

through June 2009) for 32,338 patients aged >40 years prescribed ipratropium (IPR) (N=10,617) or tiotropium (TIO) (N=9,126) in comparison to fluticasone propionate/salmeterol combination (FSC) (N=12,595). Patients initiating with IPR (and separately, TIO) were matched to patients initiating with FSC based on propensity to be prescribed IPR (separately, TIO), considering demographics, comorbidities and utilization characteristics assessed during 6 months before first IMT claim. **RESULTS:** Percentage of each group propensity matched to FSC was 80.2%, IPR and 89.1%, TIO. ORs (95% confidence intervals (CI)) for IPR vs. FSC were: ED - PM 1.86 (1.64-2.10), MR 1.81 (1.57-2.08); Hospitalization - PM 1.47 (1.27-1.70), MR 1.53 (1.35-1.75); ED/Hospitalization PM 1.67 (1.50-1.85), MR 1.72 (1.56-1.90). For TIO versus FSC, ORs (95% CI) were: ED - PM 1.34 (1.14-1.47), MR 1.34 (1.17-1.54); Hospitalization - PM 1.10 (0.94-1.28), MR 1.19 (1.04-1.37); ED/Hospitalization PM 1.21 (1.07, 1.36), MR 1.28 (1.15, 1.42). IRRs reflected similar differences between the methods. Compared to FSC patients, total COPD-related health care costs were higher for IPR (PM & MR, P<0.01) and TIO (PM P<0.05, MR P<0.01). **CONCLUSIONS:** The MR and PM methods of adjusting for baseline differences between treatment populations produce similar results.

PRS44

THE CHARLOTTE STUDY: NOVEL DATA COLLECTION, VIEWING AND DYNAMIC REPORTING MECHANISM

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OBJECTIVES: The significant burden of uncontrolled asthma can be translated into substantial direct and indirect costs to the US health care system. The objectives of the Characterization of Allergic Asthma: A Chart Review In Moderate-To-Severe Disease To Assess Asthma Control, Allergies, Patient Outcomes And Treatment Study (CHARIOT) study were to assess control of patients with moderate-to-severe asthma, examine the natural history of disease, practice patterns and resource utilization in specialty community practices according to recent National Asthma Education and Prevention Program guidelines by using a novel online approach to gathering data and quickly demonstrating results. **METHODS:** This was a retrospective, multicenter, randomized study of 1009 patient charts in 60 US allergy and pulmonology community practices. Assessment of patient control, the primary endpoint, was achieved by analyzing data entered via internet-based or paper case report forms (CRFs) Uncontrolled asthma was defined by occurrence of any of the events in the recent 12 months of continuous follow-up: systemic corticosteroid burst; frequent short-acting β_2 agonist use; ER visit; asthma exacerbation (hospitalization and/or unscheduled visit; limitations on activities; decline in lung function to <80% predicted FEV₁ or PEF); daytime dyspnea; doubling of inhaled corticosteroid dose; or addition of another controller medication. **RESULTS:** A total of 114 sites were invited to participate in CHARIOT, with a 63% response rate leading to site enrollment. Sixty investigator sites participated to completion and, after WebEx training, only 1 requested paper CRFs but later elected to use electronic forms. Data was successfully collected and analyzed within a 3-month period. Of the 365 male and 644 female patients enrolled (mean 43.2 ± 17.1 years), 81.9% were deemed to be uncontrolled. **CONCLUSIONS:** Greater than 80% of asthma patients from specialty practices were uncontrolled with regard to asthma symptoms. The novel internet technology allowed for efficient data collection from multiple sites within a short time frame.

PRS45

MODELING THE IMPACT OF MULTIPLE QUIT ATTEMPTS IN SMOKERS USING DISCRETE EVENT SIMULATION (DES)

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OBJECTIVES: Smoking cessation models have typically evaluated the impact of a single quit attempt on long term outcomes in smokers but smoking cessation is characterized by multiple quit attempts. A DES was developed to simulate lifetime smoking patterns and the impact on smoking-related complications and costs. This study evaluates the effect on predictions when modeling single versus multiple quit attempts. **METHODS:** Using data from trials, surveys, and the literature, the DES simulates individuals' lifetime smoking behaviors and their impact on outcomes. The simulation assigns and reassigns the initial outcomes of each quit attempt, time between quit attempts, relapses, and interventions used in each attempt (varenicline, bupropion, nicotine replacement, behavioral modification, unassisted). Comorbidities include myocardial infarction, stroke, COPD, and lung cancer. Market survey data are used to assign the initial intervention for quit attempts. Only direct costs (2010 \$US) are considered. All outcomes are discounted at 3%/year. **RESULTS:** When analyses are restricted to a single quit attempt, mean life expectancy in the population is 15.8 years, and QALYs 13.2; the lifetime costs of treatment and smoking related comorbidities average \$55,925. Allowing for multiple quit attempts (average 7.6 attempts/smoker) increases the average time individuals spend abstinent by 8.8 years. Consequently, predicted life expectancy increases by 1.1 years; QALYs by 0.9. Despite increased smoking intervention costs, total lifetime costs fall by \$3300/smoker. Analyses comparing initial varenicline treatment to mixed initial treatments and allowing multiple versus single quit attempts reduces varenicline-related predicted health gains and cost offsets, although both groups have better outcomes with multiple quit attempts. The reduction is apparent because individuals initially on less effective treatments are able to quit smoking in subsequent attempts. Nevertheless, varenicline is dominant or highly cost-effective in both scenarios. **CONCLUSIONS:** Allowing multiple rather than single quit attempts in simulating outcomes for smokers provides better information for decision making.

PRS46

MEASUREMENT COMPARABILITY BETWEEN PAPER AND ALTERNATE VERSIONS: RECOMMENDED ASSESSMENT STEPS USING THE LUNG FUNCTION QUESTIONNAIRE AS AN EXAMPLE

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OBJECTIVES: Providing participants with choices in how their data are collected may lead to greater participation, less missing data, improved data quality, and in some cases, decreased costs in data collection. To facilitate combining data from multiple versions, the goals of this study were to provide recommended steps to assess measurement comparability using a crossover study design and a case-finding questionnaire, the Lung Function Questionnaire (LFQ), as an example. **METHODS:** In the study, the LFQ was administered to participants via paper, Web, interactive voice response system, and interview. A randomized crossover design was used to gather data across the multiple administration types. In addition to the LFQ, participants completed demographic and health questions, and a short questionnaire regarding their administration preference. Four recommended evaluation steps are described and illustrated using data from the crossover study: 1) comparisons of the item-level responses and agreement; 2) comparison of mean scale scores; 3) classification of scores; and 4) questions designed to collect usability and administration preference. **RESULTS:** In this example, item-level kappa statistics between the paper and the alternate versions ranged from good to excellent, intraclass correlation coefficients for mean scores were above 0.70, and the rate of disagreement ranged from 2% to 14%. In addition, although participants had an administration preference, they reported few difficulties with the versions they were assigned. **CONCLUSIONS:** The steps described provide a guide for evaluating whether to combine scores across administration versions to simplify analyses and interpretation under a crossover design. The guide recommends the investigation of item-level responses, summary scores, and participant usability/preference when comparing versions. Each of these steps provides unique information to support a comprehensive evaluation and informed decisions regarding whether to combine data. Results of this particular study for each of the evaluation steps supported the use of multiple modes of the LFQ.

POSTER SESSION III:

RESEARCH ON METHODS STUDIES

Research on Methods – Clinical Outcomes Methods

PRM1

MEASURING COMORBIDITY: AN UPDATED CRITICAL REVIEW OF AVAILABLE METHODS

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OBJECTIVES: Comorbidities are conditions or diseases besides the one of primary interest. A comorbidity index condenses all the coexistent conditions to a single score and comorbidity indexes have been extensively used to adjust analyses for the impact of comorbidities. De Groot and colleagues published a literature review in 2003 listing available indexes and reporting their validity. The objective of this study was to review published methods to measure comorbidity and thereby provide an update of the publication by de Groot and colleagues. **METHODS:** A structured search, using as primary search terms comorbidity, multimorbidity, and co-existing disease, was undertaken in Embase.com to identify studies published since 2000 in which an index to measure comorbidity is described. For validity, correlation coefficients, ratios, explained variance, and the area under the receiver operating characteristic curve were used. Regression models predicting future events that were significant or significantly improved after adding comorbidity as a covariate was considered to support validity. Parameters used to assess reliability were among others correlation coefficients. **RESULTS:** Sixtyfour publications were studied resulting in twentyfive different indexes, to measure comorbidity were identified, compared to the thirteen identified by de Groot and colleagues (2003). In line with previous findings, the Charlson Comorbidity Index (CCI) generated the greatest number of studies and the most consistent results regarding validity and reliability. CCI compiles the weighted mortality association of nineteen different diseases with a number of adaptations for specific circumstances. **CONCLUSIONS:** The main finding is that the CCI remains the most used and validated index, and also a number of new comorbidity indexes have been identified in this study. Assessment of comorbidity is an area of interest for both health economists and epidemiologists and it seems to be receiving increased attention.

PRM2

MEASURING DRUG THERAPY GUIDELINES ON OUTCOMES: A TUTORIAL

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OBJECTIVES: To introduce a method that combines the propensity score matching and interrupted time-series models to measure drug therapy guidelines on outcomes. **METHODS:** Propensity score matching is used to balance groups before the trend is analyzed. The "kitchen sink" approach is used for propensity score matching. Interrupted time-series models are applied over the matched sample. The time-series model contains two predictor variables: the binary intervention variable and an interval coding for time. This model controls for the confounding influence of any underlying trend and ensures that any estimated change in the mean level of the series after intervention is not simply due to the fact that the series was already decreasing or increasing. **RESULTS:** To illustrate the model, changes in the utilization of two hypothetical drugs were analyzed after issuance of guidelines. Patients who used these two drugs were different at the baseline in