OBJECTIVES: The Acute Bronchitis Symptom Severity (ABSS) Scale is a new 7-item, 5-point Likert-scaled patient reported outcomes instrument designed to capture symptoms of acute exacerbations of chronic bronchitis (AECB) and their impact on functioning. In a multi-site international randomized controlled trial comparing a 5-day oral moxifloxacin (MXF) course to that of a 7-day standard oral antibiotic regimen (amoxicillin, clarithromycin, or cefuroxime-axetil) in the treatment of AECB (the MOSAIC trial), the ABSS demonstrated good psychometric properties and the ability to detect clinically meaningful change over time. Higher ABSS scores indicate poorer clinical status. A score drop of 0.7 point (18% of scale score) is associated with clinical improvement as rated by the clinician. The contribution of specific clinical factors to ABSS score is not yet known, however.

METHODS: To assess the contribution of clinical factors to ABSS score during an exacerbation episode, a multi-variable ordinary least squares regression equation was analyzed and the contribution of each variable to overall adjusted R² was evaluated. Indicators of chronic bronchitis severity used as independent variables were age (<65 years), gender, use of either long-term inhaled steroids or systemic steroids during the study period with their impact on functioning. In a multi-site international randomized controlled trial comparing a 5-day oral moxifloxacin (MXF) course to that of a 7-day standard oral antibiotic regimen (amoxicillin, clarithromycin, or cefuroxime-axetil) in the treatment of AECB (the MOSAIC trial), the ABSS demonstrated good psychometric properties and the ability to detect clinically meaningful change over time. Higher ABSS scores indicate poorer clinical status. A score drop of 0.7 point (18% of scale score) is associated with clinical improvement as rated by the clinician. The contribution of specific clinical factors to ABSS score is not yet known, however.

RESULTS: Adjusted model R² was 0.068. FEV₁ contributes approximately 40% of total R² (p < 0.01) followed by use of steroids (p < 0.01) and female gender (p < 0.01), which both relate to ABSS score. CONCLUSIONS: Results support a relationship between the change in symptom scores and change in productivity scores for all week combinations ranged from a low of −0.161 for presenteeism across all venues to a high of 0.422 for school absenteeism. CONCLUSIONS: The ABSS score had a strong correlation with the combined lost productivity across all venues (r = 0.577), which was mainly driven by the symptom score’s strong correlation with absenteeism across all venues (r = 0.680). Perhaps owing to the age groups affected by infectious mononucleosis, school productivity was particularly well correlated with symptom severity. Statistically significant correlations to symptom scores were observed in weeks 2 and 4 for school absenteeism (r = 0.438 and r = 0.531, respectively). The significant correlation values between the change in symptom scores and change in productivity scores for all week combinations ranged from a low of −0.161 for presenteeism across all venues to a high of 0.422 for school absenteeism. CONCLUSIONS: The ABSS demonstrated good construct validity and responsiveness, making it a useful tool for determining productivity levels across different work venues within clinical trial or survey research applications.

OBJECTIVES: Utility calculation generally relies on the use of generic measures that assess health status. Evidence suggests that such measures have limited responsiveness—largely because the health states described are of limited relevance to any specific disease. Quality of life (QoL) assessment has shown that it is not health status itself that is important to patients but the impact that this might have on their lives. Consequently, it would appear more appropriate for utility to be determined by preference for different QoL states, particularly in Quality Adjusted Life Year (QALY) type analyses. The present

VALIDATION OF THE HEALTH RELATED PRODUCTIVITY QUESTIONNAIRE DIARY (HRPQ-D) ON A SAMPLE OF PATIENTS WITH INFECTIOUS MONONUCLEOSIS: RESULTS FROM AN OBSERVATIONAL STUDY
Kumar RN, Hass SL, Li JZ
1University of Michigan, Ann Arbor, MI, USA; 2Pharmacia Corporation, Kalamazoo, MI, USA

OBJECTIVE: Assess the performance of the newly developed Health Related Productivity Questionnaire-Diary (HRPQ-D). METHODS: A multi-center observational clinical study on patients suffering from infectious mononucleosis was conducted between January and April, 2001. Patients completed the HRPQ-D daily for one-week periods during weeks 1, 2, 4, and 8. Weekly productivity loss was measured as absenteeism (sum of the number of hours missed), presenteeism (productivity decreases due to reduced effectiveness), and combined lost productivity (absenteeism plus presenteeism) for three work venues (work outside home, housework, and classes/homework). Validation was conducted by correlating the productivity measures with the patient-reported severity of seven symptoms. The responsiveness of the HRPQ-D was also assessed by correlating the change in productivity scores and the change in symptom severity scores between study weeks. RESULTS: A total of 42 patients were enrolled in the study. Symptom scores were positively correlated with lost work hours due to absenteeism and combined lost productivity scores. The symptom score had a strong correlation with the combined lost productivity across all venues (r = 0.577), which was mainly driven by the symptom score’s strong correlation with absenteeism across all venues (r = 0.680). Perhaps owing to the age groups affected by infectious mononucleosis, school productivity was particularly well correlated with symptom severity. Statistically significant correlations to symptom scores were observed in weeks 2 and 4 for school absenteeism (r = 0.438 and r = 0.531, respectively). The significant correlation values between the change in symptom scores and change in productivity scores for all week combinations ranged from a low of −0.161 for presenteeism across all venues to a high of 0.422 for school absenteeism. CONCLUSIONS: The HRPQ-D demonstrated good construct validity and responsiveness, making it a useful tool for determining productivity levels across different work venues within clinical trial or survey research applications.
study was designed to determine QoL-based utilities specific to RGH. METHODS: Discrete choice conjoint analysis (CA) and time trade off (TTO) exercises were conducted using QoL states generated from six items from the RGH Quality of Life Questionnaire (RGHQoL). RGH patients completed tasks via interview. RESULTS: One hundred ninety-two interviews were conducted (79 male, 113 female; age range 19–69 years, mean age 38.4). For CA, all attributes were statistically significantly influential in determining preferences. The application of the random effects probit model produced coefficient values that can be used as preference weights. For the TTO exercise, coefficient values (preference weights) were derived by application of the random effects tobit regression model. These coefficient values can be used to derive relative and absolute utility values respectively. As the TTO technique possesses cardinal properties, QALY scores can also be calculated. CONCLUSIONS: It is feasible to generate both relative and absolute utility values from responses to the RGHQoL questionnaire, allowing utility to be based on true QoL. The ability to derive disease-specific QoL-based utilities in this way means that the same instrument can be used to generate both QoL and utility data from the same clinical trial.

NEUROLOGICAL & PAIN DISEASES/DISORDERS—Clinical Outcomes/Healthcare Policy

GALANTAMINE REDUCES CAREGIVER TIME: AN ANALYSIS OF A NATIONAL SAMPLE OF ALZHEIMER’S PATIENTS LIVING IN THE COMMUNITY
Meletiche D, Bolge SC, Small GW
Janssen Pharmaceutica, Titusville, NJ, USA; Consumer Health Sciences, Princeton, NJ, USA; Neuropsychiatric Institute, Los Angeles, CA, USA

OBJECTIVE: Patients with Alzheimer’s disease (AD) have progressive cognitive, functional, and behavioral decline, resulting in increased reliance on caregivers for assistance with activities of daily living. Galantamine, a novel treatment for AD with a dual mode of action (acetylcholinesterase inhibition and allosteric nicotinic receptor modulation), has demonstrated benefits on cognition, global function, activities of daily living, and behavioral symptoms in patients with mild-to-moderate AD. The objective of this study was to determine differences in caregiving time between caregivers of AD patients receiving galantamine and those receiving no treatment. METHODS: The analysis was based on data from the AD Caregiver Project survey. Data were collected using a self-administered questionnaire distributed in December 2001 to a large national sample of unpaid caregivers. Caregiver time was defined as the number of hours spent by the primary caregiver during a typical week. Only patients living in the community were included in the analysis. Using linear regression, caregiving times for galantamine-treated and untreated patients were compared. Covariates included patient and caregiver demographics, including employment status and income level, and patient disease severity, functional status, and living situation. RESULTS: Galantamine patients (N = 97) differed from untreated patients (N = 803) with regard to gender (61% vs 35% males), age (74.1 vs 79.6 years), and living situation (1% vs 6% living alone). Caregivers of galantamine patients were older (66.3 vs 59.2 years) and more likely to be a spouse (77% vs 33%). After controlling for differences between the groups, caregivers of galantamine patients provided 18 fewer hours of care per week than caregivers of untreated patients (95% CI: 3.3–32.5, p = 0.016). CONCLUSION: Compared with untreated patients, patients treated with galantamine appear to require significantly less caregiving time.

IMPACT OF RIVASTIGMINE ON TIME TO FIRST ANTIPSYCHOTIC DRUG USE IN PATIENTS WITH ALZHEIMER’S DISEASE
Suh DC, Arcona S, Thomas S, Chang S, Powers C
1 Rutgers University, Piscataway, NJ, USA; 2 Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

OBJECTIVE: To investigate the effect of rivastigmine treatment on the time to first antipsychotic drug use among patients with Alzheimer’s disease (AD), compared to patients not treated with a cholinesterase inhibitor (ChEI). METHODS: This study used MarketScan® research databases from January 1, 1999 through December 31, 2001. Patient inclusion criteria included: (a) diagnosis of AD, (b) ≥ 65 years old at diagnosis, and (c) continuous insurance coverage. Patients who previously used any antipsychotics were excluded. Subjects were classified into a ChEI group with the first prescription date as the index date or a non-ChEI group. Patients on rivastigmine were further identified from the ChEI group. Chi-square test, t-test, and log-rank test were used to test differences in study variables between groups. Cox proportional hazard models were used to estimate predicted risk of the first antipsychotic drug use. RESULTS: A total of 2391 patients were included in the study (996 ChEI and 1395 non-ChEI). ChEI users were younger compared to non-ChEI users (79 vs. 81 years, P < 0.0001). However, there were no significant differences between antipsychotic users and non-users, by age or gender. Over the entire observation period, Kaplan-Meier analysis indicated that users of ChEIs were 4% (relative risk (RR) = 0.96; 95% CI:0.77–1.18) less likely and patients taking rivastigmine specifically (N = 214) were 19% (RR = 0.81; 95% CI:0.54–1.21) less likely to take antipsychotics as compared to patients not taking ChEIs. After controlling for demographic covariates, use of other psychotropics and anticonvulsants, rivastigmine patients were 34% (RR = 0.66; 95% CI:0.36–1.22) less likely to take antipsy-