ing requirements. Mobile phones provide a very effective method of collecting data in an unsupervised, naturalistic setting.

PMC37

ACCESS TO PATIENT-REPORTED OUTCOME (PRO) INSTRUMENTS AND THEIR TRANSLATIONS IN THE LIGHT OF FDA RECOMMENDATIONS

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Following the FDA recommendations of having exhaustive, reliable and documented information on an instrument and its translations when using these in an international study (draft PRO guidance in 2006), the accessibility of this information for instrument users has become increasingly important. The quality of this information is however directly impacted by how a developer chooses to release the latter into the scientific community and the way he decides to protect his instrument. It is thus necessary to review current ways in which this is done, to determine if FDA recommendations can actually be met or not and explore ways in which to facilitate this. Methods included to conduct a review of existing ways in which developers release information into the scientific community; 2) to comment on the pros and cons for each identified system with concrete examples; and 3) to make recommendations for instrument developers. Out of the 50 different cases identified and reviewed, two trends emerge with all possible variations between the following two extremes: on the one hand, the uncontrolled, de-centralised, free access to non-updated information without developer input and on the other controlled, copyright-protected, centralized, fee-paying access to reliable and updated information with input of the developer. Whilst both extremes have advantages and disadvantages, results demonstrate that the latter extreme seems to be more compliant with FDA recommendations. Concrete examples will be discussed in the presentation. Findings indicate that the way in which a developer organises (or not) the release of information on his instrument and its translations is directly related to whether a user can comply or not with FDA recommendations. Promoting a controlled, centralized system with input from the developers will facilitate access to reliable and updated information on instruments and their translations.

PMC38

USE OF A MOBILE PHONE TO ADMINISTER VISUAL ANALOGUE SCALES (VAS)

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OBJECTIVE: Handheld computer systems are increasingly being used to administer performance tasks and mood assessments in an everyday life setting. Mobile phones (cell) phones can be used in a similar way, and are highly portable and widely used. We evaluated a mobile phone implementation of a VAS scale using alcohol as a means of producing changes in subjective state. **METHODS:** Sixty-five volunteers (30 male) aged 19–54 years (mean 23) consumed a drink containing either vodka or water and orange juice in 10 minutes. Mean breath alcohol concentration 60 minutes later was 45–170 mg/100 ml (mean 94). Subjective drunkenness was rated on the mobile phone and on paper in randomised order before the drink and at 60 minutes after the drink with other test procedures in between. **RESULTS:** Changes in sober–drunk ratings (% of scale length) due to alcohol were comparable between the two testing modes (Alcohol—Placebo: 29.3 for phone, 25.3 for paper) and the agreement was excellent (Intra-Class Correlation = 0.96). The sensitivity to changes in scores between alcohol and placebo was similar for the two modes. **CONCLUSION:** We have shown that ratings made on a 2.1 cm VAS on a mobile phone screen are very similar to those on a conventional 10 cm scale on paper. Taken together with work on handheld devices, these data suggest that VAS scores are unaffected by scale length over a rather wide range, and support the use of mobile phone and handheld implementations of VAS for assessing subjective states.

PMC39

A COMPREHENSIVE PARADIGM TO ESTIMATE MINIMAL CLINICALLY IMPORTANT DIFFERENCES (MCID)

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OBJECTIVE: Due to the existence of many methods for estimating MCID and a lack of consensus on choosing among the potential estimates, an integrated approach for generating a MCID change score on Patient Reported Outcomes (PRO) measures is proposed. When incorporating PRO in clinical trials, clinicians and researchers face the challenge of determining whether a mean difference on a measure is clinically important. Currently available methods for interpreting the scores on PRO measures are often classified as being either anchor-based or distribution-based. These methods may yield a variety of candidates as potential MCID estimates. However, there is no agreed method of choosing among these candidates. **METHODS:** A strategy is proposed that integrates these two methods of MCID estimation and extends to selection among the candidate values by incorporating their natural variability and distinctions as well as the critical role of clinical judgment. The strategy consists of three steps: 1) generating multiple estimates of a MCID and corresponding confidence intervals (CIs) and range of variability; 2) integrating across the estimates from Step 1 by applying adopted normative descriptive criteria for MCID; 3) incorporating clinical judgment. An illustration of the proposed strategy is provided. **RESULTS:** Across the candidate MCID values, the maximum, minimum, mean of the estimates, minimum and mean of the 80% CI lower bounds, as well as the range of variability, were selected with consideration given to clinical insight. The comprehensive paradigm resulted in a MCID estimate that integrates normative, descriptive criteria. **CONCLUSION:** The proposed paradigm serves as a unifying approach that integrates available methods for estimating a MCID for a PRO.

PMC40

PHARMACY STUDENTS' PERCEPTIONS OF HEALTH-RELATED QUALITY OF LIFE FOR MULTIPLE CHRONIC HEALTH STATES MEASURED VIA ALTERNATIVE METHODS FOR UTILITY ASSESSMENT

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OBJECTIVES: To measure and analyze utility value assignment by professional pharmacy students to each of four chronic health states (Depression, Type 1 Diabetes, Rheumatoid Arthritis, and Hypertension) through utilization of one of the following utility assessment techniques: visual analog scale (VAS), feeling thermometer (FT), standard gamble (SG), and time-trade off (TTO). **METHODS:** Each Doctor of Pharmacy student (n = 195) was provided with a detailed patient vignette for each health state under evaluation. These cases contained information including the patient's drug therapy, overall health state and the impact of the latter on activities of daily living. Much care was given to