comprising >100 US hospitals, we identified admissions (1/1/2007 - 6/30/2010) with cSSSI who received initial antibiotic therapy with vancomycin or daptomycin. A propensity score model was estimated, using demographics, comorbidities, laboratory values, and receipt of vancomycin ≤30 days prior to hospitalization. Vancomycin patients were matched 1:1 to daptomycin patients in stepwise fashion to minimize the difference in propensity scores for each matched pair (i.e., "greedy" matching). **RESULTS:** We identified 347 patients who received daptomycin and 8963 patients who received vancomycin as initial antibiotic therapy for cSSSI. Four hospitals contributed 54% of daptomycin patients, but only 17% of vancomycin patients. Daptomycin and vancomycin patients differed significantly in a number of respects. Only 47.6% of daptomycin patients could be matched to vancomycin patients (i.e., most patients had nonoverlapping propensity scores). Unmatched daptomycin patients were older than those in the matched subset (mean age: 57.3yrs vs. 52.3yrs); they also were more likely to have chronic/ulcerative infections (23% vs. 10%), comorbidities (e.g., diabetes [19% vs. 0%], malnutrition [4% vs. 0%], alcohol/drug abuse [11% vs. 1%]), and to have been hospitalized previously (63% vs. 39%) (all $p<0.01$). **CONCLUSIONS:** While PSM is often used to control for selection bias, the problem of nonoverlapping propensity score distributions is often overlooked and can adversely impact generalizability. Use of PSM to control for selection bias in "real-world" comparisons of initial antibiotic therapy for infectious diseases may be limited; alternate study designs may be needed.

PODIUM SESSION II: COMPARATIVE EFFECTIVENESS RESEARCH & HEALTH CARE

CE1

COST EFFECTIVENESS TRENDS OF HIGH BUDGET IMPACT DRUGS (2006-2012)

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of $1.1 billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$90-100B worldwide sales) **METHODS:** The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase "cost effectiveness" in abstract of the published study. **RESULTS:** During 2005-2010, the number of published studies on "cost effectiveness" have increased by more than 30%. There is a large variability in CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, especially for time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

CE2

COMPARATIVE EFFECTIVENESS OF MONOTHERAPY WITH MOOD STABILIZERS VERSUS ATYPICAL ANTIPSYCHOTICS FOR THE TREATMENT OF BIPOLAR DISORDER IN CHILDREN AND ADOLESCENTS: A RETROSPECTIVE CLAIMS-DATA STUDY

Mehta S[1], Patel A[2], Aparasu RR[2], Perez MO[3], Chen H[2]
[1]*Pharmerit North America, LLC., Bethesda, MD, USA,* [2]*University of Houston, Houston, TX, USA,* [3]*Legacy Community Health Services, Houston, TX, USA*

OBJECTIVES: Monotherapy with a mood stabilizer (MS) or second generation antipsychotic (SGA) is recommended as the first-line treatment for pediatric bipolar disorder (PBD). The existing evidence regarding the relative effectiveness of MSs and SGAs for PBD is predominantly based on short-term studies and does not adequately address long-term effectiveness. This study compared adherence, persistence, and bipolar-related hospitalization of these treatments during a one-year observation period. **METHODS:** The 2003-2007 Medicaid Analytic eXtract data for four states were used. Bipolar children and adolescents (aged 6-18 years) initiating treatment with SGA or MS monotherapy were identified. Adherence was measured using medication possession ratio (MPR) and persistence was measured as time to medication discontinuation and time to augmentation. Survival Analyses was conducted to compare time to first bipolar-related hospitalization, time to discontinuation and time to augmentation between MS and SGA recipients during a one-year period after treatment initiation. Heckman's Two-Step Selection Correction was used in all survival models to control for treatment selection bias. **RESULTS:** A total of 8424 PBD patients were identified. Prescription of SGAs (64.08%) was predominantly higher than that of MSs (35.92%). The most frequently prescribed SGA was risperidone, followed by quetiapine and aripiprazole. Divalproex sodium and oxcarbazepine were most frequently prescribed among MSs. 55% of the patients initiated on either of the therapeutic category were fully adherent. After correcting for selection bias, there was no statistically significant difference in the MPR, time to discontinuation and time to hospitalization between the two study groups. Patients initiating on SGAs took a longer time to augment (Hazard Ratio: 0.71; 95%CI: 0.57-0.88) with MSs as compared to those who initiated with MSs. **CONCLUSIONS:** Although SGAs were prescribed predominantly more than MSs, the two therapeutic classes were comparable in adherence and preventing bipolar related hospitalization. SGAs appeared to be slightly better than MSs in terms of time to augmentation.

CE3

GRACE CHECKLIST: RATING THE STRENGTH OF EVIDENCE FOR OBSERVATIONAL STUDIES OF COMPARATIVE EFFECTIVENESS

Dreyer N[1], Velentgas P[1], Duddy A[1], Westrich KD[2], Dubois RW[2]
[1]*Outcome, A Quintiles Company, Cambridge, MA, USA,* [2]*National Pharmaceutical Council, Washington, DC, USA*

OBJECTIVES: Observational studies are often necessary for assessing the comparative effectiveness of therapeutics in "real-world" settings. The strength of evidence generated by individual studies, however, varies. We describe the development of the GRACE Checklist, a tool for rating the quality of observational CER and assessing whether studies merit consideration for decision making. **METHODS:** A checklist was developed based on existing guidelines for the conduct and reporting of observational studies, including the GRACE Principles, and existing scales for the inclusion of observational studies in systematic reviews. An external advisory board reviewed the checklist content and scoring options; majority opinion of the advisors was used to refine the question items and scoring. The construct validity of the checklist was measured using two rounds of testing where over 100 volunteer testers rated articles, to determine if the checklist can distinguish studies of known quality. Articles of "known quality" were first extracted from systematic reviews and then, in the second round, were based on reviews of observational CER studies by recognized experts. **RESULTS:** Two domains, internal validity and applicability, were identified for inclusion with a total of 15 questions. Results and proposed scoring algorithms will be presented for a categorical assessment of study quality to determine if studies are 1) of sufficient quality for decision support; 2) sufficiently flawed to make interpretation unreliable; or 3) require additional consideration. First round testing results showed that subsets of item responses could yield positive predictive values for identifying high quality studies as high as 0.86, and negative predictive values as high as 0.91. **CONCLUSIONS:** A validated checklist to assess the quality of observational CER can help decision makers recognize strong evidence without substantial advanced training.

CE4

A FRAMEWORK FOR STAKEHOLDER ENGAGEMENT IN COMPARATIVE EFFECTIVENESS RESEARCH

Lavallee DM[1], Desai PJ[1], Mullins CD[2], Deverka PA[1]
[1]*Center for Medical Technology Policy, Baltimore, MD, USA,* [2]*University of Maryland School of Pharmacy, Baltimore, MD, USA*

OBJECTIVES: Soliciting stakeholder input is becoming commonplace in comparative effectiveness research (CER), yet methods for stakeholder engagement in CER are evolving. Drawing from CMTP and University of Maryland's experiences across a variety of NIH, PCORI, and industry-funded activities as well as previously published case analyses, we describe a framework for stakeholder engagement in CER that standardizes approaches for generating meaningful evidence. **METHODS:** We conducted a literature search to explore engagement practices in biomedical sciences, social sciences, and business which included the gray literature. The results were combined with investigator experience to develop a process framework and corresponding activities for successful stakeholder engagement. **RESULTS:** We defined five steps- recruitment, preparation, engagement, dissemination, and evaluation- broadly applicable to stakeholder engagement. Recruitment should begin with clearly defined expectations for involvement and end with balanced representation of stakeholders that meet the needs of the project and disclose conflicts of interest. Preparing stakeholders for participation in CER requires customized and relevant background materials. Stakeholder engagement by an experienced facilitator should guide iterative engagement procedures by using deliberative methods that ensure a fair, competent and trustworthy process. Dissemination must document the stakeholders' input and how this information was incorporated into decision-making or pathways for implementation. Publications should also acknowledge stakeholder involvement and contributions. Following dissemination, evaluation provides both researchers and stakeholders an opportunity to assess the engagement experience and outcomes, which is necessary for refining practices for future work. **CONCLUSIONS:** CER is transitioning toward an interactive framework of stakeholder engagement that enhances the traditional research paradigm. This process model provides a standard methodology to guide this transition to stakeholder-based research. This process is adaptable across multiple CER activities including priority-setting, study design, and methods guidance as well as various therapeutic areas. Further research is needed to refine, evaluate, and apply this model to ongoing CER activities.

PODIUM SESSION II: CARDIOVASCULAR DISORDERS OUTCOMES RESEARCH

CV1

DIFFERENCES IN PROCESSES AND OUTCOMES OF CARE IN ELDERLY HYPERTENSIVE DIABETIC PATIENTS WITH AND WITHOUT DEMENTIA

Chitnis AS, Johnson ML
University of Houston, Houston, TX, USA

OBJECTIVES: To determine differences in processes and outcomes of care in elderly hypertensive diabetic patients with and without dementia. **METHODS:** This cross-sectional study was conducted using the household and medical provider component files of Medical Expenditure Panel Survey (MEPS) data from 2003, 2005, 2007 and 2009. Hypertensive diabetic patients >50 years of age were identified using