PIN49

HOW DOES PATIENT REPORT OF SYMPTOM IMPACT RELATE TO CLINICAL FUNCTIONING IN CHRONIC BRONCHITIS?

Frank L[1], Margolis MK[1], Barker C[1], Duprat-Lomon I[2], Amiot N[2], Sagnier PP[3]
[1]MEDTAP International, Bethesda, MD, USA; [2]Bayer Pharma, Puteaux, France; [3]Bayer plc, Slough, United Kingdom

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 multivariable ordinary least squares regression equation was analyzed and the contribution of each variable to overall adjusted R^2 was evaluated. Indicators of chronic bronchitis severity used as independent variables were age ($</\geq65$ years), gender, use of either long-term inhaled steroids or systemic steroids during the study period with no change in dose regimen for acute episode (yes/no), duration of chronic bronchitis ($</\geq15$ years), number of exacerbations in prior year ($</\geq4$), and baseline FEV_1 ($</\geq50\%$ predicted); ABSS score the dependent variable. **RESULTS:** Adjusted model R^2 was 0.068. FEV_1 contributes approximately 40% of total R^2 ($p < 0.01$) 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 an objective measure of lung function and patient report about bronchitis symptoms and their impact on daily activities.

PIN50

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[1], Hass SL[2], Li JZ[2]
[1]University of Michigan, Ann Arbor, MI, USA; [2]Pharmacia 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), presenteesim (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.

PIN51

ASSESSING DISEASE-SPECIFIC UTILITY IN RECURRENT GENITAL HERPES (RGH)

Doward LC[1], McKenna SP[1], Meads DM[1], Ratcliffe J[2], Langley PC[3]
[1]Galen Research, Manchester, United Kingdom; [2]Research Triangle Institute, Manchester, UK; [3]3M Pharmaceuticals, St Paul, MN, USA

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