PRELIMINARY RESULTS OF A U.S.-BASED STUDY TO VALIDATE THE ACUTE BRONCHITIS SYMPTOM SEVERITY SCALE

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OBJECTIVE: To evaluate the psychometric characteristics of the Acute Bronchitis Symptom Severity Scale (ABSS).

METHODS: The ABSS is a seven-question, bronchitis specific, instrument. Responses are measured on a scale of 0–4. The total score is calculated as the mean of the seven responses with higher scores indicating greater distress. The ABSS was pilot tested as a part of a US-based prospective, naturalistic study to patients with acute exacerbation of chronic bronchitis at the pre-treatment visit, each day of the first five days of therapy with any antimicrobial agent, and at the test-of-cure visit (TOC, 18–21 days post therapy). Item and total scale performance, internal consistency (Cronbach's alpha), construct validity (correlation with St. George's Respiratory Questionnaire or SGRQ subscale), and responsiveness to change over time (based on clinician evaluation and patient's perceived treatment efficacy) were examined.

RESULTS: Twenty-seven patients were enrolled at four study sites in the US. Mean age was 57.4 (+14.5) years; 74% were female. No floor or ceiling effects were seen. Consistent with an improvement in acute bronchitis symptoms over time, mean item and total score values declined from baseline to TOC. Cronbach's alpha at each time point ranged from 0.70 to 0.88, exceeding the reliability guideline of 0.70 for a new measure. At TOC, the correlation between the ABSS total score and SGRQ activity subscale score was strong (0.60). The 18 patients considered clinically cured or improved at day 5 reported a mean ABSS score change, from baseline, of -0.90. Patients who considered the treatment moderately effective at day 5 (n = 11) reported an average change score of -0.87, while those who considered the treatment very effective (n = 3) improved by a score of -1.50.

CONCLUSIONS: Preliminary results from this pilot test with US-based patients suggest the instrument is valid, reliable, and sensitive to change over time.

THE ASSOCIATION BETWEEN HEALTH RELATED QUALITY OF LIFE AND ADHERENCE TO THERAPY IN HEPATITIS C

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For many conditions the overall impact of treatment on health related quality of life (HRQL) involves a tradeoff between improvement in the condition being treated and unwanted side effects. When the net HRQL result is too negative, patients have difficulty tolerating medication and may fail to adhere or discontinue treatment.

OBJECTIVE: We investigated the association between reduced HRQL due to interferon treatment and premature treatment discontinuation for chronic hepatitis C.

METHODS: A pooled secondary analysis of patients (n = 1441) across three international, multicenter, open-label, randomized studies that compared peginterferon a-2a with interferon a-2a. Health-related quality of life was assessed using the SF-36 Health Survey. The Fatigue Severity Scale (FSS) was used to measure the impact of disabling fatigue. Logistic regression analysis was used to examine the association between changes in health-related quality of life and treatment discontinuation.

RESULTS: Reduction from baseline in HRQL scores was a significant predictor of in-treatment SF-36 scores (P < 0.001). The odds of discontinuing treatment early were 48% higher in the quartile of patients with the greatest worsening of fatigue scores than in the lowest quartile. The odds ratios for treatment discontinuation among patients with worsening of SF-36 domain and summary scores ranged from 1.09 (physical function) to 3.56 (role limitations-emotional).

CONCLUSION: The impact on health-related quality of life is an important consideration in optimizing treatment of patients with chronic hepatitis C. HRQL assessments during treatment may offer physicians a method for monitoring the risk of premature discontinuation.

PRESCRIBING DECISIONS IN A UTILITY MODEL

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OBJECTIVE: To build a utility-based model comparing physicians’ prescribing practices for acute sinusitis, assuming that utility is a function of repeat visits, second prescriptions and call-backs.

METHODS: An algorithm is applied to data from an open-label, multicenter, randomized trial, which documents call back times, office visits and second prescriptions for 792 Acute Bacterial Sinusitis patients treated with Amoxicillin clavulanate 875 mg, Levofloxacin 500 mg or Moxifloxacin 400 mg. The marginal effect of fewer call-backs, office visits and second prescriptions, using utility as a function of these, is represented by a decision tree. Probabilities from the trial are used. Utilities range from highest (1.00) when the patient does not call back or get a second prescription, to lowest (0.25), when the patient calls back/comes back for a visit. Intermediate utilities range in decreasing order from call-back/no action, to no call-back/second prescription, to
call-back for other reasons, to call-back/second prescription. Regardless of the drug prescribed, the utility to the physician of a given outcome is the same.

**RESULTS:** Fewer call-backs and repeat visits pursuant to moxifloxacin resulted in the highest expected value (0.90), compared to levofloxacin (0.89) and Amoxicillin (0.87), when the lowest utility was 0.25. A sensitivity analysis showed consistent results, with 0.86 for Moxifloxacin, 0.85 for Levofloxacin and 0.82 for Amoxicillin when the lowest utility was zero. When the lowest utility was 0.75, all drugs yielded 0.96.

**CONCLUSION:** Physicians who seek to reduce events of call-backs, repeat visits and second prescriptions may favor certain antibiotic regimens, such as Moxifloxacin, for the treatment of acute sinusitis. This is more relevant when physicians put a higher premium on reduced events, that is when the spread in utilities is larger (0.25 and 1.00), than when the spread is smaller (0.75 and 1.00).

**INFECTION—Health Policy Presentations**

**PHYSICIAN PRESCRIBING PATTERNS FOR PEDIATRIC OTITIS MEDIA IN AMBULATORY PATIENTS**

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**OBJECTIVES:** Appropriate use of antibiotics is a major healthcare issue in view of increasing worldwide bacterial resistance to antibiotics. Treatment of otitis media is the most frequent reason for administering antibiotics to children in the United States. This study examined physicians’ prescribing pattern(s) for otitis media in children and compared them with therapeutic guidelines issued by the American Academy of Pediatrics, Family Physicians, and Otolaryngology, for appropriateness.

**METHODS:** Appropriateness of antibiotics was estimated across patient and physician factors. Patient factors such as age, sex, race, geographical location and payment source were compared with physician variables such as specialty, practice settings, geographic location and referral status for prescribing appropriateness. Data from the (1997) National Ambulatory Medical Care Survey (NAMCS) were utilized. Patients of age less than or equal to 12 years with a principal diagnosis of otitis media were analyzed using multiple linear and binomial logit regression models. Appropriate antibiotics were defined as those that are recommended by the guidelines. The dosage of antibiotics was confirmed by IMS Health Inc. and the advice of a practicing otolaryngologist.

**RESULTS:** Pediatricians and otolaryngologists prescribed more appropriate and less expensive antibiotics such as amoxicillin, ampicillin and sulfamethoxazole (R2 = 0.144). Internists and family practice physicians prescribed more expensive second line antibiotics (R2 = 0.178). There was no relation between the physician’s specialty and patient’s age for inappropriate antibiotics prescribing (R2 = 0.345). The probability of appropriate prescribing was higher for a physician from the northeast and midwest than for a physician from the south (R2 = 0.167). Appropriate prescribing was not influenced by whether the patient was referred (R2 = 0.436).

**CONCLUSIONS:** Physician’s specialty influences antibiotics prescribing for otitis media. Otolaryngologists and pediatricians appear to prescribe appropriately, while general practice physicians may not be prescribing the appropriate, less expensive antibiotics.

**SECOND-LINE THERAPY FOR OUTPATIENT TREATMENT FOR COMMUNITY-ACQUIRED PNEUMONIA**

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In the USA, macrolides are the dominant choice for initial outpatient treatment for community-acquired pneumonia (CAP). However, there is no consensus on second-line therapy. Cephalosporins, quinolones, beta-lactams and other macrolides are all commonly prescribed.

**OBJECTIVE:** To compare outcomes for different second-line treatment strategies in outpatient treatment of CAP.

**METHODS:** We employed a previously developed and validated probabilistic model to calculate treatment failure rates for adult CAP with no major comorbidities. We considered four choices for second-line therapy following initial treatment with the macrolide azithromycin (AZI): cefuroxime (CEF), levofloxacin (LEV), amoxicillin-clavulanate (AMC) and clarithromycin (CLA). Distribution of causative pathogens was based on literature. We used surveillance data for the USA from the 1999–2000 PROTEKT study, and applied pharmacokinetic/pharmacodynamic breakpoints to determine resistance levels for streptococcus pneumoniae (SP) and haemophilus influenzae (HI). Intracellular organisms were assumed 100% susceptible to CLA, LEV but resistant to CEF, AMC. Other bacteria were assumed 50% susceptible to all four drugs. We used published estimates of pathogen-specific rates of spontaneous resolution. We assumed 20% of initial treatment failures and 100% of second-line treatment failures were hospitalized. We estimated that 90% of susceptible organisms would respond to treatment.

**RESULTS:** In SP, the most common cause of CAP, there was substantial cross-resistance between AZI and the second-line drugs, except for LEV. For example, SP was 86.6% susceptible to CEF when it was susceptible to AZI, but only 16.3% susceptible to CEF when resistant to AZI. The model estimated that in 59.5% of cases the initial treatment with AZI would be successful and 5.9% would be hospitalized following initial treatment failure. An additional 5.2% would be hospitalized if treated with LEV, 9.1% with AMC, 13.3% with CEF and 19.3% with CLA.