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

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INTRODUCTION

- The importance of PROs is widely recognized, both for the assessment of subjective well-being in patients, and in the assessment of medical products to support labeling. The United States Food and Drug Administration (FDA) has issued guidance on the development of PROs emphasizing the importance of establishing content validity through qualitative interviews with the target population (both concept elicitation and cognitive interviews).
- Children represent 24% of the U.S. population [U.S. Census, 2011], yet no standardized methodology exists for the establishment of content validity in patient-reported outcomes (PROs) for children. The development of PROs for child populations is complicated by multiple factors, such as age, developmental stage, literacy, and language ability.
- CP is a motor impairment condition caused by abnormal brain development or damage to the brain during birth or in early childhood. CP-related disorders include limb spasticity, as well as impaired cognition, behavioral problems and visual and hearing disorders.
- Children with CP present a spectrum of cognitive and communication abilities due to actual age, cognitive age, literacy, and motor/sensory impairment. Each of these factors impacts the child's ability to understand questions, and to provide responses about experiences and symptom status.

OBJECTIVES

- Develop a methodology for qualitative concept-elicitation interviews with children/adolescents with CP, for the assessment of content validity for the 'Questionnaire on Pain caused by Spasticity' (QPS), a PRO assessing spasticity-related pain (SRP);
- Utilize this interview methodology to conduct concept elicitation interviews of CP patients (2-17 years).

METHODS

Target Population

The interview methodology needed to be flexible enough to work with a broad age range, and wide range of CP-related issues such as cognitive and motor skill limitations:

- Children/adolescents with CP could range in age between 2 and 17 years;
- Children/adolescents could have variable cognitive ages, regardless of actual ages;
- Functional ability (by Gross Motor Function Classification System [GMFCS] levels) could range between I (moving without limitations) to V (not able to move independently) [Palisano et al., 1997];
- Educational levels could range between 0 (no school) to grade 12;
- Sensory abilities and deficits could vary (visual, auditory, or tactile-dominant, e.g.);
- Ability to communicate could vary greatly;
- Children/adolescents could have either upper limb SRP and/or lower limb SRP as their reference.

Development of Interview Methodology

The following resources were used to inform the interview methodology:

- A literature search to: 1) assess specific needs of children/adolescents with CP; 2) locate any extant methodology that would meet, in part or in full, the needs of this project; and 3) ensure that the content of the interview protocol focused on relevant symptoms and impacts of spasticity-related pain;
- Interviews with specialists who had direct, practical experience working with and communicating with children/adolescents with CP, to 1) gather expert recommendations about how best to conduct interviews; 2) suggest communication strategies with children/adolescents of varying developmental ages and physical mobility; 3) suggest how to prepare for challenges that might come up in interviews with this specific population; and 4) train interviewers.

Based on these interviews and literature search, an adult-oriented concept elicitation interview methodology was heavily modified to produce the child-oriented CP interview methodology described in the Results section.

RESULTS

Child/Adolescent Interview Methodology Developed for this Special Population

- Flexibility** – The interview methodology was developed to be highly flexible to allow for the wide range of participants (in terms of age, development, and communicative capacity);
- Interviewer training** – Prior to beginning interviews, interviewers met with CP-specialists and were trained both in assessment of participants' abilities, and the use of the interview toolkit described below;
- Patient assessment** – An assessment process, in which the interviewers evaluated the needs of the interview participant, was based on three criteria:
 - Criteria 1:** Data from patient screening, such as age, estimated cognitive age, communication ability, and GMFCS score;
 - Criteria 2:** Information provided by the parent/caregiver about the child's/adolescent's communication preferences, cognitive strengths and challenges, and physical capacity (e.g., ability to indicate the location of pain);
 - Criteria 3:** Information gathered in the course of the interview about the participant's preferences, strengths, and communication abilities.

- "Multisensory Toolkit"** – A "Toolkit" of potential interview questions and tactics was developed, allowing the interviewer to tailor the strategies to the patient. This toolkit included:
 - Alternate questions based on the participant's actual or developmental age, or reading ability;
 - Various large sized visual aids; in colors where possible;
 - Large, colorful illustrations of daily activities, such as eating, sleeping, and receiving physical therapy.
- Partner-Assisted Scanning** – A method of communication with participants who have significant limitations in communication;
- Compensation** – Age-appropriate compensation, such as toys, key-chains, or MP3 music gift cards, was given to the child/adolescent participants.

Results from Use of the Child/Adolescent Interview Methodology

- Interviews were conducted with 21 children/adolescents, with a mean age of 9.5 years and a range of 2 to 16 years (Table 1 summarizes the demographic characteristics of those interviewed);
- Sixty seven percent of patients (N=14) had no cognitive deficits for their age, while 33% (N=7) had mild to moderate deficit;
- Gross Motor Function Classification System levels ranged from I (higher function; 38%; N=8) to V (lower function; 29%; N=6);

Successes in Implementation

The interviews using this methodology were successful in identifying pain intensity (severity) and location;

Components of the methodology that provided the greatest assistance in eliciting conceptual data from patients include:

- Advance training of interviewers around common population idiosyncrasies;
- Flexibility in interview technique and question format;
- Use of an "answer code" based on words, sounds, or gestures;
- Use of partner assisted scanning;
- Use of a "multi-sensory toolkit" of questions and aids

CONCLUSION

- This methodology offers a model for concept elicitation techniques in the growing field of child/adolescent PROs, especially where clinical features of the participants' condition make successful interviewing difficult.
- The multisensory child/adolescent interview methodology described here allowed for the collection of usable patient data across a range of cognitive, physical, literacy, and age-ranges; results were used to develop an SRP measure, the *Questionnaire on Pain caused by Spasticity* (QPS).
- We have demonstrated that effective concept elicitation interviews can be conducted with children/adolescents with CP, including very young children and those with significant cognitive and/or motor impairment, as long as the interviews are conducted by interviewers adequately prepared for potential communication challenges involved, and supplemented with caregiver information when relevant.
- In many cases, the combined methodology of a child/adolescent PRO and Caregiver reported observations may be recommended.

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Table 1 Children/Adolescent Demographic Characteristics

CHILDREN/ADOLESCENTS	Total N=21 (100%)
Age in Years:	9.5 (3.8)
-Mean (SD)	
-Median	9.0
-Range	2-16
Gender:	
-Male	15 (71.4%)
-Female	6 (28.6%)
Highest Grade Completed:	
-0 (No school)	5 (23.8%)
-Grade 2	6 (28.6%)
-Grade 3	4 (19.0%)
-Grade 5	1 (4.8%)
-Grade 6	2 (9.5%)
-Grade 8	1 (4.8%)
-Grade 9	1 (4.8%)
-Grade 10	1 (4.8%)
Racial and Ethnic Group:	
-White/Caucasian (Non-Hispanic)	16 (76.2%)
-White/Caucasian (Hispanic)	4 (19.0%)
-Black/African American	1 (4.8%)
-Alaskan Native or American Indian	---
-Native Hawaiian or Other Pacific Islander	---
-Asian	---