The third measurement strategy was the time trade-off that the positions reflect the differences in preferences for these adjusting the distances between the array of states in such a way considered a step-by-step paired comparison task. In addition, strategy consisted of ranking the health states, which can be known that a description of their own health status was added to toid arthritis, n

of the general population when these are made by elementary

Patients’ assessment of health states are similar to assessments

group of rheumatoid arthritis patients. Ten studies for diabetes, 52 to osteoporosis 43 to schizophrenia, and zero to diabetes, 52 to osteoporosis 43 to schizophrenia, and zero to

were found between patients and healthy people for the ranking task or for the V AS. The TTO values, however, showed substan- tate divergence for certain health states, no overall differences

were reported using 5%, 5%-25% and >25 thresholds of non-compliance. Other studies reported total savings among compliers, or differential medical charges between compliers and non-compliers. Further, important differences were found in the type of clinical and economic outcomes, window period, and adjustment for confounders not only within disease-specific studies but also across studies. CONCLUSIONS: There are sig- nificant methodological differences in studies of costs of non-compliance in patients with chronic diseases. Readers should be aware of those differences when comparing results of a specific disease. Better and standardized methodology should be devel- oped to allow comparison of non-compliance costs.

MEASUREMENT METHODS

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OBJECTIVES: To explore whether discrepancies in values for health states exist between the general population (healthy people) and people who actually experience illness (patients). It was hypothesized that the more elementary measurement methods are, the more similar the responses of patients and healthy people would be. This means that standardization of own assessments supplemented with comparative judgment would largely eliminate differences. METHODS: A sample of the general population (n = 298) and two patient groups (rheuma-toid arthritis, n = 27; cancer, n = 48) assessed the same 17 hypo-thetical health states in an experimental setting. Patients did not know that a description of their own health status was added to the set of states. The first and most elementary measurement strategy consisted of ranking the health states, which can be considered a step-by-step paired comparison task. In addition, we used a multi-item visual analogue scale (VAS). This assessment task can be considered as ranking supplemented with adjusting the distances between the array of states in such a way that the positions reflect the differences in preferences for these states. The third measurement strategy was the time trade-off (TTO) elicitation technique. RESULTS: Except for some moder- ate divergence for certain health states, no overall differences were found between patients and healthy people for the ranking task or for the VAS. The TTO values, however, showed substan- tially higher patient values (>0.20) for almost all moderate and severe health states. This was more profound for the chronic group of rheumatoid arthritis patients. CONCLUSIONS: Patients’ assessment of health states are similar to assessments of the general population when these are made by elementary measurement methods. Therefore, valuation techniques based on simple judgmental tasks such as ranking or discrete choices may be better suited for deriving valid value-based health states.

USE OF AND COMPLIANCE WITH ELECTRONIC PATIENT REPORTED OUTCOMES WITHIN CLINICAL DRUG TRIALS

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OBJECTIVES: The use of electronic patient reported outcomes (ePRO) within clinical trials has grown rapidly with the increasing acknowledgement by regulatory authorities that ePRO is an acceptable method and one that directly addresses many of the limitations of paper PROs. METHODS: A study of the characteris- tics of ePRO use in clinical drug trials was undertaken to understand the breath of therapeutic areas in which ePRO is being used as well as to understand the dimensions affecting compliance with ePRO. A dataset of 136 clinical trials was analyzed by using fields that describe each protocol’s key elements including ePRO instrument, Phase, Therapeutic Area, Disorder and mean and median compliance broken down by age deciles. RESULTS: The analysis determined that CNS (36 studies) and gastrointestinal disorders (21) represented 42% and 15% of ePRO use by the biopharmaceutical industry for this dataset. Within CNS, ePRO was used heavily in depression (24.3%), insomnia (9.6%) and anxiety protocols (8.1%). Overall, ePRO was used in 16 different major disorders and therapeutic areas. 57% of the time a named PRO instrument is used electronically; the balance of the instruments is diaries or symptom questionnaires which may not have undergone formal validation. A sub-analysis of 8 pain studies representing 6% of the studies showed that, with one exception, patients 46 years of age and older are significantly (means of 81.6% vs. 72.5%) more compliant than study subjects younger than 46 years. The median compliance for patients 66 of age and older was 87%. CONCLUSIONS: This research shows that ePRO use within clinical trials is both broad and deep; that patients can be highly compliant; and that elderly patients are more compliant. Limita- tions of this study include the clinical trials of this dataset which can not be necessarily generalized as representative of all ePRO use.

THE SIGNIFICANCE OF PATIENT-REPORTED OUTCOMES TO FACILITATE MARKET ACCESS DURING A PRODUCT LIFECYCLE

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OBJECTIVES: To demonstrate the significance of patient-reported outcomes (PROs) in facilitating market access using evidence from deferasirox for iron-overload. METHODS: Reviews of European reimbursement (NICE/French Transpar- ency Commission) and regulatory authority (EMEA/CHMP) guidance and opinions were performed. A PUBMED search was implemented using PRO keywords and iron chelation therapy (ICT). We considered the added value of deferasirox (oral-ICT) demonstrated by PROs at various timepoints of the product lifecycle. RESULTS: PROs in a product lifecycle can address market access stakeholders’ concerns by demonstrating: 1) disease/treatment burden on patients, and its impact on adher- ence; 2) clinically meaningful outcomes from clinical trials and benefit to clinical practice; and 3) patient-perceived benefits over current treatments that may increase adherence, potentially reducing health care costs. In our example, 28 studies were identified. Medical importance and unmet needs were