OBJECTIVES: In aesthetic surgery, the assessment of patient-reported outcomes is especially pertinent to clinicians because patient satisfaction and improved quality of life are the predominant considerations determining success. In order to appropriately measure the impact of these procedures, well-developed and validated questionnaires are needed. The objective of this study was to develop a new patient-reported outcome (PRO) measure to evaluate patient satisfaction and quality of life following facial cosmetic procedures (surgical and non-surgical). The main scale ‘Satisfaction with Face Overall’ will be presented. Preoperative patients were > 18 years of age and scheduled to undergo a facial cosmetic procedure. Postoperative patients had undergone a facial cosmetic procedure within 2 weeks-5 years. Patients received a questionnaire with standard incentives and reminders. Rasch analysis was used for item reduction and scale development (RUMM2030®), each scale and item were examined according to 7 measurement criteria (clinical meaning, thresholds for item response options, item fit, item locations, DIF, standardized residuals, person separation index). RESULTS: A total of 344 facial cosmetic patients (preoperative n=79, post procedure n=265) participated. Scales were constructed for each area defined as important to patients by the qualitative data. This was achieved by choosing sets of items hypothesized to constitute a scale, analyzing the data against measurement criteria and making decisions on item selection and deletion. The main scale ‘Satisfaction with Face Overall’ fulfilled Rasch and traditional psychometric criteria (including Person Separation index 0.94, Cronbach’s alpha 0.95). CONCLUSIONS: The FACE-Q is a new PRO measure that will provide essential information about the impact and effectiveness of surgical and non-surgical facial aesthetics procedures from the patients’ perspective. It is conceptually grounded in patient perceptions and fulfills criteria for rigorous measurement. It will support multi-center studies, while also being clinically useful.

APPLICATION OF THE BOTHER CONCEPT ACROSS CULTURES

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OBJECTIVES: The objective of this study was to analyze the concept of bother as it is used in translated Patient Reported Outcomes (PRO) instruments. In American English, bother is versatile as it may connote negative mental, physical, and social conditions. Because of this versatility, the concept may have different meanings across languages and cultures. In observing the term bother in PRO instruments, it will be determined whether the concept remains equivalent when translated. METHODS: To determine the meaning of bother across many languages, linguists, cognitive debriefing interviewers, and cognitive debriefing subjects were asked to complete a questionnaire following the linguistic validation of a product's PRO instrument which contained bother as the key concept. Furthermore, all instances of bother as it appeared in back-translated instruments and cognitive debriefing reports were analyzed. RESULTS: By analyzing questionnaires completed by respondents, we identified many instances where bother was described as an ambiguous concept. At the item level, it became clear that the term “bother” may only be applicable 55% of the time and the concept was back-translated as something conceptually different 20% of the time. During cognitive debriefing, 16% of subjects paraphrased bother incorrectly, while several suggested the removal or replacement of bother. CONCLUSIONS: Developing PRO instruments for cross-cultural consideration should pay attention to the equivalence of key concepts across different languages and cultures if they are to be useful in multinational clinical trials. In this study we discovered that while respondents understood bother to have a negative connotation, data across languages shows a lack of conceptual equivalency. As a result, bother may not be the most ideal measurement of disease symptom severity and quality of life. Therefore, in the development of PRO instruments, ambiguous concepts such as bother ought to be replaced with more specific concepts to measure many components of one’s quality of life.

PHS55

MOBILE PHONE USE IN PATIENT REPORTED OUTCOMES - ACADEMIA AND BEYOND

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OBJECTIVES: To demonstrate that mobile phones can be used to collect patient reported outcomes. METHODS: A literature search was conducted looking at articles published between 2009 and 2011 that referenced electronic diaries of some description. These were then filtered to pull out those that referenced mobile or cellular phones. RESULTS: Ninety articles were found that referenced electronic diaries specifically. Out of these, 8 articles specifically referenced mobile/cellular phones. The studies referenced in these articles were carried out on populations with an age range of 9 years up to 70 (reported mean 21.8; SD - TBD). The studies were split into 6 therapy areas: physical activity, weight management, sexual activity, asthma, alcohol related and pain, and all but one of the studies included both males and females, with the other being female only. Population size ranged from 15 to 994 (mean 249.8; SD-TBD), in the USA, Europe, Australasia and Asia, and subjects reported for a minimum of 7 days (but up to 6 reports per day) to a maximum of 365 days (mean 110.4 days; SD-TBD). Pain data were only collected in one study; mortality reporting occurred in half of the studies and subject preferences were collected in four of the studies and 3 studies reported giving the subjects training. Notably, 5 out of 8 of the studies allowed the subjects to use their own mobile phone for the reporting. CONCLUSIONS: All of the articles concluded that mobile phones were suitable to collect data from subjects, especially momentarily reporting. It was noted that the use of mobiles was acceptable to the populations as they used them in everyday life and found them to be convenient, and the researchers found the technology to be inexpensive to implement.

PIHS9

PATIENT-REPORTED OUTCOMES: THE GROUNDED ITEM TECHNIQUE FOR GENERATING CONTENT VALID QUESTIONS

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OBJECTIVES: Qualitative research methods have become increasingly important to Patient Reported Outcome (PRO) measure developers since the emphasis on content validity in the Food and Drug Administration’s guidance for the development of PROs. The Critical Incident Technique (CIT) is a rigorous data collection protocol to provide empirically-derived data on human behavior. More than 130 research studies employing the CIT have been published in the medical and health services research literature alone (according to PubMed indexing for 2002-2011). We describe here our work building on the CIT to develop a rigorous method for generating content-valid items for patient-reported measures which we call the Grounded Item Technique. METHODS: The CIT was not developed to generate items. Its most common use is to develop conceptual frameworks or taxonomies in conjunction with Grounded Theory (Glaser & Strauss, 1967) data analysis. By contrast, the Grounded Item Technique (GIT) is specifically focused on item generation, and developed a five-phase approach. GIT is conceptually grounded in qualitative data analysis and validation. RESULTS: Application of GIT to 27 cases resulted in 365 cases. 5 subjects reported giving the subjects training. Notably, 5 out of 8 of the studies included both males and females, with the other being female only. Population size ranged from 15 to 994 (mean 249.8; SD-TBD). Pain data were only collected in one study; mortality reporting occurred in half of the studies and subject preferences were collected in four of the studies and 3 studies reported giving the subjects training. Notably, 5 out of 8 of the studies allowed the subjects to use their own mobile phone for the reporting. CONCLUSIONS: All of the articles concluded that mobile phones were suitable to collect data from subjects, especially momentarily reporting. It was noted that the use of mobiles was acceptable to the populations as they used them in everyday life and found them to be convenient, and the researchers found the technology to be inexpensive to implement.