patients who recover to their pre-hospitalization EPO dose, post-hospitalization ESO dose increases frequently persist for several months, possibly due to missed ESA doses, lower Hb from hospital-related inflammatory states post-hospitalization. Strategies to address the causes of this should be evaluated.

PUK30
ONCE MONTHLY ERYTHROPOIESIS STIMULATING AGENT (ESA) DOSING MAY REDUCE ESA UTILIZATION COMPARED TO THREE-WEEKLY ESA DOSING
Band TC1, Rubin RJ1, Wang X4, Yang A2
1DaVita Clinical Research, Minneapolis, MN, USA; 2Affymetrix, Palo Alto, CA, USA
OBJECTIVES: US dialysis centers typically dose ESA at every session (3x/wk), enabling frequent titrations. A once-monthly ESA is currently under FDA consideration. We recently demonstrated that more frequent Hb measurements and cost savings of $5,028/month.
RESULTS: ESA dose increases frequently persist for several months, possibly due to increasing volumes of mean titrations and tests. Price (derived from published sources), dose and clinical equivalences were assumed across ESAs. Model outcomes include incremental cost-effectiveness ratios (ICERs) and incremental quality-adjusted life years (QALYs).
CONCLUSIONS: A systematic review using MEDLINE (search terms VUR, treatment, and cost) for 2006-2011. RESULTS: Dextranomer/hyaluronic acid injection is the more cost-effective option compared to ureteral reimplantation when success rates for dextranomer/hyaluronic acid injection are 58% per ureter for patients with unilateral reflux and 75% per ureter for bilateral reflux. If increasing grades of reflux requires increasing volumes of dextranomer/hyaluronic acid, success rates of 73% for unilateral reflux and 94% for bilateral reflux represent the break-point for cost-effectiveness. In models where dextranomer/hyaluronic acid injection is repeated if VUR does not resolve after initial injection, break-even success rates are 11% and 60% with unilateral reflux if success rates of initial injections were 70% and 55%, respectively. Break-even success rates for second dextranomer/hyaluronic acid injections are 29% and 77% per ureter with bilateral reflux, if success rates of initial injections are 70% and 55%, respectively. Based on 2011 epidemiologic estimates of 508,000 children who are candidates for ureteral reimplantation, short-term studies are needed to refine the range of outcomes and downstream costs.

PUK31
HOW COMMON IS CO-OCCURRING ED AND BPH IN A HEALTH CARE CLAIMS DATABASE?
Schoenberg M, Shorthand E, Emmick JT, Shen W, Cui Z
Newlin, IN, USA
OBJECTIVES: in the medical literature of co-occurrence of erectile dysfunction (ED) and benign prostatic hyperplasia (BPH) in men range from 20 to 80% depending on different as they age.
METHODS: Patients in the sample were categorized as having BPH, ED, or co-occurring conditions. METHODS: Patients with ED and/or BPH were identified by diagnostic codes in the Thomson Reuters MarketScan® Database from January 1, 2007 to June 30, 2010. Patients in the sample were categorized as having BPH, ED, or co-occurring conditions (i.e., BPH and ED). Study definition included: 1) diagnosis of type 2 diabetes; 2) ≥12 months of continuous health plan eligibility; and 3) ≥2 non-zero serum creatinine lab values, at least 90 days apart, between Jan 1, 2004 and June 30, 2011. We identified 12 ICD-9-CM code groups potentially indicative of CKD stage 3-5 and validated them against a “gold standard”, defined as two laboratory claims, at least 90 days apart, with an estimated glomerular filtration rate (eGFR) > 60 ml/min. eGFR was calculated using the CKD Epidemiology Collaboration equation and the Modification of Diet and Renal Disease (MDRD) equation. We calculated sensitivity, specificity, positive predictive value (PPV) and negative predictive value for the selected codes. Exact binomial 95% confidence intervals (CIs) were derived, and codes with a PPV whose lower CI bound was > 80% were considered valid.
RESULTS: The study sample consisted of 383,970 patients. Approximately 16% of the sample (N=61,052) had stage 3-5 CKD based on the “gold standard”. ICD-9-CM codes for chronic renal failure, stage 3-5 (585.3-5), had a PPV of 84.2% (CI: 83.7 - 84.7). ICD-9-CM code 585.6, for end-stage renal disease (ESRD), had a PPV of 84.7% (CI: 83.6 - 85.7). ICD-9-CM code 285.3, used to describe aseptic necrosis in CKD, had a PPV of 85.4% (CI: 84.6 - 86.2%). For the remaining code groups, PPV ranged from 50% to 78%, with CIs of ± 2 percentage points. Similar results were obtained when eGFR was calculated using the MDRD equation. CONCLUSIONS: This cross-sectional validation study suggests that diabetic patients with stage 3-5 CKD can be accurately identified in administrative claims data using selected ICD-9-CM codes.

PUK35
EQ-5D (UK AND THAI PREFERENCE WEIGHTS), SF-6D, AND VAS SCALES IN DIALYSIS THAI PATIENTS
Khamnoppachan T, Vaseeputtaka S, Noparatayawar P
Mahidol University, Bangkok, Thailand
OBJECTIVES: To evaluate the utility scores from EQ-5D (UK and Thai preference weights), VAS, and SF-6D in dialysis patients and to compare the correlation between these scores and the disease specific scores using KDQOL-36. METHODS: This study was a cross-sectional study. A Face-to-face interviews using EQ-5D and KDQOL-36 were conducted from April to August 2011 with 160 hemodialysis pa-
CONCLUSIONS: SF-6D presented better correlation with kidney specific scales while the responsiveness of EQ-5D utility scores was poor. One explanation might be a “ceiling effect” of the EQ-5D. These findings implied that SF-6D utility scores could reflect HQOL status of dialysis patients better than EQ-5D and VAS.

PUE36

USING BOOTSTRAP CONFIDENCE INTERVALS TO COMPARE RELATIVE VALIDITY COEFFICIENTS: AN EXAMPLE WITH PRO MEASURES OF CHRONIC KIDNEY DISEASE (CKD) IMPACT

Deng J, Ware J

Department of New England, Massachusetts Medical School, Worcester, MA, USA

OBJECTIVES: To evaluate bootstrap techniques in comparing the validity of PRO measures in discriminating among CKD patients and responding to longitudinal changes.

METHODS: The Kidney Disease Impact Scale (KDIS), CKD-specific legacy (KDIS, KID-36, KID-12), generic health (SF-12) scales were administered to 453 patients and re-administered to 110 patients after three months. ANOVA-based relative validity (RV) coefficients were used to compare how well each scale discriminated between three clinically-defined groups ordered in terms of severity (Dialysis > Stage 3-5 > Transplant), and how responsive each scale was to change over time. RV was higher for self-evaluated Better. Same and Worse groups. Bootstrap was used to construct confidence intervals (CIs) to determine whether the differences in RVs were significant in comparisons between each scale and the best legacy measure - KDQOL Burden. Sample size, number of bootstrap iterations, and type of CIs were varied to evaluate their impacts on CI using real and artificial data.

RESULTS: The sample size played a substantial role. 300 people for 3 groups were suggested as the minimum number to make meaningful comparisons between RVs using CI. Number of bootstrap replications (100 to 10,000) did not show an obvious effect on bootstrap standard error, although 300 showed improvement over 100 on CI. The bias-corrected and accelerated (BCa) type of CI was preferred for correcting both bias and skewness in bootstrap distribution and for producing narrower CIs. Using 95% CI and 300 sample size, differences in RVs were non-significant in comparisons with KDQOL-Burden (RV = 0.3) for the following scales: SF-12 PCS (RV = 0.6), PF (RV = 0.7), RP (RV = 0.77), KDQOL-Effect (RV = 0.99), and KDIS (RV = 1.13). CONCLUSIONS: Bootstrapping appears to be valuable in testing the significance of differences in the relative validity of these PRO measures from a statistical perspective. Samples of 100 per group compared and 300 bootstrap replications are recommended.

RESEARCH POSTER PRESENTATIONS – SESSION IV
RESEARCH ON METHODS STUDIES

RESEARCH ON METHODS – Clinical Outcomes Methods

PFM1

COMPLIANCE ON THE CONSOLIDATED STANDARDS OF REPORTING TRIALS (CONSORT) GUIDELINES IN RANDOMIZED CONTROLLED TRIALS

Goddin OP1, Dyson B1, Park SY2, Lee L2

1Howard University, Washington, DC, USA
2Howard University, Washington, DC, USA

OBJECTIVES: The Consolidated Standards of Reporting Trials (CONSORT) statement was published in 2001 and updated in 2010, strongly recommended the use of CONSORT diagram to report the flow of participants through each stage of the trial. This study was conducted to describe the level of compliance of the published clinical trial in following the CONSORT recommendations and to estimate prevalence of the compliance. METHODS: A systematic literature search of all randomized controlled trials of anti-inflammatory agents published in the top 10 general medicine journals and top 5 infectious disease journals published in 2010. The journals included: The New England Journal of Medicine, Journal of the American Medical Association, British Medical Journal (Clinical Research Ed), Archives of Internal Medicine, PLoS Medicine, Annals of Internal Medicine, Clinical Infectious Diseases, The Journal of Infectious Diseases, the Lancet Infectious Diseases, AIDS, Emerging Infectious Diseases Journal, Annual Review of Medicine, Canadian Medical Association Journal, and Annals of Medicine Journal. Each article was reviewed by two independent investigators based on the reporting criteria recommended by the CONSORT statement. Exclusion criteria included non-randomized control studies, and studies not including intervention or control group. RESULTS: The study identified 124 trials, of which 26 (21%) met the criteria. Of the randomized controlled trials met the inclusion criteria. Of 73 studies, 55 (75.34%) articles included the CONSORT diagram. A comprehensive depiction of the CONSORT guidelines will be made and detail descriptions on the compliances will be presented by journal types during the presentation. CONCLUSIONS: Randomized controlled trials published in the top 10 general medicine journals and the top 5 infectious diseases journals in 2010 contain significant deficiencies in reporting the CONSORT flow chart. The clarity and the completeness of a study could be improved if the CONSORT statement is followed as prescribed.

PFM2

NETWORK META-ANALYSIS OF INDIVIDUAL AND AGGREGATE LEVEL DATA

Jansen JP1, Cope S2

1Mapi Consultancy / Tufts University School of Medicine, Boston, MA, USA
2Mapi Consultancy, Boston, MA, USA

OBJECTIVES: Network meta-analysis is often performed with aggregate level data. AD has a challenge with meta-regression models using AD is that the association between a patient level covariate and relative treatment effects of the compared interventions at the study level may not reflect the individual level effect-modification relationship. In the paper, non-linear network meta-analysis models for combining individual patient data (IPD) and AD are presented to reduce bias and uncertainty of treatment effects in the presence of heterogeneity due to patient characteristics.

METHODS: The first method uses the same model form for IPD and AD. With the second method, the model form for IPD is modified to reflect that each model over the joint within-study distribution of covariates. With a simple simulation study the two modeling approaches are compared. RESULTS: Having IPD for a subset of studies improves estimation of treatment effects with network meta-analysis in the presence of patient level heterogeneity and inconsistency. Of the two, the second method was preferable.

PFM3

THE ENSEMBLE MINIMUM DATABASE: A NEW INSTRUMENT TO EXPLORE HETEROGENEITY OF TREATMENT EFFECT

Brennanen SK1, Breckle L1, Bancroft T1, Shen W1, Paccikowski R2, Berger M1, Kaplan SH1, Greenfield S1, Burschung DP2

1Optимум, Eden Prairie, MN, USA, 2Eli Lilly and Company, Inc., Indianapolis, IN, USA, 3University of California Irvine, Irvine, CA, USA

OBJECTIVES: To develop an instrument that identifies patient groups likely to have differing responses to treatment, we tested candidate measures thought to discriminate differences among patients in 4 disease cohorts: type 2 diabetes (T2D), knee osteoarthritis (OA), ischemic heart disease (IHD) and heart failure (HF). METHODS: Eligible patients identified from claims data were sent a survey including 17 scales hypothesized to comprise 4 domains (health profile, personality, behavior, life context). Proxies for treatment response were patient-reported global impression of disease severity (PGIS), global impression of improvement (PGl), and administrative claims health care utilization (HCII). Variability (SD) and internal consistency (Cronbach’s alpha) of the scales were examined, as was discriminant validity against strata of PGIS, PGl and HCII. Conceptual overlap, correlations among scales, and factor loading within and across domains were examined. Scales with desirable properties were included in the final instrument. Discriminant validity of proposed domains was analyzed by ANOVA adjusted for age and gender. RESULTS: The final ENSEMBLE MDI instrument discriminated among patients with varied diseases, the health profile provided much of the ability to discriminate. Further research is needed to assess the instrument’s potential to predict health state changes due to trial interventions.

PFM4

ENHANCING THE HEALTH ECONOMIC VALUE OF RETROSPECTIVE AND PROSPECTIVE REAL-WORLD STUDIES WITH PHARMACOGENOMIC TESTING: OPPORTUNITIES AND CHALLENGES ASSOCIATED WITH AN INTEGRATED PERSONALIZED MEDICINE APPROACH

Payne KA1, Frueh FW2, Sohail J3

1United BioSource Corporation, Dorval, QC, Canada, 2Medco Health Solutions, Inc., Franklin Lakes, NJ, USA, 3United BioSource Corporation, Hammersmith, UK

OBJECTIVES: A better understanding of a patient’s genetic make-up through pharmacogenomic testing can help achieve improved and more predictable patient outcomes, often at equal or lower total treatment cost. Stakeholders including physicians, payers and patients alike can benefit from real-world data that identify, a priori, the sub-groups of patients for whom treatments are likely to be more cost-effective. METHODS: Retrospective and prospective case study designs within which pharmacogenomic testing has been integrated are presented. Design parameters are described and opportunities and challenges alongside strategies for resolution are delineated. RESULTS: As the genetic make-up of a patient does not change, pharmacogenomic testing can be done at any point in time and paired with patient’s current level data. These approaches are highly efficient as they do not require costly longitudinal follow-up, whereas prospective studies including registries offer the opportunity to augment pharmacogenomic and other study data with patient and physician reported outcomes not otherwise available in the medical chart. Main challenges associated with either approach include optimizing the patient informed consent process, streamlining the logistics associated with pharmacogenomic testing and storage in the usual