core-set were also obtained both at baseline and 4 week apart. These included tender joint count (out of 28), swollen joint count (out of 28), physician’s and patient’s global assessment of disease activity, pain score and Westergren erythrocyte sedimentation rate (ESR). Disease activity was measured using the DAS28 score, which was obtained at baseline and at the end of the study for each patient. RESULTS: The median age of the 60 study patients was 48 yr ± 9.5 SD and the median duration of symptoms was 17 months ± 5.6 SD. Thirty of these received the English version of the HAQ and the other 30 received the Hindi version. Baseline HAQ values for English and Hindi groups were 1.84 ± 0.48 and 1.91 ± 0.49, respectively. After treatment, the HAQ values changed to 0.71 ± 0.42 and 0.62 ± 0.51, respectively, demonstrating a very good sensitivity to change (Student’s unpaired t-test; p < 0.05). Construct validity was assessed using Pearson’s correlation coefficient between the corresponding values of HAQ and DAS28, both at baseline (r = 0.47, p < 0.05) and after intervention (r = 0.60, p < 0.01). CONCLUSIONS: These results support the validity, and reliability of the IND-HAQ as a measure that captures the impact of RA on patients’ health-related quality of life. PMS93

PAPER AND WEB EQUIVALENCE OF THE ENSEMBLE MDS - A TOOL USED TO COLLECT PHENOTYPIC INFORMATION PRIOR TO TREATMENT

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OBJECTIVES: The ENSEMBLE MDS is a battery of phenotypic generic patient-reported instruments designed for use in clinical studies or comparative effectiveness research. The component instruments assess baseline patient characteristics that are believed to be either predictors (health status, illness burden, depression, anxiety, and perceived stress) or effect-modifying factors (perceived social status, objective social and/or financial support) of clinical outcomes and/or treatment response. We sought to evaluate the equivalence of the MDS across two different modes of administration – paper and web. METHODS: This study was a data collection effort that used a randomized cross-over design in the United States (English) and Singapore (Simplied Chinese). Participants were outpatients with a clinical diagnosis of one of five targeted health conditions: depression, type 2 diabetes, psoriasis, rheumatoid arthritis and chronic kidney disease. Those enrolled were randomized to initially complete the MDS on paper or web format, and returned 24 hours later to complete the alternate format. Equivalence was evaluated by the intraclass correlation coefficient (ICC) with equivalence defined as ICC ≥ 0.70, which implies a minimal acceptable level of 0.70. These analyses were performed individually for each of the nine MDS component measures. RESULTS: A total of 314 participants (258 in US, 56 in Singapore) were analyzed. In the US, mean age was 49 ± 13 years, 61% were female; in Singapore mean age was 57 ± 12, 59% female. The ICCs between paper and web administration of the different components of the ENSEMBLE MDS ranged between 0.74 and 0.98 in the US, and between 0.75 and 0.97 in Singapore. CONCLUSIONS: Equivalence between paper and web-based administration of the ENSEMBLE MDS was demonstrated statistically for the US-English Version and the Chinese version for Singapore, indicating stability of subject comprehension and response patterns across two modes of administration in two different languages and cultures. PMS94

INTEGRATING PATIENT-REPORTED OUTCOMES (PRO) AND MEDICAL RECORD DATA (MR) IN OBSERVATIONAL STUDY DESIGNS: RESULTS FROM A DIRECT-TO-PATIENT PILOT STUDY IN GOUT

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OBJECTIVES: The growth in patient empowerment and increase in on-line patient pools has given rise to new direct-to-patient research methods (i.e., direct recruitment of patients, without physician sites). One key concern, however, is the absence of physician-reported data to validate diagnosis and provide other study data. The objective of this study was to employ a direct-to-patient approach to collect patient-reported outcomes (PRO) and medical record (MR) information. METHODS: In July 2011, a random sample of US MedGuard org members age 18 to 80 who were treated for gout were invited via email based on a gout treatment or diagnosis in the previous 12 months. A total of 314 participants continued on to complete an online survey and electronic and paper medical release forms. Completed forms were provided to Outcomes Health Information Solutions to contact physicians and obtain participant charts. RESULTS: A total of 120 members clicked on 1250 emails sent (9.6%). 5 members (4%) explicitly declined to participate due to the medical record requirement, although this could be as high as 38% if all individuals closing the browser are included. Of the 50 participants completing the on-line survey and electronic release, 40 (80%) returned the paper form. With these forms, we obtained 38 of 50 charts (76%). 28 of 38 (74%) with electronic and 10 of 38 (26%) with paper; 35 charts had a gout diagnosis and an additional 2 had a gout medication; only 1 chart was missing any mention of gout. CONCLUSIONS: Patients can be recruited directly for observational study designs that include PRO and MR data with over 75% data completeness. Although concerns exist regarding validity of self-reported diagnosis, in this PRO+MR pilot, nearly all (37 of 38) charts confirmed patient-reported data.
formed independently and relative risk (RR) estimates were calculated from each study. To determine the relationship between inhaled anticholinergics and mortality, a random effects meta-analysis was performed. Between-study heterogeneity was assessed using the I^2 statistic.

**RESULTS:** Of the 684 citations reviewed, a total of 18 RCTs enrolling more than 33,000 patients met the inclusion criteria. Inhaled anticholinergics were not associated with an increased risk of all-cause mortality [RR = 1.09 (95% CI 0.88, 1.36), I^2 = 36%]. Tiotropium only study showed similar results. Subgroup analyses of soft mist inhaler trials, however, revealed a 51% increase in all-cause mortality for the intervention group [RR = 1.51; 95% CI (1.08, 2.11); I^2 = 0%]. Sensitivity analysis did not change any of the results. **CONCLUSIONS:** Inhaled anticholinergics were not associated with increased risk of all-cause mortality and might be considered as safe. Analysis of tiotropium subgroup, however, suggested an increase in mortality risk, necessitating more long-term RCTs to assess its safety.

**PS4**

**BURDEN OF COMORBID DEPRESSION/ANXIETY AMONG MEDICARE BENEFICIARIES WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

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**OBJECTIVES:** To assess the comorbid relationship between COPD and depression or anxiety among Medicare beneficiaries. **METHODS:** Fee-for-service (FFS) part A, B and D claims from the 5% Medicare Chronic Conditions Warehouse (CCW) from January 1, 2006 to December 31, 2007 were pooled to construct a prevalent cohort of COPD and depression/anxiety among Medicare beneficiaries. **RESULTS:** Among Medicare FFS enrollees, depression/anxiety was associated with $50,622 (95% CI 49,007-52,237) greater annual adjusted costs. Risk of a moderate, severe, or any exacerbation was estimated using logistic regression models. **CONCLUSIONS:** Overall, inhaled anticholinergics were not associated with worsening of asthma outcomes. Increased symptom burden, data were pooled using the random effects model (inverse variance method). To assess the comorbid relationship between COPD and depression/anxiety, we analyzed data from the 2009 Medical Expenditure Panel Survey (MEPS). Propensity score (PS) matching technique was used to form cohorts of patients with COPD and/or depression/anxiety. **RESULTS:** The study observed no significant difference between the two groups with respect to health care expenditures. The results of the current study showed that omalizumab treatment initiation was associated with statistically significant reductions in ED visits, hospitalizations and corticosteroid use.

**PS5**

**CO-MORBID DEPRESSION AND ITS IMPACT ON HEALTH CARE EXPENDITURE AMONG INDIVIDUALS WITH ASTHMA**

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**OBJECTIVES:** To assess the comorbid relationship between COPD and depression/anxiety among Medicare beneficiaries. **METHODS:** Fee-for-service (FFS) part A, B and D claims from the 5% Medicare Chronic Conditions Warehouse (CCW) from January 1, 2006 to December 31, 2007 were pooled to construct a prevalent cohort of COPD and depression/anxiety among Medicare beneficiaries. **RESULTS:** Of the 1,591,413 enrollees meeting the criteria of 12 months of FFS coverage, 137,275 were selected from the 5% CCW sample. Depression/anxiety was found in 55% (75,379) of the cohort. After controlling for sex, age, region, race, Charlson comorbidity score, and use of COPD-related medications in the baseline period, enrollees with depression/anxiety had a 51% greater risk of having a moderate exacerbation (OR 1.51, 95% CI 1.39-1.64) and 78% higher risk of a severe exacerbation (OR 1.78, 95% CI 1.50-2.11). After adjustment, depression/anxiety was associated with $50,622 (95% CI 49,007-52,237) greater annual total cost and $35,789 annual respiratory-related costs (95% CI 34,328-37,251). **CONCLUSIONS:** Clinical and economic costs associated with depression/anxiety among Medicaid enrollees are substantial. More emphasis should be placed on identification and treatment of depression/anxiety among this population.

**PS6**

**EVALUATION OF THE ASSOCIATION BETWEEN STATIN USE AND RISK OF UNCONTROLLED ASTHMA USING HIGH-DOSE INHALED CORTICOSTEROIDS**

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**OBJECTIVES:** This study evaluated the impact of omalizumab on emergency-department (ED) visits, hospitalizations and corticosteroid use among uncontrolled asthma patients using high-dose inhaled corticosteroids (ICS) and omalizumab. **METHODS:** Health insurance claims from the MarketScan database (2002Q1-2009Q1) were analyzed. Patients with ≥12 months of continuous insurance coverage prior to and after the first omalizumab dispensing, ≥8 weeks of high-dose ICS use, ≥8 weeks of long-acting beta-2-agonist (LABA) use, and uncontrolled asthma at baseline were included. A retrospective analysis was conducted to quantify the impact of omalizumab on resource use by comparing ED visits, hospitalizations, and corticosteroid use one year before and after omalizumab initiation. A one-year period was chosen to cover any potential seasonality impacts. **RESULTS:** A total of 644 patients (mean age: 49.9 years, 59.2%) formed the study population. Omalizumab was associated with a 48.6% reduction in the proportion of patients with ≥1 asthma-related ED visits (pre vs. post-omalizumab period: 21.4% vs. 11.0%, P<0.001) and 40.8% reduction in asthma-related hospitalizations (25.0% vs. 14.8%, respectively, P<0.001). Compared to the pre-omalizumab period, the use of ICS decreased significantly after omalizumab initiation (7 vs 6.5 dispersions, P<0.001; 41.9% of patients had a reduction in ICS use). A similar reduction in oral corticosteroid use was observed (5.0 vs. 3.6 dispensions, P<0.001; 36% of patients had a reduction in oral corticosteroid use). The results of the current study showed that omalizumab treatment initiation was associated with statistically significant reductions in ED visits, hospitalizations and corticosteroid use.