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 CHARIOT 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 FEV_1 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 coexisting 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

terms of observable characteristics such as age, gender, and comorbidities ($p<0.001$). Samples were balanced with nearest neighbor matching. Then segmented time-series models were applied. There was a significant association between the onset of intervention and the level of utilization of these drugs. **CONCLUSIONS:** To isolate the effects of guidelines, we need to control for three different factors: 1) baseline differences between the two groups; 2) stepwise differences at the intervention point; and 3) trend differences after the intervention. We showed that propensity score matching can be used for the first factor, and the latter two can be controlled with the interrupted time-series model.

PRM3

THE BURDEN OF CAREGIVING: ASSESSING THE STATUS OF CURRENT CLINICAL RESEARCH

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OBJECTIVES: The burden of caregiving is high. In 2009 there were an estimated 65.7 million caregivers in the U.S. (29% of the adult population) and these numbers are expected to swell in the coming years with the ageing population. Caregiving impacts on the health, wellbeing and work productivity of the caregiver, therefore research aimed at assessing and reducing the burden of caregiving is warranted. The objective of this study was to assess the status of current clinical research into the burden of caregiving. **METHODS:** Clinicaltrials.gov was searched for trials where caregiver burden (CB) was reportedly measured. Information on the care-recipient condition (CRC), the primary focus of the study, and the type of intervention being considered, was extracted from the included trials. **RESULTS:** 80 trials were identified that measured a reported outcome of CB. The most common CRC was Alzheimer's disease and related disorders (34 studies); followed by cancer (14), frail and elderly (8), mental health (7), Parkinson's disease (7), brain and spinal cord injury (5) and 'other' (5). A range of questionnaire-based instruments were reportedly used across studies to elucidate the physical, emotional (psychological), social and financial impacts of caregiving.The role or burden of the caregiver was a key focus in 55% of the studies; trials involving care of cancer patients had the highest proportion of caregiver-focused studies (12/14, 86%). Behavioural and drug interventions were the most frequently investigated intervention type (38% and 25% of trials, respectively), although no studies investigating a 'drug' intervention evaluated the effect on caregivers as a primary outcome. **CONCLUSIONS:** Current clinical research into the burden of informal caregiving is concentrated in age-related CRCs. Research interventions aimed at relieving CB are mostly behavioural in nature. The growing number of caregivers means that research into effective methods of reducing CB will be of ever increasing importance.

Research on Methods – Cost Methods

PRM4

WHAT IS IMPORTANT DURING THE PHARMACOECONOMIC EVALUATION OF CAM (COMPLEMENTARY AND ALTERNATIVE MEDICINE)?—A SURVEY RESEARCH

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OBJECTIVES: The increasing popularity of Complementary and Alternative Medicine (CAM) leading to an increasing interest of CAM assessment through pharmacoeconomic evaluation. The attempts, however, have been unsatisfactory. This study attempted to survey expert practitioners in China of TCM (Traditional Chinese Medicine) which is a major part of CAM to elucidate critical issues when assessing cost-effectiveness of TCM, and to ascertain influencing factors of measuring HR-QOL in TCM. **METHODS:** A questionnaire (with 20 close and open-end questions) was distributed to TCM practitioners who had been working in the field for at least 5 years and had published at least one related paper in the last 5 years. The questions were divided into two modules with module 1 about the issues of pharmacoeconomic of TCM, and module two about the influencing factors of measuring HR-QOL in TCM. Correlation and Partial Correlate test using age and professional field as control variable were used to module 1 and 2 respectively, non-related factors were excluded. Principal Component Analysis (PCA) was performed for remaining items. **RESULTS:** Of 429 questionnaires issued, 137 were recovered from 31 medical and research institutions of 8 provinces and cities in China giving a recovered rate 31.93%. Module 1 and 2 all passed the KMO and Bartlett's test of sphericity test ($kmo_{module\ 1}=0.56$, $kmo_{module\ 2}=0.66$). Module 1 extracted 4 common factors after the Rotation Factor Analysis with cumulative variance of 69.9%, while Moduel 2 extracted 3 with cumulative variance of 70.6%. **CONCLUSIONS:** The common factors from Module 1 prompted us to pay attention to during the pharmacoeconomic evaluation: patient preference; long-term outcomes; the alternative of TCM; and the overall economic burden of patients.The common factors from Module 2 required us to note during the HR-QOL research: Acceptance level of the measurement scale by patients and physicians; disease complexity; and whether HR-QOL scale reflects the characteristics of TCM.

PRM5

A REVIEW AND CLASSIFICATION OF CONTINGENT VALUATION METHOD STUDIES IN SUB-SAHARA AFRICA

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OBJECTIVES: The primary objective is a review, classification and critical appraisal of contingent valuation method (CVM) healthcare studies conducted in Sub-Sahara Africa based on criteria by O'Brien and Gafni (1996). The secondary objective is to determine the impact of the Bamako Initiative adopted in the early 1990s on CVM studies in the same setting. **METHODS:** CVM African healthcare studies (willingness to pay (WTP) and willingness to accept (WTA)), were identified using a comprehensive literature search in EconoLit, Google Scholar, Medline, PubMed and Web of Science between 1981 to 2010. CVM studies evaluated included WTP and WTA studies reporting primary data were included for evaluation. Primary assessment of the studies was based on the conceptual framework for evaluation of contingent valuation of healthcare programs (5 Items)(O'Brien and Gafni 1996). Secondary assessment was based on the time horizon of publication: pre-, during-(1990s), or post- BI, and area of intervention. **RESULTS:** Twenty-four CVM studies were evaluated: all used WTP and compensating variation. Elicitation techniques were dominated by bidding game (42%), followed by dichotomous choice (33%), and then payment card and the open ended formats (12.5%). Majority of studies (83%) were published after 2000, the remainder were published in the 1990s. Interventions included insurance (25%), medication (38%), and health services (38%). **CONCLUSIONS:** Healthcare CVM studies in Sub-Sahara Africa are limited despite the introduction of Bamako Initiative. The predominance of the bidding game elicitation technique in evaluated studies may be a reflection of the actual African market conditions. There is continuing debate as to which is the most appropriate CVM for healthcare studies conducted in Africa This debate will continue until these methods are compared to actual markets. CVM studies may start to engage the political market as Africa moves towards universal health coverage.

PRM6

DEVELOPMENT OF AN INCREMENTAL COST-EFFECTIVENESS RATIO WITH SOME EQUITY IMPLICATION

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OBJECTIVES: The conventional ICER (incremental cost-effectiveness ratio), which quantifies how many dollars are spent per QALY (quality-adjusted life year) gained from a specific health technology, has been criticized as unfair to the aged and/or physically challenged. **METHODS:** By taking the position that every life is equally important and every citizen is entitled to access health care services for the entire duration of his/her life expectancy, we replace the denominator of the conventional ICER, with the proportion of life, which is the quality-adjusted life expectancy (QALE) gained from the specific health technology divided by the QALE of the corresponding age- and gender-matched general population. The numerator is converted to the additional monetary cost spent over a lifetime after adjustment for annual discount rate. The new indicator quantifies how many dollars are spent to save the life of a person with a specific illness, and how much can be saved by preventing the occurrence of that illness. **RESULTS:** We have applied the estimation method to compare patients with liver cancer; breast cancer, acquired immunodeficiency syndrome, maintenance hemodialysis and peritoneal dialysis, and prolonged mechanical ventilation. **CONCLUSIONS:** Because the proposed indicator accounts for a fair opportunity for the aged and disabled more than the conventional ICER does, we recommend that this indicator be applied in future deliberations of health care resource allocation.

PRM7

DRUG DEVELOPMENT AND PHARMACEUTICAL PRICING IN THE UNITED STATES: THE INFLUENCE OF DRUG INTENDED OUTCOMES OF DRUG PRICING

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OBJECTIVES: Determination of the price of a drug starts in its early developmental stages and it is driven by various competitive health market forces. The purpose of the study is to explore associations between pharmaceutical pricing and the value of drugs. **METHODS:** Based on FDA indications we have identified three different drug categories: life saving drugs, drugs that are not life saving but save lives overtime, and drugs that only treat disease symptoms and affect QOL. We have investigated our theory of an association between drug intended outcomes and the price tag placed on a drug by performing a literature review of cost analyses for drugs selected in each category. The literature review included a combination of key words such as the name of the drug, cost-effectiveness, cost-utility, and QALY. We identified articles from the past 10 years published only in the English language. For each drug, studies reporting ICER/QALY values were selected. ICER/QALY data were recorded and the values of the three categories were compared among each other and with the published acceptable QALY threshold value of US$64,000. **RESULTS:** For the life saving drugs group the highest ICER/QALY value is US$150,843 and lowest is €6,880, for the disease ameliorating drugs group €105,599 and US$544, and for the drugs treating disease symptoms and affecting QOL £154,831 and $US1,056 respectively. The majority of drugs in the first category were found to have ICER/ QALY values greater than the $64,000 value, while the majority of the drugs selected in the second and third categories were found to have ICER/ QALY values smaller than the $64,000 value. **CONCLUSIONS:** From our study we have found that drugs that are life saving are more likely to have ICER/QALY values greater than the threshold values compared to drugs that are disease ameliorating and that are designed to improve patients' QOL.

PRM8

LEGAL RESTRICTIONS ON THE USE OF QALYS IN PHARMACOECONOMIC ANALYSIS IN GERMANY

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OBJECTIVES: In contrast to the National Institute for Health and Clinical Excellence (NICE), the German Institute for Quality and Efficiency in Health Care (IQWiG) does