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DESIGNING CORRESPONDING ASSESSMENTS FOR CHILDREN AND PARENTS TO IMPROVE DATA CAPTURE IN SPECIAL POPULATIONS

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INTRODUCTION

- The Questionnaire on Pain Caused by Spasticity (QPS) is a newly developed clinical outcome measure designed to assess spasticity-related pain in children (5-10 years) and adolescents (11 to 17 years) who have Cerebral Palsy (CP). The QPS was developed following the recommendations established by the United States Food and Drug Administration (FDA) in its guidance on the development of patient reported outcome measures (PROs).
- It has two primary versions (one for upper limb assessment and one for lower limb assessment), and for each version, it has a module for self-administration by the child/adolescent, one for interviewer administration for those children lacking sufficient reading level or motor skills to self-administer, and one for parent/caregivers (an observer reported module for parents of children that are either too young to respond, or whose CP involvement is too severe to allow them to respond to an interviewer administered version).
- The development of PROs for this pediatric and adolescent population is complicated beyond the normal issues of stages of development and reading levels. 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.
- Given these difficulties, research data for this population is likely to have numerous missing values. Mixed modes of administration are often used to help reduce missing data. However, use of a questionnaire structure that can provide for the same (or similar) data from multiple sources is important step further in increasing the quality and value of a research dataset.

OBJECTIVES

The objective of this presentation is to describe the qualitative development process and results for developing a multiple module measure where self-reported, interviewer-administered, and observer-reported scales for assessing spasticity-related pain experienced by children with Cerebral Palsy (CP) all correspond to each other in scoring and content, while still maintaining integrity within each mode of administration.

METHODS

- The target population included children and adolescents with CP between 2 and 17 years; having variable cognitive ages, varying functional and motor skill ability, and varied ability to communicate. Children could have either upper and/or lower limb spasticity, and were required to have spasticity-related pain on a weekly basis.
- The QPS was developed based on qualitative (concept elicitation) interviews with children/adolescents, parent/caregivers, and clinical and methodological expert input.
- Interview results were used to identify appropriate content, recall period, aspect of the concept to assess, recall period, instructions, and scale structure for two patient-reported modules (self-administered and interviewer-administered) and a corresponding observer-reported module.
- Cognitive interviews were conducted to confirm appropriate understanding of the parents and of children of various ages and CP severity to provide meaningful responses to the QPS items.

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Table 1: Demographic Characteristics

CHILDREN/ADOLESCENTS	Total N=21 (100%)
Age in Years:	- Mean (SD) 9.5 (3.8)
	- 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 ---

Table 2: Clinical Characteristics

CHILDREN/ADOLESCENTS	Total N=21 (100%)
Does child have a cognitive deficit?	- No 14 (66.6%)
	- Yes 7 (33.3%)
	- Able to Communicate 7 (100% of 7)
	- Unable to communicate 0 (0.0% of 7)
Of 7 children with cognitive deficit:	- Mean (SD) 67.3 months (45.2 months) (5.6 years (3.8 Years))
	- Median 60 months (5 years)
	- Range 3 months to 132 months (3 months to 11 years)
Gross Motor Function Classification System (GMFCS)*:	- GMFCS Level I 8 (38.1%)
	- GMFCS Level II 2 (9.5%)
	- GMFCS Level III 2 (9.5%)
	- GMFCS Level IV 3 (14.3%)
	- GMFCS Level V 5 (28.6%)

* The GMFCS is a 5 level classification system describing the gross motor function of children and youth with cerebral palsy on the basis of their self-initiated movement with particular emphasis on sitting, walking, and wheeled mobility. Level I indicates an ability to move freely and without help, while Level V indicates a lack of capacity for independent movement (Palisano et al, 1997)

RESULTS

Design of QPS Assessment

- Questions in the child/adolescent QPS were designed for assessment of presence and overall severity of spasticity-related pain, starting first with a general inquiry, followed by questions about pain during progressively difficult activity situations (at rest, during usual daily activities, during active mobilization, and during physically difficult activities).
- The same content and response options were utilized in both the interviewer-administered child versions as for the self-administered child versions.
- To support the patient-reported data, an observer-reported outcome measure was designed for parent/caregivers to assess presence and frequency of observable signs of spasticity-related pain in their child (using the same sequence of progressively difficult activity situations).
- Observers can only provide information about what is observable. An observer cannot provide a subjective assessment on behalf of a patient. Therefore the patient can report how much pain, but the caregiver can only report how frequently they noticed the signs of pain occur. (See Figure 1). In the case of a child who is too young or too impaired to respond by themselves, insight into the child's status can still be obtained.

Qualitative (concept & cognitive) Interview Results relating to Design

- Parent/caregivers were able to work with their children to collectively identify the location of their spasticity-related pain.
- Children age 7 and above who could read and had sufficient motor skills for independently self-administering a questionnaire could answer questions about pain severity in relation to specific activities, but were not able to reliably address the frequency or duration of their pain.
- Children 5-7 years (and those with more severe CP) who were able to communicate answered the same items but in interviewer-administered format, with the assistance of larger visual aids and specially tailored interviewing techniques.
- Parent/Caregivers were able to report the frequency of the signs of pain they observed in their child over the past week, but because low consistency of direct attention and close contact time between parent/caregivers and children varies, parent/caregiver observations of the duration of pain was less reliable.

Table 3: Design of Corresponding Components

SELF-ADMINISTERED PRO	INTERVIEWER-ADMINISTERED PRO	PARENT - CAREGIVER (Child)
Occurrence of Spasticity (Y/N)	Occurrence of Spasticity (Y/N)	Signs of spasticity (Y/N) • Identify location(s) of child's spasticity • (with child's input) • contact time with child • relation to child • Identify usual signs of pain observed in child
Spasticity-related pain (Y/N) How much pain? (Wong-Baker Faces scale)	Spasticity-related pain (Y/N) How much pain? (Wong-Baker Faces scale)	Signs of pain? (Y/N) Communication by child about pain? (Y/N) Frequency of signs of pain (never, rarely, sometimes, often, always)
Pain at rest (Y/N) How much pain at rest? (Wong-Baker Faces scale)	Pain at rest (Y/N) How much pain at rest? (Wong-Baker Faces scale)	Signs of pain at rest (Y/N) Frequency of signs of pain at rest? (never, rarely, sometimes, often, always)
Pain moving around (Y/N) How much pain moving around? (Wong-Baker Faces scale)	Pain moving around (Y/N) How much pain moving around? (Wong-Baker Faces scale)	Signs of Pain while moving around (Y/N) Frequency of signs of pain while moving around? (never, rarely, sometimes, often, always)
Pain with physical therapy? (Y/N) Identify most difficult thing to do.	Pain with physical therapy? (Y/N) Identify most difficult thing to do.	Signs of Pain with physical therapy? (Y/N) Identify most difficult thing for child to do.
Pain with difficult thing? (Y/N) How much pain with difficult thing? (Wong-Baker Faces scale)	Pain with difficult thing? (Y/N) How much pain with difficult thing? (Wong-Baker Faces scale)	Signs of Pain with difficult thing? (Y/N) Frequency of signs of pain with difficult thing? (never, rarely, sometimes, often, always)

CONCLUSION

Direct correspondence of items addressing key concepts (e.g. presence of spasticity-related pain) can provide an anchor for combining patient-reported (self-administered and interviewer-administered as needed) with observer-reported information and relating the various descriptive aspects around the concepts being measured to provide a more complete and richer dataset for compromised populations where assessment is challenging.

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