PRM143

EVALUATION OF THE ALOPECIA PATIENT ASSESSMENT (APA) QUESTIONNAIRE IN WOMEN WITH BREAST CANCER AND ALOPECIA

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OBJECTIVES: To evaluate the content, clarity, and relevance of a new patient-reported outcome questionnaire, the Alopecia Patient Assessment (APA), among women with breast cancer and alopecia. **METHODS:** 10 US subjects were recruited from oncology practices, breast cancer support websites, and other online sources, and asked to complete the APA, a five-item questionnaire assessing impact of hair loss on spending time with family/friends (Item #1), work (Item #2), ability to leave home (Item #3), self-image (Item #4), and feelings of embarrassment (Item #5). Subjects also completed a telephone interview about the APA. **RESULTS:** Mean age = 52 + 11 years (50% Caucasian, 60% married). All respondents felt the instructions were clear. Some suggestions included defining "hair loss" to include currently losing or already lost some or all of your hair, and to add instructions about how to respond if you typically wear a wig, hat or wrap. 90% found the questionnaire to be clear, with 70% reporting it was "very easy" to complete. One hundred percent correctly paraphrased the first 3 items, while 60% and 89% (8/9) correctly paraphrased Items 4 and 5, respectively. All respondents stated the 5 response options ("not at all" to "very much") were clear. Although 78% (7/9) felt it was easy to recall "the past week," 60% thought it would be clearer to use "the past 7 days." Thirty percent were uncertain how to respond to Item #2, as they weren't currently employed. Minor modifications included adding more general instructions for completion, using the past 7 days for the recall period, and adding a check box for Item #2 for those not employed. **CONCLUSIONS:** In general, the APA was clear, comprehensive, and relevant among breast cancer patients with alopecia. The APA can be considered for clinical trials to determine the patient perspective of this important symptom associated with chemotherapy.

PRM144

AN ADAPTABLE METHODOLOGY FOR THE DESIGN, IMPLEMENTATION AND CONDUCT OF A WEB-BASED SURVEY ASSESSING BURDEN OF ILLNESS AND RACIAL DIFFERENCES: CASE STUDY OF ADULT FEMALES WITH ACNE

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OBJECTIVES: To describe survey methodology used to evaluate the burden of illness and racial differences in adult female acne (AFA). **METHODS:** A targeted, web-based survey was used to recruit a racially diverse sample of US adult females (25-45 years) with facial acne vulgaris from an existing pool of internet panelists. Subjects who self-reported ≥25 visible facial pimples at screening were eligible. Recruitment was stratified by age (50% 25-35; 50% 36-45 years) and race (50% White; 50% Non-White [25% Black/African American; 25% Hispanic/Asian/Other]). Survey outcomes included: sociodemographic and clinical characteristics; resource utilization; treatment satisfaction; quality of life; perceptions; coping behaviors; work environment/productivity; anxiety/depression symptoms; and skin-specific treatment preferences (non-White females only). Validation rules were pre-programmed into the survey to improve data quality. Descriptive statistics summarize results in the total sample; racial differences (White vs. non-White) were evaluated using descriptive statistics and t-test/chi-square analyses. **RESULTS:** The survey was fielded online from Oct-Nov 2011. A total of 7245 panelists received survey invitations via email. Of 4112 survey respondents, 208 (5.1%) were eligible and completed the survey. Mean age of sample was 35±6 years; 48.6% non-White [Black (n=51); Hispanic (n=23); Asian (n=16); Other (n=11)]. Most females (80.3%) reported 25-49 visible pimples, followed by 50-75 (13.5%) and >75 (6.3%). Median survey completion time was 24.5 minutes. **CONCLUSIONS:** Web-based survey methodology with an existing pool of panelists permitted focused recruitment of respondents to reach targeted sample sizes in each age and race/ethnicity stratum. This method enabled recruitment of a targeted subset of patients, including non-White females and those with greater acne severity (≥50 visible pimples). Web-based surveys are an effective method for collecting patient-reported data for stratified patient cohorts, while minimizing both time and cost. This method was well suited for studying the burden of AFA in a real-world cohort.

PRM145

IDENTIFYING SEVERITY LEVELS ASSOCIATED WITH COMMONLY USED PAIN DESCRIPTORS USING A NUMERIC RATING SCALE

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OBJECTIVES: To quantify the usual severity range of commonly-used descriptors for pain, and to assess whether or not these different pain descriptors are associated with different ranges of the numeric rating (NRS) scale. **METHODS:** Subjects were recruited by web posting and subsequently screened. Those self-reporting active pharmacological treatment for Migraine, Low Back Pain (LBP), Osteoarthritis (OA), or Rheumatoid Arthritis (RA) were scheduled for in-person interviews using card-sort exercises with pain descriptors selected by each subject. For each selected pain descriptor, subjects associated the descriptor with one number on an 11-point NRS scale to identify the degree of severity they usually experienced for that pain sensation. Each pain descriptor was summarized with descriptive statistics (mean, sd, range), to characterize the distribution of each word along the rating scale. **RESULTS:** Subjects (n=72) ranged between 19 and 84 years (mean age of 45). The majority (68%) was female, 63% were working full- or part-time, and 61% were Caucasian. Of the 18 descriptors used by the majority of subjects across conditions, the highest mean NRS values were found for EXCRUCIATING (mean=9.4), STABBING (7.6), and PIERCING (7.5). Low mean NRS values were found for TIGHT (5.0), STIFFNESS (5.0), and ANNOYING (5.1). Some descriptors were rated relatively consistently by subjects, as evidenced by low standard deviation and range (e.g., EXCRUCIATING, sd=1.1, range=5) while others showed more variability in placement on the scale (e.g., STIFFNESS, sd=2.8, range=10). **CONCLUSIONS:** While placement on an NRS ranges broadly, some descriptors are associated strongly with particular severity levels, while others are less precisely defined relative to severity. These patterns in pain scoring should be accounted for when selecting descriptors for a pain PRO measure.

PRM146

IMPLEMENTING NEW COA INSTRUMENTS ON ALTERNATIVE DATA COLLECTION MODES: THE ELECTRONIC IMPLEMENTATION ASSESSMENT

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OBJECTIVES: The Critical Path Institute's (C-Path) ePRO Consortium, consisting of seven ePRO provider member firms, has developed a process for assessing the migratability of newly developed Clinical Outcome Assessment (COA) instruments. The objective of the electronic implementation assessment is to evaluate the viability of implementing a COA instrument on all currently available electronic platforms. **METHODS:** The electronic implementation assessment is conducted once a draft instrument has emerged from the item generation process as part of new instrument development. The assessment is conducted after a translatability assessment of the content has been completed. The assessment provides an item-level and instrument-level analysis of the instrument's suitability for implementation on various electronic data collection platforms (i.e., tablet, handheld, interactive voice response (IVR), web, and digital pen). **RESULTS:** The instruments that have emerged from C-Path's PRO Consortium's Depression and Irritable Bowel Syndrome Working Groups have undergone the electronic implementation assessment process. Some assessment findings common to both instruments include: suggestions to modify the recall period or the way the recall period is expressed to subjects; identifying the translated character length of some items that may pose a concern for small-screen devices; and highlighting that bold and underlined text are rendered differently on various operating systems and cannot be rendered on an IVR platform. Issues unique to each of the instruments were also detected. **CONCLUSIONS:** The PRO Consortium Working Groups have taken into account the feedback included in the electronic implementation assessments and have made changes to the draft COA instruments prior to additional instrument testing. The electronic implementation assessment has shown the ability to identify elements of COA instruments that should be modified to allow for easier implementation on a variety of electronic data collection platforms which is important for enhancing the quality of data collected with these instruments in future clinical trials.

PRM147

CONDUCTING QUALITATIVE INTERVIEWS IN COMPROMISED CHILD POPULATIONS: CEREBRAL PALSY (CP) AS A CASE STUDY

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OBJECTIVES: Patient reported health outcome data for children with cerebral palsy (CP) is limited by a lack of standardized protocols and effective data collection methods for this population. Children with CP present a spectrum of cognitive and communication abilities due to actual age, cognitive age, literacy, and motor/sensory impairment. Each factor impacts the ability to understand questions and provide responses about experiences and symptom status. For this study, we developed a novel approach for conducting concept elicitation interviews with CP patients (2-17 years) around spasticity-related pain. **METHODS:** Our interview protocol was developed using literature, interviews with CP specialists and input from parents/guardians. The methodology was flexible, allowing for individually tailored approaches based on the specific abilities of each patient. Techniques were adjusted based on: 1) screening data (age, estimated cognitive age, communication ability, Gross Motor Function Classification System [GMFCS] score); 2) information on strengths/limitations from parent/caregivers; and 3) observation during the interview. **RESULTS:** Interviews were conducted with 21 children and adolescents. Sixty seven percent of patients (N=14) had no cognitive deficits for their age, while 33% (N=7) had mild to moderate deficit. GMFCS levels ranged from I (38%; N=8) to V (29%; N=5). Components of successful interview techniques included: advance training of interviewers around common population idiosyncrasies; use of an "answer code" based on words, sounds, or gestures; use of partner assisted scanning; and use of a "multi-sensorial toolkit" of questions and aids. **CONCLUSIONS:** Children with CP represent a compromised population whose needs have been largely neglected in development of patient-reported outcomes (PROs). This multisensory methodology allowed us to collect usable data across a range of cognitive, physical, literacy, and age-ranges, and it offers a model for concept elicitation techniques in the growing field of child PROs, especially where clinical features of the participants' condition make successful interviewing difficult.

PRM148

PREDICTORS OF MEDICATION NON-ADHERENCE AMONG YOUNG ADULTS: COMPARING TWO SCALES

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