satisfaction domains exhibited the strongest significant results amongst all three tests. However, while the convenience domain exhibited strongly significant measurement equivalence for the CTT, it only exhibited significant results for the SEM and DIF. **CONCLUSIONS:** While all three methods indicated the same overall results, there is some suggestion of differing sensitivity amongst the tests.

PMC44

EXPERTS' JUDGEMENT ON PATIENT-CENTRED COORDINATED CARE

Mühlbacher AC, Juhnke C, Bethge S
Hochschule Neubrandenburg, Neubrandenburg, Germany

OBJECTIVES: Delivering care coordination services is often described as the key to effectively meet patients' needs and expectations. Patient empowerment and patient participation is highly discussed and postulated, but there is a lack of knowledge of how to design patient-centered coordinated care. This study intends to provide health policy and decision-makers with a comprehensive assessment on experts' priorities in the relative value of different dimensions of coordinated care. **METHODS:** A questionnaire with 88 items was conducted with N = 251 health care experts. Exploratory and confirmatory factor analysis was performed using SPSS©18. The number of factors to be retained was controlled by Kaiser's criterion (eigenvalues above 1), validation of the scree plot, and the interpretability of the items. Cronbach's alpha was used to assess the internal consistency of the subscales identified. **RESULTS:** The exploratory factor analysis leaded to 25 factors. After analyzing the screeplots and qualitative results confirmatory factor analysis was computed for an 8 factor solution accounting for 42,828 % of the total variance and with KMO of 0.723. Cronbach alpha reliability coefficients were computed for each of the sub-scales and ranged between 0.849 and 0.745. Based on the existing literature and the analysis conducted, coordinated care could be differentiated into eight dimensions: access, knowledge transfer, technical care, interpersonal care, patient-centeredness, continuity, infrastructure and participation in social life. **CONCLUSIONS:** The aim of the study was to structure the key attributes for future stated preference research. Differences in experts' judgment and patients' perspective will be analyzed in upcoming research. If expectations of stakeholders are taken into account adequately, it can be assumed that this will increase the motivation to participate in and the satisfaction with coordinated care programs.

PMC45

GLOBAL INDUSTRY USE OF ELECTRONIC PATIENT-REPORTED OUTCOME INSTRUMENTS: PRELIMINARY RESULTS FROM A 2010 EPRO SURVEY

Bergstrom F[1], McGinley D[2], Ackerman S[3], Cole J[3]
[1]Covance Market Access Services, Gaithersburg, MD, USA; [2]Covance, Conshohocken, PA, USA; [3]Covance Market Access Services, San Diego, CA, USA

OBJECTIVES: While eClinical Forum's 2009 survey findings suggest that electronic data capture (EDC) is used in 58% of clinical trials, little is known about the use of electronic patient reported outcome (ePRO) technologies for data collection. The purpose of this survey study was to describe the experiences and perceptions regarding use of ePRO as reported by pharmaceutical, biotech, medical device, and other industry professionals. **METHODS:** Global industry professionals were invited to complete a web-based survey fielded in early 2010. Participants were asked about their professional demographics, PRO and ePRO experiences, as well as challenges and advantages of using ePROs. Responses were analyzed descriptively. **RESULTS:** To date, 153 industry professionals completed the survey. Forty-four percent of respondents were from pharmaceutical companies, followed by other (41%), biotech (10%) and medical device (6%). Forty nine percent had previous PRO study experience among which 51% had prior ePRO experience. Among respondents using a PRO measure in an international study, 43% used ePRO for data collection. Hand-held device (tablet, PDA) was the most common ePRO technology (42%), followed by interactive web-response (29%) or voice-response (29%). Reported advantages of ePROs include accuracy of information collected (79%), increased compliance (73%), and ease of use (64%); challenges include patient training (65%), study start-up costs (64%) or time (54%), and patient burden (54%). Validation of PRO for EDC use was an important factor when considering paper-based versus ePRO data collection (21%). Among those responding, 26% indicated they used ePRO data collection in >50% of their clinical trials, and 82% strongly agreed/agreed they would use ePRO in future studies. **CONCLUSIONS:** Preliminary results from this survey suggest that among those who use PRO measures in studies, the percent of industry professionals using ePROs is similar to the overall percent of industry using EDC as a data collection method in clinical trials.

PMC46

TRANSLATION AND LINGUISTIC VALIDATION OF PRO MEASURES: RESPONSE OPTION ISSUES

Griffin AJ, Furtado T, Wild D
Oxford Outcomes Ltd, Oxford, Oxon, UK

OBJECTIVES: PRO measures use a variety of response scales/options. These vary according to the type of measure, and can include frequency (time-based) scales, severity (intensity) scales, visual analogue scales (VAS) and levels of agreement. The translation and linguistic validation of response options can cause semantic or conceptual difficulties. This research aims to identify the issues raised during the translation of some response scales, with the aim of aiding the translatability of response options. **METHODS:** Examples of issues in the translation and linguistic validation of response options were collected from past Oxford Outcomes projects. Those response options which were problematic across PRO measures and languages were evaluated. **RESULTS:** Numerous cultural and linguistic issues became apparent throughout the translation process which require careful attention being paid to the response options during the translation and linguistic validation process: /Some mid-scale words used in severity scales are particularly difficult to translate, e.g. rather, somewhat. Two response options on a scale, e.g. rather confident, fairly confident can be very small and unclear. /Frequency scales (how often . . .) are often translated as "how many times," in some languages (particularly Indian). When using "level of agreement" scales the word "strongly" often proves problematic as some languages find it difficult to express levels of agreement. **CONCLUSIONS:** Various issues with response options were recognised during the linguistic validation of a considerable number of PRO measures. a full translation and linguistic validation procedure can help to overcome such problems, but care should be taken when choosing response scales during the development of PRO measures. In general, response options, which are particularly close in meaning, e.g. somewhat, rather, are usually more problematic to translate than those with clear parameters, e.g. never, rarely, sometimes, often, always.

PMC47

FURTHER INSIGHT INTO DESIGNING WEB-BASED PATIENT REPORTED OUTCOMES FOR USE ON PERSONAL COMPUTERS IN GLOBAL STUDIES

Tulkki-Wilke RK[1], Bushnell D[2], Martin ML[3], Jewett G[4]
[1]CRF Health, Helsinki, Finland; [2]Health Research Associates, Inc, Mountlake Terrace, WA, USA; [3]Health Research Associates, Inc, Seattle, WA, USA; [4]CRF Health, Lansdale, PA, USA

OBJECTIVES: Capturing patient-reported outcomes (PRO) via the web can be an efficient tool in larger-population clinical studies. Enabling patients to use their own computers means that web-based PROs are administered to patients on a wider variety of screen sizes and resolutions. As indicated in the recent ISPOR ePRO Report by Coons SJ, et al, this creates an issue of ensuring equivalency of the instruments across all screen sizes. This research describes a practical approach for maintaining validity of instruments when patients use their own computer. It aims to evaluate whether the PRO is presented as intended on various screen sizes and browsers. The research also takes into consideration variability of computer infrastructure in different geographical areas, as this is a major factor limiting web-based data collection. **METHODS:** The EuroQoL EQ-5D was programmed for use on smaller screens and scaled up to larger sizes and put into an ongoing usability testing study in the US, UK, Spain, Finland, Singapore, and China for sufficient coverage of languages and technologies. The sample size is 30 healthy volunteers. Screen sizes varied from small mini laptop screens to large LCD screens (9″ to 24″). **RESULTS:** Early results show that the questionnaire fits on all screens without a need for patients to scroll either in left-right or up-down directions. On 15,4″ screen, the questionnaire occupies 71% of the screen versus 57% on a 24″ display. The difference in relative size is 19%, which indicates that the questionnaire remains usable even if the screen size increases by 56%. Further results are forthcoming. **CONCLUSIONS:** As the presentation of the PRO is the same on all screens, conducting psychometric validation may be more straightforward. In addition, finding a method to ensure one PRO design works on all computers is a major factor in conducting global studies efficiently.

PMC48

UPDATES AND INNOVATIONS IN ELECTRONIC PATIENT-REPORTED DATA CAPTURE: A REVIEW OF THE EVOLUTION AND FUTURE DIRECTIONS OF EPRO

Curry C
PHT Corporation, Boston, MA, USA

OBJECTIVES: In clinical trials, the capture of patient-reported outcome (PRO) data has increased over the past decade. Regulatory guidelines, including the EMEA's concern of Health-Related Quality of Life (HRQL) measurements and the FDA's emphasis on PRO data to support labeling claims, have led to a greater inclusion of PRO as clinical trial endpoints. As sponsors include more PRO measurements, many turn to electronic PRO (ePRO) data capture. This presentation summarizes literature from the last 9 years to report changes in the use of ePRO including projections for future applications in clinical trials, disease management and health policy. **METHODS:** This presentation is a synthesis of literature in peer reviewed journals regarding ePRO from 2000 to 2010. Key search terms include "patient reported outcomes", "electronic patient reported outcomes", "electronic diaries", "interactive voice response system", "interactive web response system" and "digital pen". The literature review made use of meta-databases such as PubMed and Medline. **RESULTS:** The use of ePRO has increased since a decade ago, due to greater movement in health care towards electronic solutions and to regulatory emphasis on PRO collection in clinical trials. The presentation will detail how ePRO is being used and provide a synthesis of recommendations for future ePRO use based on the literature. The session will examine the indications and therapeutic areas, population types, and applications of ePRO within health care and will review *evidence showing whether ePRO data quality is higher than that of data captured using paper methods*. **CONCLUSIONS:** The presentation deals with the evolving questions of ePRO—projected limitations and actual scope of experience with ePRO. Due to literature emphasis, the presentation will focus on clinical trials but will also examine other health care fields such as disease management and health policy. Attendees will learn about the evolution of ePRO and forthcoming directions and receive a bibliography of current literature.