time trade-off for Polish population were used to evaluate influence of demographic, social and cultural factors on EQ-5D utility value. Based on additional data concerning demographic and lifestyle factors collected, adjusted modeling was performed using GRETL and WinBugs software. Impact of this factors was analyzed by directly including variables in the model, as well as adjusting for variables corresponding interaction between the factors and health domain. **RESULTS:** Data from 230 interviews (5280 valuations) were analyzed. Preliminary random effects model was developed, with constant and N3 factor, all coefficients statistically significant, R^2 equal to 0.37 and value –0.647 for 33,333 health state. After adjusting base model for gender and smoking no influence on utility value was observed. Including the interaction terms between age (0–1 variable defined as above/below median of 38 years) and belief in life after death (defined as strong agreement) with health domains (level 3) proved to be statistically significant and improved model R^2 up to 0.40. Direct influence of belief in life after death on the utility value of health states was significant, R^2 equal to 0.38 and coefficient value 0.16. **CONCLUSIONS:** Demographic and cultural factors influence the utility value of health in Polish population. According to results based on preliminary data belief in life after death significantly reduces utility loss.

PMC39

WHAT DOES ACCEPTABILITY MEAN FOR PATIENTS AND HOW SHOULD IT BE MEASURED? QUALITATIVE STEPS FOR THE DEVELOPMENT OF A NEW MEASUREMENT INSTRUMENT IN PHARMACIES

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OBJECTIVES: Patient-Reported Outcomes (PRO) are routinely used to measure disease severity, perceived treatment impact, or patient attitude toward treatment. However, adherence can only partially be explained by clinical and PRO variables alone. Our objective is to develop a generic Acceptability measure assessing how patients balance out between advantages and disadvantages of long-term treatments. It could be used in future adherence studies through pharmacies. **METHODS:** A literature review was conducted in biomedical databases using keywords related to acceptability, perceptions, motivations and barriers linked to treatment. From 434 abstracts reviewed, 29 articles containing relevant concepts were retained to form the initial conceptual model of Acceptability. Exploratory interviews were performed with 5 pharmacists and 18 patients. They were recorded, transcribed word-for-word and systematically analysed. Concepts captured were organised into a detailed model used as a basis for the development of the test-version of the Acceptability questionnaire. **RESULTS:** The initial model of Acceptability included 6 global concepts: treatment perception, disease perception, judgement, behaviour, individual characteristics and medical context. The pharmacist interviews confirmed this model. The patient interviews confirmed the influence of treatment attributes on their Acceptability, but invalidated the concept of a judgment. The model adopted for the conceptual content of the Acceptability questionnaire covers 23 attributes organised in three major domains: efficacy, safety and convenience. Patients will be asked to rate how the treatment suits them, for each of the attributes. **CONCLUSIONS:** Qualitative research on Acceptability confirms the relevance of the concept for patients, but it also shows that judging whether a drug is good or not is left to the expertise of the health care professional. Appropriate wording was critical during item generation to capture the information in a way that make sense for the patients. After the testing and revision of the questionnaire, it will be able to be included in adherence studies.

PMC40

STABILITY OF TREATMENT SATISFACTION WITH MEDICINES QUESTIONNAIRE (SATMED-Q) STRUCTURE IN DIFFERENT PATHOLOGY SAMPLES

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OBJECTIVES: Treatment Satisfaction (SATMED-Q) is a generic PRO instrument measuring Treatment satisfaction with medicines in chronic health conditions. Several multisample analysis are carried out in order to assess the stability of the questionnaire structure across of different types of patients, and to discover possible differences in dimension correlations for different drug treated pathologies. **METHODS:** Four samples of patients with different known pathologies following regular medication treatment were gathered from specialized units, and primary attention centres: hypertensive, drug-refractory-epilepsy subjects, caregivers of patients with dementia of the Alzheimer type and a normative sample. Exploratory factor analyses on each separate sample were carried out to assess sample specific structures. Multi-sample confirmatory factor analysis was used to assess the degree of agreement between sample structures using the known theoretical structure. Congruence statistics were also used with exploratory structures. **RESULTS:** A total of 2777 patients were gathered: 1,025 hypertensive patients –47% women, 63 (±11.3) years old-, 768 epileptic patients –65% women, 41 (±13.4) years old-, 842 Alzheimer patients caregivers –63% women, 78 (±6,8) years old-, and the normative sample used to develop the SATMED-Q composed by 442 patients of different pathologies –50% women, 62 (±13.6) years old-. The theoretical 6-factor solution identified in the original instrument was attained in all sample specific exploratory analyses. The multi-sample confirmatory analysis matched the 6-dimensional solution but usual goodness of fit problems with large sample sizes were found. Sample specific confidence intervals for factor loadings and factor correlations were obtained. Congruence statistics were reasonable, but were not able to explain differences in the obliqueness of factors. Meaningful differences in dimension correlations between samples were found. **CONCLUSIONS:** The structure of the SATMED-Q questionnaire is shown to be stable across different type of treatments and patients, but the relations between dimensions vary depending on the pathology studied.

PMC41

METHODOLOGICAL ISSUES IN THE LITERATURE ON COSTS OF NON-COMPLIANCE IN CHRONIC DISEASES

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BACKGROUND: In the last decade various studies have been published that reported the costs of non-compliance. However, the quality of those studies has been questioned. **OBJECTIVES:** To systematically review and critically appraise the literature to identify the main methodological limitations related to estimating and reporting costs of non-compliance in patients with diabetes, schizophrenia, rheumatoid arthritis and osteoporosis. **METHODS:** A literature review was conducted using PubMed,

Cochrane Database, EMBASE and CINAHL electronic databases. Studies included were published in the last decade, irrespective language that reported data on costs of adherence, non adherence, or costs by adherence range. Two independent researchers reviewed the titles and abstracts by disease. A template was developed to extract data. Methodological issues were compared both within and among each disease area. **RESULTS:** A total of 145 full manuscripts were identified: 50 related to diabetes, 52 to osteoporosis 43 to schizophrenia, and zero to rheumatoid arthritis. Ten studies for diabetes, six for psychosis and four for osteoporosis (20 total) were reviewed. Most studies used cohort designs. Medication possession ratio was the most common measure of compliance. There was significant variation in how outcomes were reported. Some non-compliance costs 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 significant 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 developed to allow comparison of non-compliance costs.

PMC42

PATIENT AND POPULATION HEALTH-STATE VALUES ARE COMPARABLE WHEN DERIVED BY ELEMENTARY 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 (rheumatoid arthritis, n = 27; cancer, n = 48) assessed the same 17 hypothetical 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 moderate 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 substantially 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.

PMC43

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 characteristics 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 (56 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. Limitations of this study include the clinical trials of this dataset which can not be necessarily generalized as representative of all ePRO use.

PMC44

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 Transparency 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 adherence; 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