under varying DEPs. All costs and revenues are discounted. The drugs are then grouped into 10-drug portfolios and the profitability of each portfolio is determined. The percentage of portfolios that are profitable under each DEP length is divided by the percentage of portfolios that are profitable under a indefinite DEP to give a relative level of innovation. **RESULTS:** A DEP of 0 years yields a 60% decrease in the level of innovation and there are no increases in innovation for DEPs above 34 years. For a DEP of 12 years, there is an expected 8.1% decrease in the level of innovation. **CONCLUSIONS:** The 12-year DEP implemented as a part of healthcare reform is likely to decrease innovation in biologic drugs. The expected 8.1% decrease in innovation may or may not be worth the expected decrease in prices once biosimilar competitors enter. The model also indicates that there would be no returns to innovation by increasing DEP above 34 years, and as such, it is likely that this would represent a maximum when selecting a DEP.

PHP100

PRICING AND REIMBURSEMENT OF ORPHAN DRUGS IN CANADA

Kumar J, Bachman EM
HERON Evidence Development LLC, Somerville, NJ, USA

OBJECTIVES: The Canadian Organization of Rare Diseases (CORD) defines a rare disease as one that afflicts less that 1 person in 200 000. Significant market access and pricing challenges exist for ODs in Canada both at a federal and the provincial level. The scope of this study is to describe the ODs regulations in Canada, evidence requirements by the national regulatory agency, national and regional funding criteria, market access challenges associated with ODs, and approaches to obtain access to ODs in Canada. **METHODS:** Non-systematic PubMed search, Health Canada, the Canadian Agency for Drug and Technology in Health (CADTH), Common Drug Review (CDR), Canadian Organization of Rare Diseases (CODR) and different provinces Ministries of Health websites. **RESULTS:** Health Canada reviews ODs to ensure that the drug meets the criteria of efficacy, safety, and manufacturing quality. The CDR conducts the clinical and cost effectiveness review compared to existing therapies and makes positive or negative recommendations to provinces to list ODs in their respective formularies. At the federal level, pricing of ODs is regulated by Patented Medicine Pricing Review Board (PMPRB). At the provincial level, different provinces can make their own independent reimbursement decision irrespective of CDR's recommendation. Due to the large budget impact of ODs, most provinces do not provide access. The specialized access mechanism, criteria for eligibility, extent of coverage, and different data requirement to obtain access in three important provinces of Canada (Ontario, Alberta, and Quebec) will be discussed in the poster. **CONCLUSIONS:** In the absence of a national orphan drug policy, patients suffering from rare diseases face challenges in obtaining access to ODs in Canada. However, significant opportunities exist for manufacturers to provide access to ODs in Canada.