examined. **RESULTS:** Approximately 26% (n = 7,354) of patients in SP1 were excluded from SP2. Reasons for exclusion were death (22%), loss to follow-up (34%), and right-censoring (44%). Age, gender, and calendar year of the index event were not dramatically different between the two populations. Both crude and age-adjusted prevalence rates of most comorbid conditions at index date were lower in SP2. Incidence rates showed a similar pattern. Mortality was significantly higher in SP1 (5.7 vs. 3.8/100 PY; $p < 0.05$). There was a decrease in the proportion of patients never treated with drugs for the selected condition from 42% in SP1 to 36% in SP2. Mean and median values for annualized rates were lower in SP2, possibly indicating that some patients with higher resource use were selectively excluded. **CONCLUSIONS:** The impact of selection bias associated with defining patient cohorts based on minimum follow-up time affects both economic and epidemiologic analyses. Overall, the results of this study suggest that researchers should define a cohort without regard to follow-up whenever possible. The appropriate and necessary follow-up period will clearly vary by condition and perhaps by local practice patterns. The data themselves can help inform the appropriate time frame for follow-up.

MD4

AUTOMATING ECONOMIC ANALYSIS OF CO-MEDICATION USE IN CLINICAL TRIALS

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OBJECTIVES: Resource utilization of co-medication use in clinical trials is often cumbersome because it involves thousands of co-medications, which are not assigned standard codes, such as National Drug Codes (NDC), making analysis difficult at the individual drug level. We developed an automated routine that allowed each co-medication to be matched to published NDC prices, in turn allowing, costing at the individual drug level. **METHODS:** Computer-based automated mapping routines (SAS, v8.2) were developed to handle co-medication trial data collected using the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system, along with the daily dose. Our approach was to map the ATC code descriptions to their generic names, and merge these with those in the Food and Drug Administration's (FDA) NDC table, thereby obtaining the NDC for each co-medication used. An average cost was calculated by averaging the average wholesale price (AWP) per milligram for each NDC that matched the generic names. The average daily cost for the co-medications was then calculated by multiplying the daily dose by the average costs. **RESULTS:** A random sample of 1000 observations of co-medications data was drawn from a randomized cardiovascular trial. This sample contained 238 unique WHO ATC codes. Our computer-based automated procedures matched 209; i.e., about 88% of the codes. This translated into 956 out of the 1000 observations being matched (96%). Comparing the entire trial dataset with NDC table showed a 92% match. **CONCLUSIONS:** The proposed methodology provides an automated routine allowing WHO ATC coded co-medications to be transcribed to unique NDC codes. This methodology can also be extended to handle medications described as generic or brand names in any format. This allows co-medication costs to be assigned at the individual drug level, improving the feasibility and rigor of within-trial economic analysis.

QUALITY OF LIFE/PATIENT PREFERENCES

QL1

QUALITY OF LIFE, UTILITY, AND WILLINGNESS TO PAY IN PATIENTS WITH DIABETES

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OBJECTIVE: The objectives of this study were to measure diabetic patients' quality-of-life (QOL), utility, and willingness-to-pay (WTP), and to examine the interrelationship between these measures. **METHODS:** Diabetic patients ≥18 years old were randomly selected from 2 hospital endocrinology clinics. Patients were interviewed to measure utility values using a visual analogue scale (VAS) and standard gamble (SG), and measure WTP for pharmacist-provided education using contingent valuation. QOL was measured via self-administered questionnaire containing the 36-item Short-Form health survey (SF-36), Diabetes Quality of Life instrument (DQOL), and Health Utility Index (HUI). Relationships between scales of QOL instruments, utilities, and WTP were tested using Spearman's correlation coefficients and regression analysis, and differences by study variables were tested using t-tests and analysis of variance. **RESULTS:** Two-hundred eighty-three patients completed the interview and questionnaire. Mean health-utility was 0.72 from VAS, 0.83 from SG, 0.83 from HUI2 and 0.73 from HUI3. Mean scores for SF-36 physical component (PCS) and mental component (MCS) were 45.4 and 50.2, respectively, and mean score for total DQOL was 0.70. Patients' mean WTP was $32.65. Age and number of diabetic complications were significant factors for VAS. The PCS and MCS were both significantly positively correlated with total DQOL, HUI2, HUI3, and VAS (all $p < 0.0001$), but not SG or WTP. VAS and total DQOL were significantly correlated with each other, SF-36 subscales, HUI2, HUI3, and SG (all $p < 0.05$), except for WTP. WTP was neither significantly correlated with any utility values (VAS, SG, HUI2, and HUI3) nor any QOL measures (SF-36 and total DQOL), but correlations were in the expected directions. **CONCLUSIONS:** The DQOL demonstrated strong correlation with SF-36 and utility values measured using VAS, SG, and HUIs, but weak correlation with WTP. Further research is warranted to

comprehend the underlying factors relating QOL, utility, and WTP.

QL2

CLINICAL IMPROVEMENT AND RESPONSIVENESS OF PHYSICAL FUNCTION MEASURES: TREATMENT WITH CTLA4IG (BMS-188667) IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS

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OBJECTIVES: To examine the treatment effect of CTLA4Ig on physical function and to evaluate the responsiveness of different domains of physical function compared to tender joint count, a highly sensitive efficacy measure for rheumatoid arthritis (RA). **METHODS:** In a randomized, double blind, placebo-controlled trial, 339 subjects with active RA receiving methotrexate (MTX) were randomized to 3 treatment arms (CTLA4Ig 2 or 10 mg/kg and placebo) given intravenously once monthly. The Modified Health Assessment Questionnaire (mHAQ) was used to assess physical function and was administered monthly. It consisted of questions assessing eight domains of physical function: dressing, arising, eating, walking, hygiene, reach, grip, and common activities. Mean change from baseline in the mHAQ scores were compared between the CTLA4Ig and the placebo groups. Relative efficiency of mHAQ domains were calculated as $(SES_{mHAQ} / SES_{tender\ joint\ count})^2$, with SES denotes standardized effect size. A relative efficiency >1 suggested that the domain was more efficient than the tender joint count in detecting the observed treatment effect. **RESULTS:** At 6 months, the mHAQ summary score improved 42% for the CTLA4Ig 10 mg/kg group compared to 14% for the placebo group. This improvement was considered to be clinically meaningful based on the commonly accepted threshold. Patients in the 10 mg/kg group also experienced statistically significant improvements compared to the placebo group in the following domains: eating (32% more improvement), hygiene (32% more), grip (24% more), dressing (20% more), and walking (16% more). Moreover, these physical domains were shown to be as responsive as the tender joint count to detect a treatment effect, with relative efficiencies close to one. **CONCLUSIONS:** treatment with CTLA4Ig significantly improved physical function in patients with active RA, especially in areas related to eating, hygiene, grip, and walking ability. Measures in physical function are efficient in detecting clinical improvements important to patients.

QL3

DIABETIC PATIENTS' WILLINGNESS TO PAY FOR DIABETES EDUCATION BY PHARMACISTS: VALIDITY OF CONTINGENT VALUATION METHOD

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OBJECTIVES: This study was conducted to measure diabetic patients' willingness-to-pay (WTP) for diabetes education provided by pharmacists utilizing the contingent valuation method, to determine factors which influence patients' WTP, and to test starting point bias and scope effects. **METHODS:** Diabetic patients, randomly selected at 2 hospital endocrinology clinics, were interviewed to measure their WTP for education resulting in 3 hypothetical risk-reductions in diabetic complications (reduction from 75% without education to 37.5% with education, 50%®25%, and 25%®12.5%) using a bidding game with randomly assigned starting amounts ($10/$40). Sample mean (SM) and mean based on log-normal distribution (LNM) were calculated. Mean WTP was calculated using 2-part model (PM) with a smear estimator, and Heckman 2-stage model (HM) for sample selection correction, which were further used to determine significant factors influencing WTP amount. **RESULTS:** A total of 283 patients were interviewed. Patients' mean age and household income was 53.5 years and $60,202 respectively. In total, 59% of patients were willing-to-pay. SMs were $36 ± $49 for 75%→37.5%; $35 ± $50 for 50%→25%; and $26 ± $42 for 25%→12.5%. SMs were similar to LNMs. Means based on HM were $41 ± $23 for the 75%→37.5%, $38 ± $19 for 50%→25%; and $27 ± $16 for 25%→12.5%, which were nearly the same as means calculated based on PM. In HM model, patients were willing-to-pay significantly larger amounts as risk-reduction level increased ($P < 0.001$), as starting amount increased ($P < 0.001$), and if neuropathy was present ($P < 0.001$). Patients' age, race, hemoglobin A_{1c}, type of diabetes, and history of retinopathy were not significant factors in predicting WTP amount. **CONCLUSIONS:** Patients, on average, were willing-to-pay between $26 and $41 for pharmacist provided diabetes education, depending on risk reduction level (scope effect) and starting amounts (starting point bias). The contingent valuation method is useful for determining the economic value of pharmacists' education. Further investigations are recommended to elucidate factors influencing patients' WTP for a variety of other services.

QL4

SMOKING STATUS AND HEALTH-RELATED QUALITY OF LIFE (HRQOL): FINDINGS FROM THE BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM (BRFSS) DATA

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OBJECTIVES: Smoking is one of the leading causes of preventable mortality in the United States. The benefits of smoking cessation have been well documented, and understanding the relationship between smoking and