PAIN—Patient Reported Outcomes

ELICITING UTILITY SCORES FOR HEALTH STATES ASSOCIATED WITH SEVERE CHRONIC PAIN

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OBJECTIVES: This study was designed to capture utility values for health states related to malignant (MP) and non-malignant (NMP) severe chronic pain treated with intrathecal (IT) analgesia. METHODS: Literature review and in depth interviews with clinical experts (n = 5) led to the development of health state descriptions. These were defined using visual analogue scale of pain intensity (VASPI) ranges 0–40, 41–60, 61–80 and 81–100 for both MP and NMP. Additionally 8 health states representing common adverse events associated with IT therapy were produced. A discussion guide based on the dimensions of the EQ-5D was developed. Health states were piloted with cognitive debriefing with five members of the UK general public. Time trade off interviews were administered to the UK general public (n = 102) to estimate utilities for the health states. A repeated measurement model on the TTO utilities was estimated to account for intra-patient correlation in the data. Using the predicted values from this model, utilities were obtained for all possible VASPI scores.

RESULTS: Participants were generally well matched to the census profile of England and Wales with some small differences in mean age, race and education. Utilities ranged from 0.84 for VASPI 0–40 (for NMP & MP) to 0.15 and 0.20 for VASPI 81–100 (NMP & MP respectively). The values for side effects (irrespective of the context of chronic pain) were as follows: dizziness (0.40); nausea (0.45); pruritis (0.82); confusional state (0.41); abnormal gait (0.67); urinary retention (0.69); weight gain (0.77) and erectile dysfunction (0.69). The results also show a substantial decline in utility scores related to more severe VASPI values for non-malignant, and malignant disease. CONCLUSION: The study shows a significant decrement in utility moving from less severe to more severe levels of chronic pain. The general public recognise the very significant impact that severe chronic pain has on HRQL.

SKIN—Clinical Outcomes Studies

IMPACT OF SECONDARY PROPHYLACTIC USE OF TACROLIMUS 0.1% OINTMENT ON QUALITY-OF-LIFE, TREATMENT OUTCOMES AND COSTS IN PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

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OBJECTIVES: To evaluate the impact of secondary prophylactic use (PU) of tacrolimus 0.1% ointment on the quality of life (QoL), outcomes and costs in comparison to standard use (SU) of tacrolimus 0.1% ointment in adults with moderate to severe atopic dermatitis (AD) over one year. METHODS: Data were generated as part of a multi-centre, pan-European, phase III clinical trial. Patients were randomised to tacrolimus 0.1% ointment (PU) or vehicle ointment (SU) twice a week, during a 12-month disease control period. In both groups disease exacerbations were treated with tacrolimus 0.1% ointment twice daily. Data on health-related QoL were obtained by using SF-36 questionnaire. Based on these data, utility values were calculated by using the algorithm by Brazier et al. 2002. Resource consumption data was derived from a patient questionnaire and pooled to estimate the costs using German unit cost data. RESULTS: Seventy-five patients with PU (57% moderately affected) and 59 patients with SU (59% moderately affected) participated. The number of disease exacerbations was 2.4 (PU) vs. 5.5 (SU) (p = 0.0004; moderate AD) and 2.3 (PU) vs. 7.4 (SU) (p = 0.0002; severe AD). Health-related QoL (utility values) in PU patients increased from 0.71 to 0.79 (p = 0.0004; moderate AD) and from 0.66 to 0.75 (p = 0.0002; severe AD). In the SU arm utility values increased from 0.69 to 0.72 (NS; moderate AD) and from 0.67 to 0.71 (NS; severe AD). In moderately affected patients mean (SD) total annual cost per patient in the PU arm was €1525 (1081) vs. €1729 (1209) in the SU arm. Mean (SD) total annual cost per patient was €2045 (13) (PU) vs. €2904 (1,510) (SU) in the group of severely affected patients. CONCLU-