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Content Validation of a Patient-reported Outcome Measure for Pediatric Clients With Hand and Upper Extremity Impairment

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CONTENT VALIDATION OF A PATIENT-REPORTED OUTCOME MEASURE FOR PEDIATRIC CLIENTS WITH HAND AND UPPER EXTREMITY IMPAIRMENT

DISSERTATION

A dissertation submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in the
College of Health Sciences
at the University of Kentucky

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ABSTRACT OF DISSERTATION

CONTENT VALIDATION OF A PATIENT-REPORTED OUTCOME MEASURE FOR PEDIATRIC CLIENTS WITH HAND AND UPPER EXTREMITY IMPAIRMENT

Occupational therapists and physical therapists practicing in hand therapy have adopted routine use of patient reported outcome measures (PROMs) for evaluating treatment outcomes. However, the PROMs currently used in pediatric hand care are limited in clinical utility for the pediatric population. Thus, a need exists for developing a PROM that is tailored to the pediatric hand therapy population. The overarching purpose of this dissertation is to establish the content validity of a novel PROM for children with hand and upper extremity impairment – the Upper Extremity Life Impact Measure-Youth (UE LIM-Y).

This three-part dissertation applies published standards for PROM development to achieve this aim. The first study, an interpretive descriptive study, accomplished two aims. First, it characterized the experience pediatric hand therapists have with outcomes assessment. Secondly, this qualitative study elucidated the outcomes that pediatric hand therapists perceive their patients desire from hand therapy intervention. A second study linked patient-identified treatment goals to the International Classification of Functioning, Disability and Health (ICF) to identify the treatment outcomes pediatric hand therapy patients desire most. In this ICF linking study, the meaningful concepts in patient-identified treatment goals were assigned to associated ICF codes. Then, frequency distributions of the ICF codes identified the most frequently desired treatment outcomes in context of the ICF. Findings from these two studies were merged into a conceptual model to develop a draft of the UE LIM-Y.

Finally, a cognitive interviewing (CI) study was used with a sample of patients from the target population to refine the UE LIM-Y. In this CI study, three rounds of data collection were performed using 1:1 interviews with children who were 8-20 years old and receiving care for a hand or upper extremity impairment at Cincinnati Children's Hospital. Each round of data collection included 9-11 interviews with a diverse study sample selected with a purposive sampling technique. Interviews were recorded and transcribed verbatim and then analyzed using previously established coding methods to identify necessary PROM revisions. Data analysis was performed iteratively so that the draft PROM was revised after each round of data collection.

In combination, this approach established the content validity of the UE LIM-Y. Thus, this dissertation completes the entire qualitative phase of a mixed methods approach for developing a new PROM. Future work will involve subsequent psychometric studies to complete the quantitative phase of establishing the UE LIM-Y's reliability and validity.

KEYWORDS: Pediatric hand therapy; Patient reported outcome measure; Content validity; International Classification of Functioning, Disability and Health; Canadian Occupational Performance Measure

Jenny M. Dorich

04/07/2022

Date

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DEDICATION

To my parents, Michael and Debra Brodfuehrer, who have always encouraged me to follow my dreams and fostered my passion for life-long learning.

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CHAPTER 1. INTRODUCTION

1.1 Introduction

Hand therapy, a specialty practice area of rehabilitation science comprised of occupational therapists and physical therapists, was formally established in 1977 with the establishment of the American Society of Hand Therapists (ASHT).[1] As the profession of hand therapy has grown, subspeciality in pediatric hand therapy has emerged. In 1995 the Pediatric Hand Study Group, a professional organization of surgeons and therapists dedicated to the care of children with hand and upper extremity impairment was founded.[2] Since then, the growth in pediatric hand therapy as a recognized subspeciality is notable, with the publication of the first professional reference book dedicated entirely pediatric hand therapy in 2019.[3]

Simultaneous to the evolution of pediatric hand therapy, the professions of occupational therapy and physical therapy have increased their focus on assessment and documentation of treatment outcomes. A review of outcome measurements used in pediatric hand therapy is lacking. Therefore, the scope of outcomes assessment within the entire profession of hand therapy provides perspective to the practice of outcomes assessment within the full profession of hand therapy.

Takata et al.[4] performed a mapping review of hand therapy literature published in the *Journal of Hand Therapy* (*JHT)* from 2006 to 2015 to identify the diagnoses, interventions and outcomes addressed in recent hand therapy literature. In this review, body function and physiological outcomes (e.g., range of motion, strength, sensation) were the most frequently reported (69.6%, *n*=133) outcome measures. Only 46% (*n*=87) of the included studies utilized measures of performance and function.

Similarly, Rose et al.[5] examined the prevalence of the World Health Organizations International Classification of Functioning Disability and Health (ICF)[6] domains within hand therapy literature published from 1987 through 2010. They evaluated articles pertaining to hand therapy that were published in both the *JHT* and in other refereed journals (e.g., non-*JHT* articles). This review provides further evidence of a historically strong focus on body function in hand therapy literature. Rose et al.[5] found 99% of *JHT* articles and 100% of non-*JHT* articles addressed body function and structures. Studies addressed all other ICF domains to a lesser extent. Articles with a focus on activities were 59% (*n*=46) and 41% (*n*=323) and a focus on participation were 43% (*n*=34) and 37% (*n*=292) in non-*JHT* and *JHT* articles, respectively.

Taken together these reviews[4, 5] suggest that measures of body function and physiological function are utilized most routinely in hand therapy research to establish evidence for guiding practice. Thus, for the past three decades hand therapy has drawn on a biomechanical model of assessment and intervention focused on measures of body function impairments, such as strength and range of motion.[7]

With occupational therapists predominately comprising hand therapy membership,[8] the field of hand therapy has been challenged to increase its focus on patients' occupational performance in the delivery of care.[9] Drawing on the Canadian Model of Occupational Performance and Engagement (CMOP-E) in which patients' abilities in their self-care, productivity (e.g., school, work and volunteering) and leisure comprise their occupations,[10] Robinson, Brown and O'Brien[9] contend that a biomechanical approach focused on using only body function and structure measures to guide care is limited in being client-centered. The authors emphasize that hand therapists

need to assess patients' functional abilities within their areas of occupation, in addition to traditional body function measures, to fully address patients' occupational needs and participation in meaningful activities. This focus on occupational performance and activity participation aligns with the Occupational Therapy Practice Framework[11] and facilitates a client-centered approach in hand therapy practice.[12] Given the need to utilize quantifiable measures for assessing patient's functional abilities and occupational performance, hand therapists must draw upon assessment tools which provide these data. Patient-reported outcome measures (PROMs) are tools which can be used to place the patient at the center of care by allowing assessment of the patient's activity participation and occupational performance from their perspective.

Patient-reported outcomes (PROs) are any measures of a patient's health status that are derived solely from the patient's report without interpretation from a healthcare professional.[13] Patient-reported outcome measures (PROMs) are tools designed for specific patient populations for standardized assessment of patient health outcomes.[14] PROMs provide information uniquely from the patient's perspective on the impact of a medical condition and associated treatment on a range of aspects including symptoms, functional abilities and occupational performance, and general quality of life.[15] PROMs provide valid measurement of patients' perceptions of their health status which are otherwise challenging for healthcare providers to assess through traditional body function measures.[16]

Few authors[4, 17, 18] have explored the utilization of PROMs in hand therapy. Takata et al.'s [4] review of hand therapy literature revealed that 50% of published studies from 2006 to 2015 included standardized PROMs. Valdes et al.'s[17] survey study of

ASHT membership examined PROM utilization in clinical practice and found 92.5% of respondents reported using more than 38 unique PROMs. Naughton and Algar[18] identified the PROMs utilized in randomized controlled trials (RCTs) of individuals with orthopedic hand, wrist, forearm, and elbow injury and linked the meaningful concepts identified within the PROMs to ICF[6] . Naughton and Algar[18] found 11 PROMs were used among the 43 included studies. Taken together, these three reviews[4, 17, 18] suggest that hand therapists apply a broad range of PROMs in practice[17, 18] with the Disability of Arm, Shoulder, and Hand (DASH) and QuickDASH being the most frequently used PROMS in all three studies. Thus, while hand therapy practice has utilized body function measures most routinely in practice,[4, 5] these studies[4, 17, 18] suggest that practice patterns are beginning to shift toward incorporating more patient-centered measures of health in the form of PROMs.

Evidence is scant regarding PROM utilization among hand therapists practicing in pediatrics. Valdes et al.[17] did not provide demographic data on survey respondents; therefore, patterns of PROM use specific to the age of therapists' patients cannot be determined from their study. In a mapping review of hand therapy literature, only 5/191 (3%) of the included studies involved patients below the age of eighteen.[4] Furthermore, the information specific to PROMs used in the included studies was not analyzed based upon the age of study participants. Similarly, Naughton and Algar[18] excluded any studies that had patients under the age of eighteen. Yet, within the entire profession of hand therapy, at least 14% of the patient population is children.[8] Thus, there is a need to understand PROM use among hand therapists practicing with pediatric patients. This dissertation intends to fill this knowledge gap in two ways. First, Chapter 2 will include a

literature review to identify which PROMs are used currently in pediatric hand therapy literature and evaluate those PROMS according to established standards for evaluating the psychometric properties of PROMs. Secondly, Chapter 3 employs qualitative inquiry of hand therapists practicing in pediatric hand therapy to explore their experiences with outcomes assessment and using PROMs. In Chapter 4 this dissertation aims to elucidate the outcome priorities of children and adolescents with hand impairment. Enhanced understanding of the pediatric populations' priorities for activity participation, occupational performance, and treatment outcomes will inform the development of a PROM for the pediatric hand therapy population. A PROM designed to assess the pediatric hand population's priorities for activity participation, occupational performance, and treatment outcomes will improve the quality of life of children by aligning hand therapy care to their outcome priorities. The overarching aim of this dissertation is to initiate the development process of a pediatric-focused hand therapy PROM by establishing content validity of a draft PROM.

1.2 Theoretical Underpinnings

1.2.1 Occupational Therapy and Quality of Life

The World Health Organization defines quality of life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."[19] Among individuals participating in rehabilitation, quality of life is associated with a person's societal participation.[20] As such, quality of life has been posited as a participation measure.[21] The profession of occupational therapy is committed to promoting well-being

through maximizing individuals' participation in meaningful occupations and activities that enhance quality of life.[22] Thus, philosophically, occupational therapy is congruent with maximizing individuals' quality of life.[23] By focusing occupational therapy assessment and intervention on enhancing individuals' quality of life, occupational therapists provide client centered care.[21]

1.2.2 Canadian Model of Occupational Performance and Engagement (CMOP-E)

The CMOP-E is a theoretical model that underpins occupational therapy practice.[24] The CMOP-E is comprised of three levels (Figure 1.1). At the first level, the person level, the individual engaged in occupational therapy services (e.g., the client) is at the center of the model (e.g., the person level). The person level is comprised of the individual's cognition, affect, physical factors and spirituality. The second level is the occupation level. At the occupation level, the client engages in occupations of self-care, productivity (e.g., school, work, and volunteering), and leisure. The interplay between the client and occupation occurs within the third level, the environment level. The environment level includes the physical, cultural, social, and institutional factors in which the client functions. The occupational therapist's role is to collaborate with the client and identify meaningful areas of occupation for which therapeutic intervention is directed to enable the client's occupational performance.

Figure 1.1: Three levels of the Canadian model of Occupational Performance and Engagement[25]

The Canadian Occupational Performance Measure (COPM)[26] is a valid[27] and reliable[28] individualized outcome measure used to establish and measure performance and satisfaction with client-specific therapy outcomes pertaining to self-care, productivity and leisure.[29] The COPM was developed from the theoretical perspective of the CMOP-E. Using the COPM, the occupational therapist interviews the client and/or the client's caregivers to identify the client's occupational performance concerns. Then the therapist collaborates with the client and/or caregivers to derive meaningful goals for occupational therapy intervention aligned with the identified occupational performance concerns. The design of the COPM fosters a client-centered approach to therapy intervention in which the intervention is focused on enabling the client to optimize their occupational performance in the areas of the client's identified therapy goals.

Scholars have challenged hand therapists to adopt a client-centered approach to hand therapy intervention and go beyond providing care that is grounded solely in a biomechanical model that relies on body structure and function measures.[7, 9, 30-32]

Robinson et al.[9] challenged that hand therapists "should not become so fixated on specific anatomical structures that they neglect an individual's occupational needs and participation issues" (p.3). Focusing therapy intervention on enabling a client to maximize their performance in meaningful occupations allows hand therapists to motivate clients by demonstrating a link between therapy intervention and engagement in the client's meaningful occupations.

While few authors have explored application of the COPM in hand therapy practice, the COPM has demonstrated value as a functional outcome measure in both adult and pediatric hand therapy populations. Case-Smith[33] compared the COPM with two PROMs, the DASH questionnaire and the Short Form 36 (SF-36), in measuring functional outcomes among adults receiving hand therapy services. The COPM was identified as the most sensitive of these three measures. In a pediatric hand therapy population, the COPM also was more responsive to patient change and exhibited less ceiling effect than the Pediatric Outcomes Data Collection Instrument (PODCI).[34]

Given the established utility of the COPM in the pediatric hand therapy population,[34] this dissertation utilizes COPM goals of pediatric hand therapy patients to identify their outcome priorities for hand therapy intervention in Chapter 4. Currently, a knowledge gap exists with respect to the outcomes that pediatric patients desire from hand therapy. In Chapter 4, the COPM goals of children with hand impairment are linked to the ICF. The COPM goals identify the pediatric populations' outcome priorities for hand therapy intervention. Thus, this ICF linking process in Chapter 4 contributes to the content validation of a PROM for the pediatric hand population by informing the constructs the PROM should measure.

1.2.3 The International Classification of Functioning, Disability and Health (ICF)

In 2001 the World Health Organization introduced the ICF[6] as a framework for understanding health and disability. The ICF provides a universal framework for understanding health and disability across international healthcare sectors.[35] In the context of the ICF, health and disability are seen as common human experience and an interplay of biological, individual, and social variables.

Within the ICF framework are two dimensions (Figure 1.2). The first is the dimension of Functioning and Disability. Functioning and Disability, which comprises the center of Figure 1.2, is comprised of two domains: 1) Body Functions & Structure, and 2) Activities & Participation. Secondly, Contextual Factors, on the bottom of Figure 1.2, includes two domains: 1) Environmental Factors, and 2) Personal Factors.

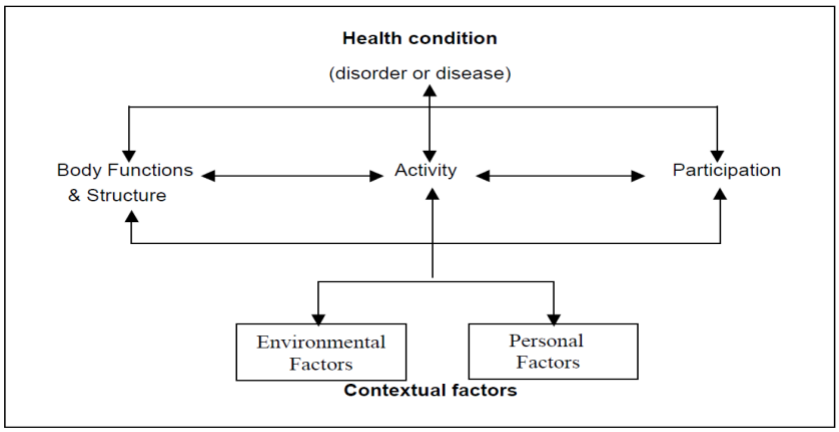

Figure 1.2: ICF model of disability. From: ICF Beginners Guide[35]

The ICF broadens the scope of health beyond a biomechanical[7] model, which is focused solely on Body Functions and Structure. By adding Activity and Participation, Environmental Factors, and Personal Factors as dimensions that contribute to an

individuals' overall health, the ICF expands the scope to encompass a more holistic view of health that considers health as a factor impacting individuals' quality of life.

With the ICF expanding the concept of health and disability beyond the biological components of health, a method of assessing the alignment of health status measures with the ICF framework was desired. Thus, Cieza et al.[36-38] introduced and refined an ICF linking process for evaluating health status measures. ICF linking has been applied in hand therapy literature. Following Cieza's introduction of the ICF linking, Drummond et al.[39] evaluated the alignment of the commonly used DASH with the ICF. Forget and Higgins[40] linked the six PROMs for upper extremity musculoskeletal disorders most used in published studies to the ICF and evaluated the percentage of coverage each PROM has with the Brief ICF Coreset for Hand Conditions. More recently, Naughton and Algar's[18] systematic review included linking the item banks of nine PROMs most used in adult hand therapy literature to the ICF. Finally, Smith-Forbes et al.[41] expanded ICF linking applications to characterize the functional limitations reported by adult patients with shoulder pathology on the Patient-Specific Functional Scale (PSFS).

This dissertation draws upon the ICF as a framework in two ways. First, by applying ICF linking in Chapter 4, similar to Smith-Forbes et al.,[41] to understand the health outcomes children and adolescents who have upper extremity impairment want from hand therapy intervention. Secondly, in Chapter 5, the ICF informs the conceptual model for deriving the draft content of a PROM for pediatric patients with upper extremity impairment.

1.2.4 The CMOP-E and the ICF

The *CMOP*-E is a theoretical model that originates from the discipline of occupational therapy; whereas the ICF was derived from a broader perspective of health and developed to provide a universal language for understanding health among all healthcare sectors of health. Hand therapy itself is a multidisciplinary field of practice comprised of occupational therapists and physical therapists. Furthermore, hand therapy practitioners often practice in multidisciplinary settings. Thus, an understanding of the link between the *CMOP*-E and ICF is beneficial to hand therapists. In an ICF linking study of occupational therapy conceptual models, Stamm et al.[42] found that all *CMOP*-E concepts at the person, occupation and environmental levels linked to the ICF (Figure 1.3). They concluded "there are strong conceptual connections between the ICF and occupational therapy models, which encourage occupational therapists to use the ICF in their practice (p. 17)."

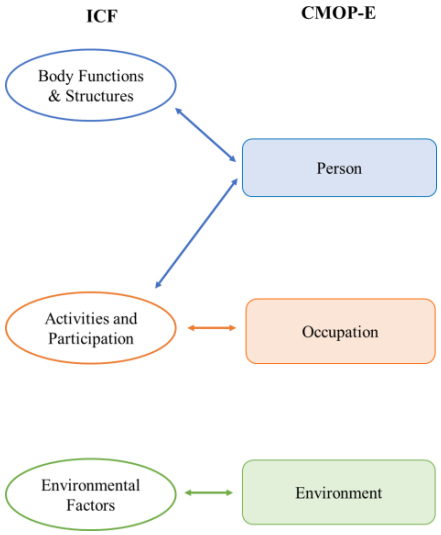

Figure 1.3: Relationship of the CMOP-E and ICF.[42]

1.2.5 The Occupational Therapy Practice Framework

The *Occupational Therapy Practice Framework* (OTPF)[11] guides occupational therapy practice. The fourth edition of the OTPF aligns with the ICF. The OTPF is comprised of two components: 1) The OT *process*, and 2) The OT *domain*. The *process* includes the dimensions of practice which therapists engage in the provision of OT services: evaluation, intervention, and outcomes; whereas, the domain encompasses the scope of the occupational therapist's practice, which is aligned closely with the ICF (Table 1.1). The domain includes client factors, occupations, contexts, performance patterns and performance skills.

Table 1.1: How the OTPF Aligns with the ICF

Occupational Therapy Practice Framework domains	**International Classification of Functioning Disability, and Health domains**
Body functions and structures	Performance Skills
Activity and Participation	Occupations
Environmental Factors	Context
Personal Factors	Client Factors

At the center of the OTPF is the result of the occupational therapy process: "achieving health, well-being, and participation in life through engagement in occupation."[11] This outcome of the occupational therapy process aligns with the ICF's focus of health encompassing an individual's quality of life.

In summary, the CMOP-E, the ICF and OTPF are complimentary and come together throughout this work to inform the development of the draft content for a novel

PROM for children with upper extremity impairment. The relationship of the three is portrayed in Figure 1.4.

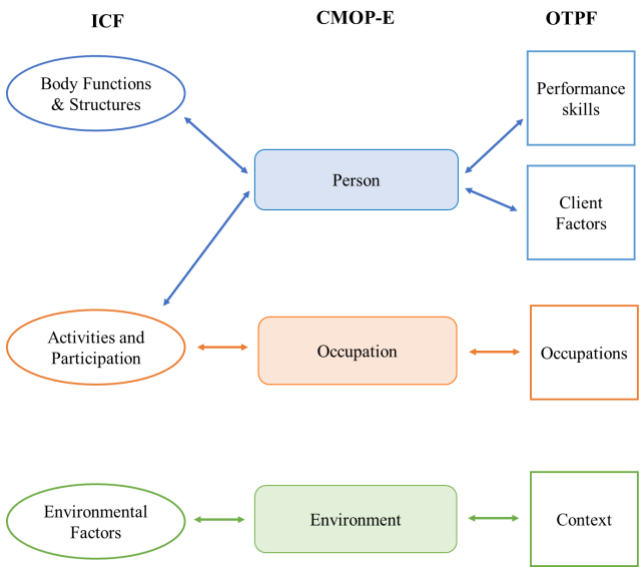

Figure 1.4: Relationship of the CMOP-E, ICF, and OTPF.

1.3 Process for PROM Development

The overarching aim of this dissertation requires knowledge of the process for developing a PROM. As utilization of PROMs has increased in research[43] and clinical practice,[44] experts in outcomes measurement have established standards for PROM development and utilization. In 2007, Terwee et al.[45] first established "quality criteria (p. 35)" for PROMs. Subsequently, the COSMIN study (COnsensus based Standards for the selection of health Measurement INstruments) employed a Delphi process to bring consensus to terminology and definitions of PROM measurement properties[46] and develop a checklist for evaluating psychometric studies of PROMs.[47] Thus, the COSMIN study brought further standardization to PROM development. Shortly following the COSMIN study, the International Society of Quality of Life (ISOQOL) Scientific

Advisory Task Force (SATF) drew upon a literature review and survey of ISOQOL membership to define the minimum standards for PROMs to be used in PRO research and comparative effectiveness research.[48] In 2017, the original COSMIN checklist was revised and updated into the COSMIN Risk of Bias checklist for systematic reviews of patient-reported outcome measures.[49] Taken together these standards serve as a guide for PROM development.

Broadly, PROMs should exhibit validity, reliability, responsiveness and interpretability.[45, 47-49] With respect to validity, the ISOQOL[48] and COSMIN[47, 49] standards establish that evidence of both content validity and construct validity is a minimum design standard for PROMs. In developing a PROM, content validity is established through the initial stages of development. Content validity is the extent to which the content of the PROMs relates to the constructs it is intended to measure.[45, 46] Content validity is considered so paramount to the PROM's overall validity that the COSMIN guidelines for systematic reviews of PROM advise no further analysis of the PROM if the content validity is deemed insufficient.[50] Content validity is achieved by gathering qualitative data from the population the PROM is intended to be used with. Thorough analysis of the qualitative data informs the content of the preliminary PROM questions.[51] Then cognitive interviews with the target population are performed with the preliminary PROM to further refine the measure and align it with the patient population's priorities.[52] This process for deriving a PROM ensures that the tool is well-aligned to measure the outcomes that are most meaningful to the patient population for which it is designed.[53] Because the PROM content is derived qualitatively, there are no statistical

measures for content validity; it is assessed subjectively through analysis of how the PROM's content was derived.[50]

1.4 Significance of the Study

The establishment of the Affordable Care Act[54] heightened an emphasis on quality in healthcare service delivery. Subsequently, the profession of occupational therapy has been challenged to "define [occupational therapy's] evidence-based and patient-centered care processes to enhance the delivery of occupational therapy services and improve patient outcomes, thereby demonstrating the value that the profession contributes to patient care." (p. 1)[55] Similarly, Jewell, Moore and Goldstein[56] outlined physical therapy's value proposition citing the profession's need to identify, adopt, measure and evaluate the cost-effectiveness of best practices. Because hand therapy includes occupational therapy and physical therapy professionals, the specialty of hand therapy draws upon the principles of both professions. With both professions emphasizing the need to demonstrate value, hand therapists are challenged to demonstrate value in the care they provide. Thus, measurement of hand therapy treatment outcomes is necessary to demonstrate the value of hand therapy intervention.[57]

Currently, the profession of hand therapy lacks a PROM which has been developed for the pediatric hand therapy population. The studies presented in this dissertation will fill current knowledge gaps necessary to establish the content validity of a PROM for pediatric hand patients. In the first study (Chapter 3), the experience of outcomes assessment is explored among hand therapists practicing in pediatrics. In the second study (Chapter 4), the treatment outcome priorities identified by pediatric hand therapy patients are examined in the context of the ICF to determine the most frequently

desired outcome priorities. In the third study (Chapter 5), data from the first two studies is combined to develop the conceptual model for developing the draft PROM and refine the measure's content through cognitive interviews with pediatric hand therapy patients. In combination, these studies establish the content validity of the Upper Extremity Life Impact Measure – Youth (UE LIM-Y).

1.5 Problem

This dissertation aims to address three problems. First, knowledge of pediatric hand therapists' experiences with outcomes measurement is lacking. While studies examining PROM utilization in hand therapy practice are available,[4, 17, 18] these studies either do not analyze their findings specific to pediatric patients or are limited to an adult population. The practice of outcomes assessment with pediatric hand therapy patients has been unexplored. This understanding is necessary to identify if a PROM unique to pediatric hand therapy patients is needed. Further, gaining knowledge of current practice patterns and pediatric hand therapists' perceptions of the outcomes that pediatric hand patients want from hand therapy intervention is necessary to inform development of a measure that is feasible to use in clinical practice.

Second, knowledge of the treatment outcome priorities of pediatric patients with hand impairments seeking hand therapy care is limited. Furthermore, evidence exists that PROMs with item banks for assessing upper extremity function which were developed for other patient populations and applied to assess treatment outcomes in the pediatric hand population are limited by a ceiling effect.[34, 58] However, the COPM, a PROM that derives treatment goals specific to each unique patient, was found to have less of a ceiling effect in the pediatric hand therapy population.[34] Thus, there is a need to understand what the

treatment outcome priorities of pediatric patients with hand impairments desire from hand therapy. Such knowledge is necessary for developing a draft PROM for this patient population according to established PROM development standards.[45, 51]

Third, a PROM's content should be written in a language that is relatable to the patient population.[45] Once the conceptual model for a PROM is derived[45, 48] and data to inform the content of the PROM is obtained,[45, 51] a draft PROM was developed and a cognitive interview process was undertaken to refine the PROM's content. [52, 53] Currently, evidence of a PROM for pediatric clients with established readability and content validity is lacking.

1.6 Purpose and Aims

The overarching purpose of this dissertation was to develop the conceptual model for a PROM for pediatric patients with upper extremity impairment and establish the measure's content validity. The first purpose was to explore pediatric hand therapists' experiences with outcomes assessment for pediatric patients with upper extremity impairment to determine the need for such a PROM and further inform the conceptual model for developing the PROM. The second purpose was to identify what pediatric patients with upper extremity impairment prioritize as treatment outcomes to inform the conceptual model and draft PROM. The third purpose was to further refine the PROM for pediatric patients with hand impairment, the Upper Extremity Life Impact Measure – Youth (UE LIM-Y), to meet established content validity standards.

Specific Aim 1: The first aim has two purposes. The primary research question: "*How do pediatric hand therapists describe their experience measuring treatment outcomes and using PROMs*?" Secondarily, we explored the question "*What do therapists perceive*

children and adolescents desire as treatment outcomes from hand therapy?" From this Aim we learned 1) If a perceived need for a pediatric specific PROM exists and what clinician factors inform the conceptual model for such a PROM, and 2) Content that therapists believe should be included in a pediatric specific PROM to further inform the conceptual model for drafting a PROM.

Specific Aim 2: The second aim is two-fold. First, we identified what outcomes priorities pediatric patients with hand impairment most frequently report in COPM goals when receiving hand therapy care. Secondly, we examined how these outcome priorities align with the ICF. From this Aim we learned 1) What treatment outcomes are desired most frequently by pediatric hand therapy patients, and 2) How outcomes priorities inform the conceptual model of a PROM for pediatric hand patients.

Specific Aim 3: Introduce the conceptual model for the UE LIM-Y and refine the UE LIM-Y's content to establish interpretability of the items with a pediatric hand therapy population. The aim of this study was to assess children's understanding and ability to indicate valid responses on the UE LIM-Y to inform content refinements and establish content validity in a population of potential users of the measure.

1.7 Operational Definitions

Client-centered care: health care that embraces respect for the individual's values, beliefs, experiences, and contexts that impact their participation and that includes active involvement of the individual receiving care throughout the process with the emphasis placed on the patient over the health care practitioner's perspective. Client-centered care includes open communication and inclusion of the individual's significant others, support for the individual's participation in their care, and seeks to provide hope.[59] This

terminology is rooted in occupational therapy theory and utilized in this dissertation when occupational theory is discussed.

Content Validity: the extent that a health-related outcome measurement tool measures the constructs it being applied to measure.[45, 46]

Hand therapy: an international practice specialty area comprised of occupational therapy and physical therapy practitioners who provide rehabilitative care to individuals with diagnoses and conditions affecting the upper limb.[8]

Occupations: the activities that an individual engages in, including their activities of daily living; instrumental activities of daily living (e.g., more complex daily living roles in the home, such as meal preparation, and community); productivity (e.g., school, work and volunteering); play and leisure; rest and sleep; and social participation.[11]

Occupational performance: the act of an individual engaging in their occupations.

Occupational therapy: a profession that utilizes therapeutic intervention to facilitate clients' optimal performance in the occupations of self-care, productivity, and leisure through the lifespan.[60]

Outcome measure: any quantified measurement of a patient's status.

Patient-centered care: health care that is considerate of individual patient values, preferences and needs and allows for the patient's perspective to guide clinical decision making.[61] This terminology is consistent with the medical model. Throughout the studies in this dissertation the terminology patient centered care is utilized due to the multidisciplinary nature of hand therapy practice for which the medical model of terminology is most universal.

Patient-reported outcome measure (PROM): tools designed for specific patient populations for standardized assessment of patient health outcomes in which the measurement reflects the patient's perception of their health status.[14, 15]

Pediatric hand therapist: an occupational therapist or physical therapist who provides hand therapy evaluation and intervention services to pediatric patients with upper extremity impairment.

Pediatric patient: an individual seeking medical care who is under the age of twenty-one.

Upper extremity impairment: any body function or structural limitation, perceived cosmetic concern, or functional ability restriction affecting the shoulder, elbow, forearm, or hand.

1.8 Assumptions

It will be assumed that:

1. Pediatric hand therapists will be candid in their responses to interview questions
2. Patient COPM goals provide adequate insight into patients' desired treatment outcomes
3. Participants will provide honest responses during cognitive interviews
4. The researcher will maintain objectivity with qualitative data analysis

1.9 Delimitations

1. Participants in the first study (Chapter 3) were delimited to occupational therapists and physical therapists who practice at least 20 hours per week in a pediatric hand care setting in the United States.

2. COPM goals used in the second study (Chapter 4) were delimited to patients aged 6 to 18 years old with acquired upper extremity impairment affecting the elbow, forearm, wrist, or hand.
3. Participants in the third study were delimited to 8 to 20 years old with an acquired hand condition, an upper extremity congenital anomaly, a chronic musculoskeletal condition affecting the upper extremity, or a neuromotor pathology impacting the upper extremity.

1.10 Limitations

These studies were all conducted in a pediatric academic medical center in the midwestern United States. Consequently, results of this dissertation are only generalizable to patients with similar characteristics to the study sample.[62]

CHAPTER 2. REVIEW OF THE LITERATURE

2.1 Introduction

The purposes of this review were to: 1) discuss literature describing standards for patient reported outcome measures (PROM) development, 2) discuss evidence of the PROMs currently used in literature evaluating outcomes in pediatric hand therapy and their psychometric properties for application in pediatric hand therapy, and 3) establish the Canadian Model of Occupational Performance and Engagement (CMOP-E) and the International Classification of Functioning, Disability and Health (ICF) as theoretical models that underpin the conceptual model of a pediatric hand therapy PROM.

2.2 PROM Development Standards

As healthcare has expanded the utilization of outcomes assessment tools, the focus on delivering patient centered care and measuring treatment outcomes which are meaningful to patients has increased.[63] Health care providers use many tools to assess treatment outcomes.[64] One type of tool which healthcare providers can use to measure treatment outcomes is PROMs. PROMs are standardized tools for assessing patients' perspectives of their health care outcomes and assessing treatment effectiveness for specific medical conditions.[65] Thus, PROMs can bring a more patient-centered perspective to assessing treatment outcomes than measures of body function, such as measures of strength or range of motion.[66, 67]

Over the past two decades multiple scholars have established and refined standards for PROM development.[13, 45, 46, 48, 51-53, 68-70] More recently, guidelines for systematic reviews of PROMs have been published.[49, 50] While the guidelines for

systematic reviews of PROMs are not intended to be standards for studies of PROM development, they do inform measure development by setting forth criteria for evaluating studies of the psychometric properties of PROMs.[49, 71, 72] Simultaneously, the field of mixed methods research (MMR) has grown with applications in an increasing range of fields,[73] and MMR has been advocated as necessary in the PROM development process.[66] Curry et al.[74] proposed mixed methods as an effective methodology for developing psychometrically sound PROMs with patient involvement to align PROMs with the patients' perspectives. The following figure synthesizes these published measurement development standards into a comprehensive sequential mixed methods[75] approach to PROM development.

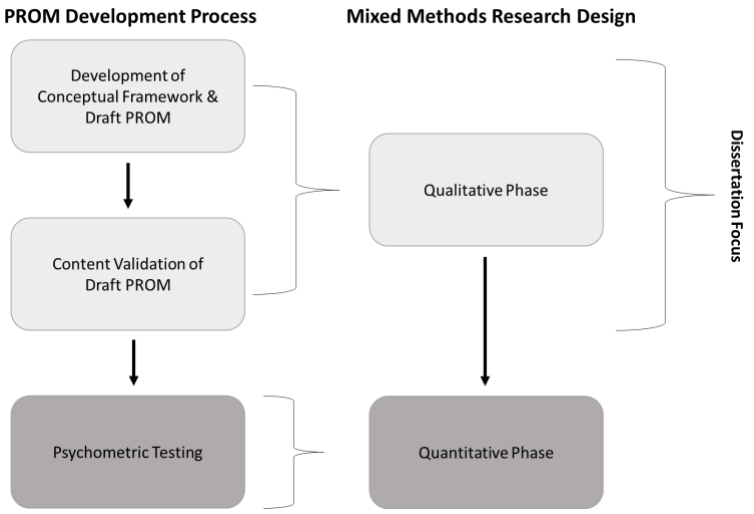

Figure 2.1: Sequential mixed methods approach to PROM development

2.2.1 Development of a Conceptual Model and Draft PROM.

Establishing a conceptual model to guide PROM development is universally accepted among scholars.[13, 45, 48, 49, 51, 68, 69] The conceptual model is the framework

which informs the PROM's design and content. It sets forth the concepts the PROM is designed to measure. The conceptual model may be modified based upon findings from the content validation phase of PROM development.[13, 51] The draft PROM is grounded in the conceptual model and informed by qualitative inquiry with the patient population and clinicians for which the PROM is designed.[45, 48, 49, 51, 68] Thus, this stage of PROM development begins with the qualitative phase of the sequential mixed methods approach.[75]

2.2.2 Content validation of the draft PROM

Early in the establishment of PROM development standards it was recognized that patients should be involved in informing of the measure's content.[45, 68] More recently, Patrick et al.[51] thoroughly outlined qualitative methods for including the patient population in designing the conceptual model for the draft PROM. Involvement of key stakeholders who will be administering the PROM is also recommended at the stage of item generation. [45, 49, 68] Readability of the PROM questions is critical in this stage of PROM development.[13, 45, 48, 68] Terwee et al.[45] advised that questions are written at a sixth grade reading level, while other standards recommend no minimum standard reading level, but rather a literacy level that is justified for the population the PROM will be used with.[48]

Once the draft PROM is developed with readability appropriate for the intended population,[45, 48] the PROM content is refined using cognitive interviewing techniques[76, 77] with the target patient population.[52] Cognitive interviewing (CI) is a qualitative method that allows identification of potential sources of error in PROM and involves refinement of content to mitigate identified problems.[76] Cognitive interviewing uses an iterative

process of data analysis using repeat rounds of interviews and PROM refinement until sufficient evidence of resolved comprehension concerns with the draft PROM is achieved.[52] The cognitive interviewing process with the target patient population allows researchers to identify refinements to the PROM necessary to ensure that the questions are measuring the intended constructs.[52] The conclusion of the content validation stage is also the end of the qualitative phase of the sequential mixed methods approach to PROM development.[74]

As highlighted in figure 2.1, the focus of this dissertation is to complete the qualitative phase (i.e., the development of the conceptual model and draft PROM with establishment of its validity) of developing a new PROM for children with upper extremity impairment, named the Upper Extremity Life Impact Measure (UE LIM-Y). Chapter 3, a qualitative interpretive study of pediatric hand therapists' experiences using PROMs, contributes findings from the PROM-user perspective to the design of the UE LIM-Y draft version. In Chapter 4, ICF linking of patient-identified treatment goals is used to identify the treatment outcomes most frequently desired by children with upper extremity impairment, thus informing the content of PROM from the patient perspective. A draft PROM was developed from these study findings and in Chapter 5 it is refined with the target patient population using cognitive debriefing methods.

2.2.3 Psychometric Testing

Once the draft PROM is refined in the content validation stage of PROM development, the quantitative phase of PROM development begins.[74] Comprehensive psychometric analysis of the PROM includes studies establishing the PROM's structural validity which can result in further refinement of the draft PROM.[49, 52] Accepted methods

to establish the PROM's structural validity vary among scholars. Generally, researchers employ Classical Test Theory and/or Modern Test Theory methods, most commonly Item Response Theory and Rasch analysis, to establish a PROM's structural validity and reduce the item bank to the fewest number of questions needed to adequately measure the constructs aligned with the PROM's conceptual model.[49, 78, 79] At the end of the structural validation phase the finalized version of the PROM is ready to complete testing to establish the overall reliability, validity, responsiveness, and interpretability of scores.[13, 45, 48, 68] This phase of PROM development is beyond the scope of this dissertation and will be future work informed by this dissertation.

2.3 PROMs Used in Pediatric Hand Therapy Literature

Evidence is scant regarding PROM utilization specifically among hand therapists practicing in pediatrics. Few authors[4, 17, 18] have explored the utilization of PROMs in hand therapy. Of the three authors evaluating PROM utilization in hand therapy, only Valdes et al.'s[17] survey study of American Society of Hand Therapists (ASHT) membership examined PROM utilization in clinical practice; however, they did not include demographic data on respondents. Therefore, PROM utilization practices specific to the age of therapist s' patients cannot be ascertained from Valdes et al.'s[17] study. Similarly, in their ICF linking study of PROMs used in randomized controlled trials (RCTs) of individuals with orthopedic hand, wrist, forearm, and elbow injury, Naughton et al.[18] excluded studies with patient populations younger than eighteen years old. In Takata et al.'s[4] mapping review of hand therapy literature exploring what outcome measures are being used in hand therapy literature and other characteristics of published hand therapy literature only 3% (e.g., 5/191) included studies involved patients who were

younger than eighteen. Furthermore, Takata et al.'s[4] analysis did not evaluate PROM use related to the age of study participants. Therefore, this literature review aims to fill this knowledge gap using two sequential literature reviews (see Figure 2.2). First, literature review #1 is performed to ascertain which PROMs are utilized in published pediatric hand therapy studies. Then, the psychometric properties of the PROMs identified in literature search #1 will be evaluated according to established psychometric standards for PROMs to evaluate their relevancy for application in pediatric hand therapy. To complete this second step, literature search #2 was utilized to identify what constitutes the established psychometric standards for PROMs.

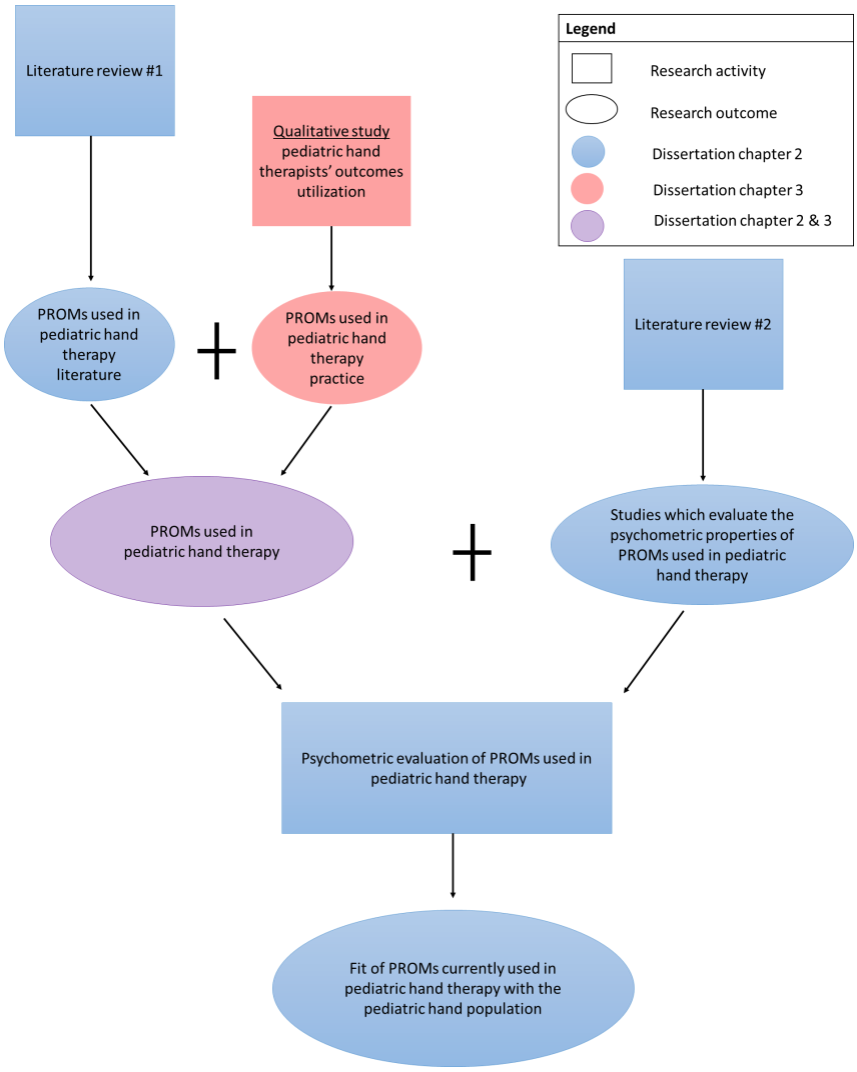

Figure 2.2: Process for evaluating the psychometric fit of PROMs used in pediatric hand therapy with the pediatric hand population

For literature search #1, identifying which PROMs are used in pediatric hand therapy, a comprehensive literature search was completed in PubMed, CINAHL, and OTSeeker on December 28, 2021. Search terms included "hand therapy" AND (pediatric OR child OR adolescent), ("hand therapy" AND child) AND (congenital OR cerebral palsy) and "occupational therapy" AND (congenital AND hand). No limit was set for the date of publication. The search (Figure 2.3) returned 225 articles for which duplicates (*n*=41) were removed. Two articles were excluded for being greater than 15 years since

publication and eight were excluded for being published in a language other than English. Titles of the 161 studies were screened with 81 abstracts reviewed to identify studies that evaluated treatment outcomes for pediatric hand therapy intervention. A total of twenty-one full text articles were included in the final review (Figure 2.3). Studies were included if they met the following inclusion criteria: 1) Involved a pediatric study population (21 years or younger), 2) Evaluated outcomes of hand therapy intervention or were an expert opinion or review article addressing outcomes assessment in pediatric hand therapy, 3) Published in 2006 through the date of the search, and 4) Published in English.

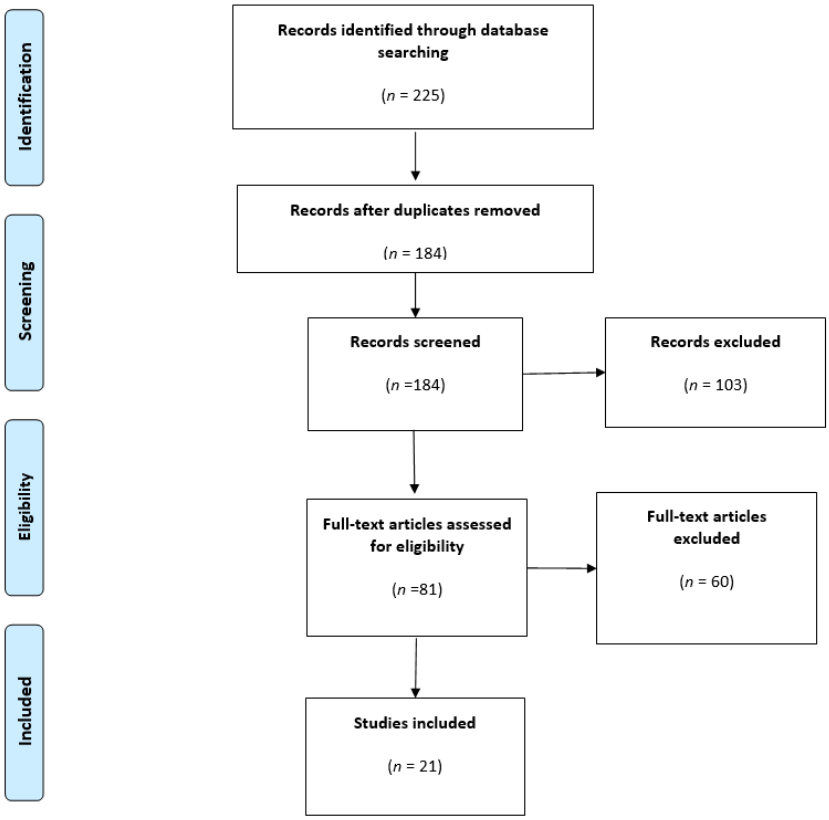

Figure 2.3: PRISMA of literature search for literature review #1

The 21 included articles were graded using The Oxford Centre for Evidence-based Medicine Levels of Evidence.[80] The outcome measures and PROMs used to report treatment outcomes were extracted from each included article (Table 2.1).

Table 2.1: Research Articles Evaluating Outcomes of Pediatric Hand Therapy Intervention

Authors	**Year**	**Level of Evidence**	**Outcomes Assessed**	**Patient Reported Outcome Measure(s) Used**
Ardon et al.[81]	2014	4	ROM, grip strength, pinch strength, and thumb opposition strength	Prosthetic Upper Extremity Functional Index (PUFI)
Hansen & Tromborg[82]	2014	4	Spontaneous use of the affected hand, grip span, grip strength, ROM	None
Fu et al.[83]	2020	5	Assisting Hand Assessment, Fugl-Meyer Assessment, Melbourne Assessment 2	None
Ho et al.[84]	2018	5	ROM and sensation	None
Ho et al.[85]	2010	5	ROM and grasp pattern	None
Ho et al.[86]	2005	1	ROM, sensation, grip strength, pinch strength, and dexterity	None
Kepenkek-Varol & Hosbay[87]	2020	5	ROM, Jebsen-Taylor Hand Function Test, and grip strength	Canadian Occupational Performance Measure (COPM)
Kuo et al.[88]	2020	4	Fugl-Meyer, EMG	ABILHAND-Kids
Lake[89]	2010	5	ROM, grip strength, pinch strength, sensation	None
Lake & Oishi[90]	2014	5	None	None
Netscher et al.[91]	2015	5	ROM	None

Table 2.1 Continued

Palomo-Carrion, Romero-Galisteo et al.[92]	2020	5	Shriners Hospital Upper Extremity Evaluation, Quality of Upper Extremity Skills, grip, and pinch strength	None
Palomo-Carrion, Pinero-Pinto et al.[93]	2020	2	Shriners Hospital Upper Extremity Evaluation, Quality of Upper Extremity Skills	None
Palomo-Carrion, Zuil-Escobar et al.[94]	2021	2	Assisting Hand Assessment, Jebsen-Taylor Hand Function Test, EMG, grip strength	None
Patane et al.[95]	2019	4	ROM, grip strength, wrist and finger flexion and extensor strength	Michigan Hand Outcomes Questionnaire (MHQ)
Plonczak et al.[96]	2017	4	Patient satisfaction	None
Ragni et al.[97]	2021	5	ROM, Assisting Hand Assessment, The Thumb Grasp and Pinch Assessment	None
Sikora et al.[98]	2013	4	ROM	None
Tan et al.[99]	2021	2	ROM, grip, and pinch strength	Upper Limb Functional Index (ULFI)
Wang et al.[100]	2019	1	ROM and patient satisfaction	None
Zuniga et al.[101]	2019	4	Dexterity, wrist flexion and extension strength	None

From literature review #1 the following PROMs were identified as measures used in pediatric hand therapy: Prosthetic Upper Extremity Functional Index (PUFI), Canadian Occupational Performance Measure (COPM), ABILHAND-Kids, Michigan Hand Outcomes Questionnaire (MHQ) and Upper Limb Functional Index (ULFI). Additionally, data from a qualitative study investigating pediatric hand therapists' use of outcomes assessments[102] revealed pediatric hand therapists are also using the following PROMs in clinical practice: the QuickDASH, the Patient Specific Functional Scale (PSFS), the Pediatric Outcomes Data Collection Instrument (PODCI) and the PROMIS® Pediatric Upper Extremity Function, Short Form. Thus, this literature review evaluated the psychometric properties of nine PROMs (Table 2.2): five discovered in the literature search outlined above and four from recently obtained qualitative data.[102]

Table 2.2: Patient-Reported Outcomes Measures Used to Assess Treatment Outcomes in Children Receiving Hand Therapy

PROM Name	**Type of PROM**	**When PROM's Psychometric Properties Established**	**Population of Original Psychometric Testing**
ABILHAND-Kids[103]	Standard item bank of questions	2004	Children (6-15 years old) with cerebral palsy
Canadian Occupational Performance Measure (COPM)[27]	Interview-based to identify the patient's treatment goals	2004	Adults (>18 years old) referred to occupational therapy who perceived themselves to have one or more limitations in activity participation

Table 2.2 Continued

Michigan Hand Outcomes Questionnaire (MHQ)[104]	Standard item bank of questions	1998	Adults (>18 years old) referred to therapy for hand conditions with symptoms of 3 months or more
Patient Specific Functional Scale (PSFS)[105]	Interview-based to identify the patient's treatment goals	1995	Adults with low back pain
Pediatric Outcomes Data Collection Instrument (PODCI)[106]	Standard item bank of questions	1998	Children 1-18 years old with musculoskeletal conditions (cerebral palsy, rheumatoid arthritis, and other congenital musculoskeletal conditions)
PROMIS® Pediatric Upper Extremity Function, Short Form[107]	Standard item bank of questions	2011	Children 8-17 years old
Prosthetic Upper Extremity Functional Index (PUFI)[108]	Standard item bank of questions	2001	Children 3-18 years old with a unilateral upper extremity limb deficiency who used a prosthesis
QuickDASH[109]	Standard item bank of questions	2011	Adults with upper limb conditions

Table 2.2 Continued

Upper Limb Functional Index (ULFI)[110]	Standard item bank of questions	2006	Adults (>18 years old) with upper limb conditions receiving medical or therapeutic care

Literature search #2 was then performed to obtain articles that evaluated the psychometric properties of the nine PROMs used in pediatric hand therapy practice. The protocol for this literature review evaluating the psychometric properties of PROMs used in pediatric hand therapy practice followed the PRIMSA[111] and COSMIN guidelines.[50] The literature search was completed in PubMed, CINAHL and OTSeeker on December 28, 2021. Search terms (Table 2.3) were created for each of the seven PROMs. No limit was set for the date of publication.

Table 2.3: Search terms for literature search #2 for articles included in the analysis of psychometric evidence of PROMs used in pediatric hand therapy

Patient Reported Outcome Measure	**Search Terms**
ABILHAND-Kids	(“ABILHAND” OR ABILHAND-Kids) AND (reliability OR validity OR psychometric OR responsiveness OR measurement error)
Canadian Occupational Performance Measure	(“Canadian Occupational Performance Measure” OR COPM) AND (reliability OR validity OR psychometric or responsiveness OR measurement error)

Table 2.3 Continued

Michigan Hand Outcome Questionnaire	("Michigan Hand Outcome Questionnaire" OR MHQ) AND (reliability OR validity OR psychometric OR responsiveness OR measurement error)
Patient-Specific Functional Scale	("Patient-Specific Functional Scale" OR PSFS) AND (reliability OR validity OR psychometric OR responsiveness OR measurement error) AND (hand OR arm OR "upper extremity")
Pediatric Outcomes Data Collection Instrument	("Pediatric Outcomes Data Collection Instrument" OR PODCI) AND (reliability OR validity OR psychometric or responsiveness OR measurement error)
PROMIS® Pediatric Upper Extremity Function, Short Form	("PROMIS Pediatric Upper Extremity") AND (reliability OR validity OR psychometric or responsiveness OR measurement error)
Prosthetic Upper Extremity Functional Index	("Prosthetic Upper Extremity Functional Index" OR "PUFI") AND (reliability OR validity OR psychometric or responsiveness OR measurement error)
QuickDASH	QuickDASH AND (reliability OR validity OR psychometric or responsiveness OR measurement error) AND (child OR adolescent OR pediatric)

Table 2.3 Continued

Upper Limb Functional Index (ULFI)	("Upper Limb Functional Index (ULFI) OR "ULFI") AND (reliability OR validity OR psychometric OR responsiveness OR measurement error)

After duplicates were removed the following criteria were applied for study inclusion: 1) Studies were specific to only the upper extremity, 2) The study population was only children (i.e., less than 21 years old), and 3) The study was evaluating psychometric properties of the PROM(s). Studies with populations only greater than or equal to 18 years old were excluded. All twelve included[34, 58, 103, 108, 112-119] studies were graded using the COSMIN Risk of Bias checklist[71] and associated user's manual.[72] Data were extracted from included articles and tabulated in accordance with the previously discussed PROM development standards.[45, 46, 48-53, 69, 71, 72] The following is a synthesized description of each standard according to these published standards for PROMs.

2.3.1 PROM Development

The conceptual model is considered the framework for the PROM.[69] It defines the population for which the PROM is designed to be used and the intended application. Furthermore, the conceptual model illustrates the constructs included in the PROM and defines them.[48, 69, 71] Deriving a conceptual model to guide PROM development is fundamental in established standards.[48, 53, 69-71]

2.3.2 Validity

Several dimensions of validity are identified as standards for PROMs. *Content validity* measures the extent the content of the PROM relates to the constructs it is designed to measure.[45, 47] Content validity is considered essential to the PROM's overall

validity. According to the COSMIN guidelines for systematic reviews of PROMs a PROM should not be included in the systematic review of PROM psychometric properties if the content validity is assessed to be insufficient.[50] Content validity is established through qualitative data gathered from the population the PROM is designed for. The content of the preliminary PROM item bank(s) is derived from in-depth analysis of the qualitative data obtained from the target patient population and informed by qualitative data gathered from the PROM users.[51] The preliminary PROM item bank(s) are refined through cognitive interviews with the target population. This cognitive interviewing process further refines the measure to align it with the patient population's priorities.[52] The content validation process for deriving a PROM ensures that the tool is well-aligned to measure the outcomes that are most meaningful to the target patient population.[53] Because the PROM content is derived qualitatively, statistical measures of content validity are not feasible. As such, content validity is assessed by subjective analysis of the methods used to derive a measure's content.[50]

Construct validity is the measure of how the PROM's scores relate to those of other identified similar and different PROMs. It is assessed by establishing predefined hypotheses of these relationships and testing the hypotheses.[46] Reeve et al.[48] identified construct validity as a "critical component" (p. 1897) of a PROM's validity.

Structural validity[46] is the extent to which a PROM's scores reflect the dimensionality of the construct being measured. Structural validity is typically assessed using Classical Test Theory (CCT) or Modern Test Theory (MTT) - Item Response Theory/Rasch analysis.[50, 71] Prinsen et al.[50] suggested if a PROM is lacking good

evidence of structural validity that the PROM should not be included in any further analysis of the PROM.

Criterion validity is the measure of how scores on the PROM correlate to those of a gold standard measure. While identified as a psychometric standard for PROMs,[45, 50] question of the applicability of criterion validity is raised since there may be the absence of a "gold standard" for comparison may not be available.[48]

Mokkink et al.[46] introduced *cross-cultural validity* as a standard for PROMs. Cross-*cultural validity* is the measure of how translated or culturally revised versions of the PROM correspond to the original version of the PROM.[46, 50] Measures of multiple group confirmatory factor analysis (MGCFA) and differential item functioning (DIF) are used to assess cross-cultural validity.[50]

2.3.3 Reliability

Reliability is also a standard consistently established among scholars of outcomes measurement.[45, 46, 48, 50] Reliability is the measure of how much the variation among different applications of the PROM reflect a true change in the construct being measured.[46] An intraclass correlation coefficient (ICC) of agreement or weighted Kappa greater than or equal to 0.70 is the established standard for reliability for a PROM.[45, 50]

Mokkink et al.[46] suggested that *internal consistency* is also a measure of a PROM's reliability. Internal consistency is the measure of the relatedness of the items on the PROM.[46] A Cronbach's alpha greater than or equal to 0.70 for each subscale or unidimensional scale and a minimum of low evidence of structural validity is the standard for establishing a PROM's internal consistency.[50]

2.3.4 Interpretability of Scores

There is agreement among scholars that a measure of minimal important change (MIC) should be established for a PROM[45, 46, 48, 50] so that scores on a PROM can be interpreted consistently. The MIC is the smallest value that indicates a true change in the construct being measured by a PROM.[120] Like internal consistency, Mokkink et al.[46] suggested that an established MIC falls within the boarder scope of the PROM's overall reliability.

2.3.5 Responsiveness

Consistently identified as a standard for PROMs,[45, 48, 50] responsiveness is the measure of the degree to which a PROM detects change over time. A priori hypotheses pertaining to how scores on the PROM will change over time in a longitudinal study are used to establish a PROM's responsiveness. A specific timeframe for assessing responsiveness of a PROM has not been standardized. Terwee et al.[45] suggested responsiveness as a "measure of longitudinal validity (p. 37)."

2.4 Results

In literature search #2, the electronic database searches for manuscripts evaluating the psychometric properties of the PROMs pediatric hand therapists use yielded 786 manuscripts. Removal of duplicates reduced the total screened articles to 623. Title and abstract review reduced the total articles for full review to 43. Upon full-text review, an additional 31 articles were excluded for not meeting inclusion criteria, thus limiting the included studies to twelve (Figure 2.4).

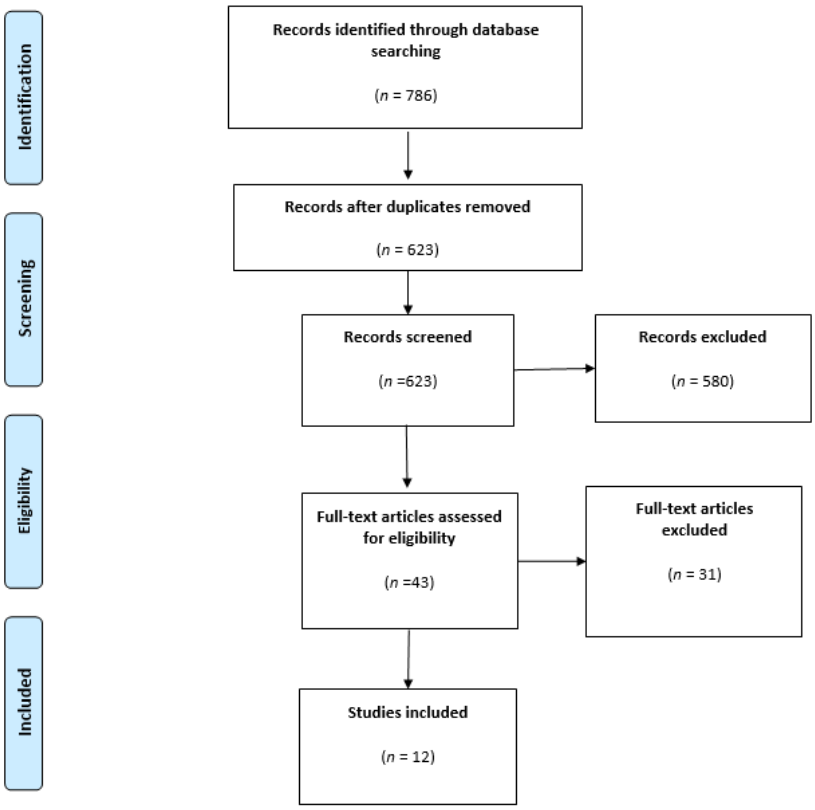

Figure 2.4: PRISMA of Literature Search for Literature Review #2

The overall quality of included studies varied with respect to the COSMIN Risk of Bias guidelines.[49] Table 2.4 summarizes the previously outlined PROM standards and the findings from literature search #2, illustrating the scope and quality of psychometric evidence for PROMs used in pediatric hand therapy. All PROMs which are used in pediatric hand therapy practice are listed in alphabetical order with any studies evaluating the psychometric properties listed below the respective PROM. The quality of the studies respective to each of the psychometric properties the study evaluates according to the COSMIN Risk of Bias guideline is indicated using color coding. Studies receiving the highest rating ("very good") are shaded green for the respective psychometric property.

Yellow indicates an “adequate” rating, orange a “doubtful” rating, and red an “inadequate” rating.

Table 2.4: Scope and Quality of Psychometric Evidence for PROMs Used in Pediatric Hand Therapy

	PROM Development	Content Validity	Construct Validity	Structural Validity	Criterion Validity	Cross-cultural validity	Reliability	Internal Consistency	Interpretability of Scores	Responsiveness
ABILHAND-Kids										
Arnould et al. 2004		–	–		–	–		–	–	–
COPM										
Dorich & Cornwall 2020	–	–		–	–	–	–	–	–	
MHQ	–	–	–	–	–	–	–	–	–	–
PSFS	–	–	–	–	–	–	–	–	–	–
PODCI										
Dorich & Cornwall 2020	–	–		–	–	–	–	–	–	
Kunkel et al. 2011	–	–		–	–	–		–	–	
Shotwell & Moore 2020	–	–		–	–	–			–	–
Wall et al. 2019	–	–		–	–	–	–	–	–	–
PROMIS® Upper Extremity Function, SF										
Broughton, et al. 2020	–	–	–	–		–	–	–	–	–
Waljee et al., 2015	–	–		–	–	–	–	–	–	–

Table 2.4 Continued

Wall, et al. 2019	–	–		–	–	–	–	–	–	–
PUFI										
Buffart, Roebroeck, Van Heijningen et al. 2007	–	–		–	–	–		–		–
Buffart, Roebroeck, Janssen et al. 2007	–	–		–	–	–		–		–
Wright, et al. 2003	–	–		–		–		–	–	–
Wright, et al. 2001		–	–	–	–	–		–	–	–
QuickDASH										
Quatmann-Yates et at. 2014	–	–		–	–	–	–		–	–
ULFI										

Notes: Colors indicate the COSMIN Risk of Bias rating for studies for the associated psychometric construct. Red = inadequate, orange = doubtful, yellow = adequate, and green = very good.

Abbreviations for PROMs are as follows: COPM = Canadian Occupational Performance Measure; MHQ = Michigan Hand Outcomes Questionnaire; PSFS = Patient Specific Functional Scale; PODCI= Pediatric Outcomes Data Collection Instrument; PROMIS® = Patient-Reported Outcomes Measurement Information System, SF = short form; PUFI = Prosthetic Upper Extremity Functional Index; ULFI = Upper Limb Functional Index

The ABILHAND-Kids was adapted from the previously established ABILHAND.[103] The ABILHAND was developed to measure patient reported manual ability and validated in adult populations with rheumatoid arthritis[121] and hemiplegia from a cerebral vascular accident.[122] Arnould, et al.[103] described their methods for adapting the ABILHAND to apply it as a PROM for assessing manual ability in children with cerebral palsy. Anrould, et al.'s study, one of only two studies[103, 108] in this

review that include a description of their PROM development methods, received and "adequate" score for PROM development of the ABILHAND-Kids. Arnould, et al.[103] also evaluated structural validity and reliability of the ABILHAND-Kids, receiving an "adequate" rating for their methods evaluating both of these psychometric properties. The ABILHAND-Kids' items demonstrated an ordered rating scale, comparable discrimination, and fit in a unidimensional Rash model in an adequately sized sample to establish structural validity. Test-retest reliability was adequately established using a Pearson correlation (R = 0.91, p<.001) with unclear evidence of both the stability in the study sample's health status and testing conditions. No studies were returned that evaluated the following psychometric properties of the ABILHAND-Kids: content validity, construct validity, criterion validity, cross-cultural validity, internal consistency, interpretability of scores, and responsiveness.

Only one study explored the COPM's psychometric properties in a pediatric hand therapy population.[34] The COPM is an individualized measure administered as a semi-structured interview to develop treatment goals unique to each patient. The COPM measures overall patient-rated performance and satisfaction with respect to the patient's individualized treatment goals, with independent scores for each dimension (subsequently referred to as the COPM Performance Scale and COPM Satisfaction Scale). The COPM has established validity[27] and reliability[28] in adult populations. Additionally, children receiving therapy for developmental disabilities have established efficacy in setting achievable COPM goals.[123] Dorich and Cornwall[34] were the first to evaluate its application in a pediatric hand therapy population. The COPM's responsiveness and construct validity in comparison to the PODCI were explored. This study was graded

"adequate" for evaluating construct validity and "doubtful" for assessing responsiveness. Limitations with the comparator instrument exist for both psychometric evaluations and insufficient statistical methods contribute to the lower rating for assessing responsiveness. With respect to construct validity, the COPM Performance and Satisfaction scales demonstrated very weak to weak correlation (r=0.16 to r=0.40) with the PODCI Upper Extremity Function and Comfort/Pain scales in children with acquired hand impairment. Responsiveness was assessed using measures of effect size (Cohen's D coefficient). Both COPM scales demonstrated strong responsiveness to change from baseline to end of treatment, displaying a huge effect of treatment (d=2.50 for COPM Performance; d=2.39 for COPM Satisfaction).[34] This sole study evaluating the COPM's psychometric properties in a pediatric hand therapy population only assessed these two properties. Thus, only weak evidence of the COPM's psychometric fit for a pediatric hand therapy population is available.

Four studies explored psychometrics of the PODCI in a pediatric hand therapy application. The PODCI was originally validated in children, ages 1-18 years, with chronic, progressive musculoskeletal conditions.[106] The PODCI has five scales which can be administered together or separately. The scales measured the following constructs: upper extremity function, transfers and basic mobility, sports and physical function, comfort/pain, and happiness with physical condition. As previously noted, Dorich and Cornwall[34] evaluated the PODCI's construct validity and responsiveness in comparison to the COPM. This study received an "adequate" rating for establishing construct validity and "doubtful" for evaluating responsiveness. Weaknesses in study methods outlined above contribute to the overall study grades. The PODCI Upper Extremity Function scale

and Comfort/Pain scales have very weak to weak correlation (r=0.16 to r=0.40) with the COPM Performance and Satisfaction scales.[34] The PODCI exhibited a large effect (d=1.01) for the PODCI Upper Extremity Function Scale and very large for the PODCI Comfort/Pain scale (d=1.21)[34] showing good responsiveness, but less than the COPM in children with acquired hand impairment.

Kunkel et al.[116] also examined construct validity and responsiveness of the PODCI for children with acute wrist and hand injuries, as well as a third psychometric property, reliability. For all three psychometric properties the study quality was graded "inadequate." Construct validity was evaluated using comparisons between subgroups, an accepted method. However, the study did not include a priori hypotheses of the mean differences between subgroups, had some subgroups that were smaller than 30, and used suboptimal statistical methods for discriminative testing of construct validity. Weakness in statistical methods accounts for the "inadequate" ratings for assessing responsiveness and reliability. With this study receiving an "inadequate" grade for all psychometric properties it evaluated, the study findings are not reported here as the study grade makes them irrelevant.

Application of the PODCI Upper Extremity Function and Comfort/Pain scales in children (<18 years old) receiving therapy for upper extremity impairments associated with joint hypermobility spectrum disorder has been examined.[112] Construct validity, reliability and internal consistency were evaluated, with the study graded as "adequate," "doubtful" and "very good" for each psychometric property respectively. The PODCI Upper Extremity Function scale was strongly correlated (r_s = 0.79, p<.001) with the PROMIS® Upper Extremity Function scale in this population, establishing construct

validity for children seeking hand therapy for concerns related to hypermobility spectrum disorder.[112] Regarding pain, the PODCI Comfort/Pain scale was compared to the numeric rating scale (NRS). These scales have an inverse relationship, with a high score on the PODCI Comfort/Pain scale indicating less pain and a high score on the NRS representing more pain. Therefore, the strong negative correlation ($r_s = 0.73$, $p<.001$) indicates construct validity of the PODCI Comfort/Pain scale in this population.[112] Lack of clarity of the time interval for the test-retest period, inconsistent test conditions between timepoints and inadequate statistical methods account for the study receiving a "doubtful" rating for establishing reliability. Thus, Shotwell and Moore's[112] finding of very high test-retest reliability ($p_c = 0.80$) in this population should be interpreted with caution. In contrast, study methods were rated "very good" for establishing internal consistency. Therefore, internal consistency of the PODCI Upper Extremity Function scale ($\alpha = 0.81$ time 1; $\alpha = 0.76$ time 2) and the PODCI Comfort/Pain scale ($\alpha = 0.88$ time 1; $\alpha = 0.83$ time 2) indicate sound internal consistency of these two scales in the population.

Wall et al.[58] examined the construct validity of the PODCI Upper Extremity Function, Comfort/Pain and Happiness scales and the PROMIS® Upper Extremity Function, Pain, Depression, Anxiety and Peer Relations scales for children with congenital upper limb anomalies. Methods in their study were consistent with a "very good" overall study grade. They found very strong correlations between the PODCI Upper Extremity Function and PROMIS® Upper Extremity Function scales (r=082; 95% CI, 0.78 to 0.85; $p<.001$). Strong correlations occurred between the PODCI Comfort/Pain scale and PROMIS® Pain scale (r= -060; 95% CI, -0.66 to -0.53; $p<.001$) and between the

PODCI Happiness scale and the PROMIS® Depression scale (r= -053; 95% CI, -0.60 to -0.45; p<.001). Thus, construct validity was established for children with congenital upper limb differences for the PODCI Upper Extremity Function, Comfort/Pain, and Happiness subscales.

While four studies undertook elucidating the psychometrics of relevant PODCI subscales for the pediatric hand therapy population, only construct validity, reliability, internal consistency, and responsiveness were explored. Studies specific to PROM development, content validity, structural validity, criterion validity, cross-cultural validity, and interpretability of scores for the PODCI in a pediatric hand therapy population are absent in the literature.

The National Institutes of Health has undertaken the development of the PROMIS® measures over the past twenty years.[124] The PROMIS® measures include multiple PROM scales that have been designed for application with the general population and individuals with chronic medical conditions.[125] Since the introduction of the initial PROMIS® measures, researchers have developed additional measures. In 2011, Dewitt et al.[126] developed and validated the PROMIS® Upper Extremity Function, short form. Since then, three studies examined psychometric properties of the PROMIS® Upper Extremity Function, short form within pediatric hand therapy populations. As outlined above, Wall et. al.[58] evaluated construct validity of this PROMIS® scale in a comparison study with the PODCI Upper Extremity Function scale. With the study quality being graded "very good," their findings of very strong correlations (r = 0.82; 95% CI, 0.78 to 0.85; p<.001) between the two scales establish the construct validity of the PROMIS® Upper Extremity Function short form for children with congenital upper limb anomalies.

Waljee et al.[119] also evaluated the construct validity of the PROMIS® Upper Extremity, short form within a population of children with congenital upper limb differences. They used three comparator instruments in their study: the MHQ, the DASH, and the PODCI. Two of these comparator instruments, the MHQ and DASH, do not have any established psychometric fit with the pediatric hand therapy population. Thus, a study grade of "adequate" was assigned to this study. Strong correlations were found between the PROMIS® Upper Extremity Function and the PODCI Upper Extremity Function scales ($r>.80$, $p<.001$) and between the PROMIS Upper Extremity Function and DASH ($r>.80$, $p<.001$). The MHQ and PROMIS Upper Extremity Function scale were moderately correlated ($r>.40$, $p<.05$). Therefore, Waljee et al.[119] provide further evidence the PROMIS® Upper Extremity Function scale demonstrates construct validity for children with congenital upper limb anomalies.

Children with osteochondritis dissecans (OCD) of the elbow are the other population in which the PROMIS® Upper Extremity Function, short form has been psychometrically tested.[118] The criterion validity is evaluated comparing the PROMIS® Upper Extremity Function, short form to three legacy measures: The Kerlan-Jobe Orthopaedic Clinic (KJOC) score, the quick Disabilities of Arm, Shoulder and Hand questionnaire (QuickDASH), and the patient response portion of the Liverpool Elbow Score (LES). Neither the KJOC[127] nor the LES[128] have been validated in a pediatric population. Therefore, despite good statistical methods, Boughton et al.'s[118] study was graded as "adequate." The PROMIS® Upper Extremity Function, short form was moderately correlated ($|r| >0.54$, $p<.001$) with all three comparator instruments. Thus, the

criterion validity of the PROMIS® Upper Extremity Short Form is adequately established for children receiving therapy for OCD lesions of the elbow.

Like all PROMs discussed thus far, the full complement of psychometric properties for the PROMIS® Upper Extremity, short form is not evaluated within the pediatric hand population. In fact, only construct validity[58, 119] and criterion validity[118] are assessed and all studies are narrow in scope with respect to the breadth of the pediatric hand therapy population.[102]

The PUFI is the only PROM other than the ABILHAND-Kids with reported methods of PROM development.[108] The PUFI was developed to measure children's use of an upper extremity prosthesis. The questions in the PUFI item bank were generated from pediatric upper extremity functional assessments and refined using teacher and occupational therapists' constructive review rather than being generated from qualitative data derived from children with experience using an upper extremity prosthesis. Therefore, similar to the ABILHAND-Kids, the methods used for creating the PUFI are "inadequate" with respect to established standards.[49] Wright et al.[108] also performed reliability testing of the PUFI in a population of children using upper extremity protheses age 7 to 16 years old. This study was graded "adequate" with respect to methods for reliability testing. While strong statistical methods were used, the testing conditions for test-retest administration of the PUFI were not consistent. Overall, test-retest reliability is adequately established as fair to good (ICC = 0.41 to 0.83) for the PUFI in a population of children using upper extremity protheses.

Three additional studies establishing psychometric properties of the PUFI have been published.[113-115] All three psychometric studies[113-115] sought to establish construct

validity of the PUFI in three separate pediatric hand therapy populations: children with upper extremity prostheses,[115] children with radial deficiency,[113] and children with congenital transverse limb deficiency.[114] The studies that aimed to evaluate construct validity of the PUFI in children with radial deficiency[113] and transverse limb deficiency[114] received "very good" grades and the study evaluating construct validity of the PUFI in children with upper extremity protheses[115] was graded adequate. Results from these studies establish evidence of the PUFI's construct validity for children with upper extremity prostheses with moderate correlation to the comparator instrument ($0.48<r>0.58$, $p<.01$)[115] and for children with radial deficiency with moderate correlations to comparator instruments ($0.50 < r < 0.61$, $p<.05$).[113] The evidence is weaker for construct validity of the PUFI in a population of children with transverse limb deficiency with weak to moderate correlations between the PUFI and the comparator instrument ($0.23<r>0.54$, $p<.05$). Wright et al.[115] also tested criterion validity of the PUFI for children using upper extremity prostheses. This study was graded "doubtful" due to limitations with the referenced gold standard measure and statistical methods. Thus, their finding of moderate agreement between the PUFI and referenced gold standard (weighted K = .44 to .65) should be interpreted with caution with respect to establishing criterion validity of the PUFI in this population. Finally, Wright et al.[115] examined interrater reliability between parent and child ratings on the PUFI scales, receiving a "very good" rating for the psychometric analysis of interrater reliability. Thus, they established evidence of adequate to excellent reliability between parent and child ratings on the PUFI scales (ICC = .60 to .81).

Test-retest reliability and interpretability of scores also is explored within populations of children with radial deficiency[113] and transverse limb deficiency.[114] Both studies[113, 114] were graded "very good" with respect to their methods for evaluating these psychometric properties in the respective populations. For children with radial deficiency, Buffart et al.[113] set forth evidence of test-retest reliability (ICC= 0.82; 95% CI, 0.45 to 0.95) and established that the PUFI is able to detect change within six steps of total measurement range (SDD_{90}= 16.0, SDD_{90}/range ration= 0.16). Similarly, evidence of test-retest reliability (ICC=0.88; 95% CI, 0.58 to 0.97) and the ability to detect change within four to nine steps of total measurement range (SDD_{95}= 13.5, SDD_{95}/range ration= 0.13) is established for children with transverse limb deficiency.[114]

Despite what these four studies accomplished in proving the psychometrics of the PUFI for children using upper limb prostheses and children with radial or transverse limb deficiencies, no studies exist establishing the content validity, structural validity, cross-cultural validity, internal consistency, and responsiveness of the PUFI. Therefore, comprehensive evidence of the psychometric fit of the PUFI with the pediatric hand therapy population is lacking.

The QuickDASH is a condensed version the DASH.[129] The DASH was developed to measure patient reported symptoms and physical function for conditionings affecting the upper limb. The QuickDASH was initially validated in a population of adults with upper limb impairment. Only one study evaluated the psychometric properties of the QuickDASH with the pediatric population.[117] This study received a "very good" rating for assessing internal consistency. Therefore, Quatman-Yates et al.[117] established high internal consistency (α_{coef}=0.91) for the QuickDASH in a population of adolescents

receiving therapy for upper extremity injuries. Yet, their statistical methods lack the rigor necessary to establish construct validity of the QuickDASH within this population, rendering a grade of "doubtful" in evaluating this psychometric property in a pediatric hand therapy population. Therefore, the finding that QuickDASH scores were a significant predictor of scores on the comparator instrument, the PedsQL, among children 8-12 years old (β= -0.64, t-value = -8.69, p<.01) and children 13-18 (β= -0.76, t-value = -9.02, p<.01) must be interpreted with caution as evidence of construct reliability for the QuickDASH in a pediatric hand therapy population. Furthermore, like all other PROMs in this review, studies examining the breadth of psychometric properties necessary to establish the QuickDASH for application in a pediatric hand therapy population are lacking.

While the MHQ and ULFI have been used as PROMs in a study evaluating outcomes for children receiving therapy for upper extremity fractures,[95, 99] the literature search returned no studies evaluating the psychometric properties of the MHQ and ULFI in a pediatric population. Both the MHQ and ULFI were developed for applications in adult populations.[104, 110] Similarly, despite pediatric therapists' report of using the Patient Specific Functional Scale (PSFS)[102] in clinical practice, no studies were found evaluating its psychometric properties within a pediatric hand therapy population.

In addition to this review returning no studies that explored the psychometric properties of the MHQ, the PSFS, and the ULFI within a pediatric hand therapy population, this review revealed that comprehensive assessment of the psychometric properties of all PROMs included in this review is also lacking. It is noteworthy that no studies evaluated the content validity of PROMs for the pediatric hand therapy

population. Published guidelines for systematic reviews of PROMs recommend that any studies determined to have insufficient content validity or structural validity be excluded from the systematic review of PROMs.[50] Of the studies meeting inclusion criteria for this review, Arnould et al.'s [103] study of the ABILHAND-Kids is the only one that evaluates the structural validity of the PROMs used in pediatric hand therapy practice. Thus, since literature pertaining to the psychometric properties of PROMs used with the pediatric hand therapy population is scant, all ten studies were included in this analysis of psychometric evidence for application of PROMs in the pediatric hand population.

This review highlights that of the PROMs applied in pediatric hand therapy practice only two, the PUFI and ABILHAND-Kids, have published evidence that the measure's item bank was developed with involvement of therapy professionals. When the ABILHAND was adapted for application in the cerebral palsy population, patients and families had limited involvement in reviewing the draft item bank of questions. No PROMs used with the pediatric hand therapy population have an item bank of questions derived from qualitative findings with the patient population as set forth by PROM development standards.[51, 53, 71] Furthermore, the scope of the ABILHAND-Kids' and PUFI's scopes are narrow, being children with cerebral palsy and children with either upper limb prostheses, transverse limb or radial deficiencies respectively. Pediatric hand therapists provide care to children with upper extremity impairment arising from a wide range of conditions.[102] Therefore, these measures don't apply to the breadth of the pediatric hand therapy population.

The PODCI and PROMIS® Pediatric Upper Extremity Function, short form were developed for pediatric populations. Yet, both have limited established evidence of their

psychometric fit with a pediatric hand population. Furthermore, the overall quality of the studies[34, 58, 112, 116] which evaluated the psychometrics of the PODCI in pediatric hand therapy populations is predominately less than "adequate" according to the COSMIN Risk of Bias standards.[71] Therefore, evidence that the PODCI has a strong fit in the pediatric hand therapy population remains limited. While the quality of the studies examining the PROMIS® Upper Extremity Function, short form is "adequate" to "very good," these studies also have narrowly defined patient populations. Thus, application of the PROMIS® for the breadth of conditions seen in pediatric hand therapy has not been established.

Other tools examined (i.e., QuickDASH, ULFI, MHQ and PSFS) were developed for adult populations with psychometric studies for these measures also occurring within adult populations. Of these PROMs, psychometric evaluation within a pediatric population has only been with the QuickDASH.[117] However, statistical methods for evaluating construct validity of the QuickDASH in a pediatric hand therapy population rendered the study a "doubtful" grade. Thus, Quatmann-Yates, et al.[117] only provided strong evidence of the QuickDASH's reliability in the pediatric hand therapy population. In summary, this review illuminates a gap. Currently, evidence of a PROM with strong evidence of psychometric fit for application in a pediatric hand therapy population is lacking.

2.5 Theoretical Underpinnings to The Conceptual Model for a Pediatric Hand PROM

As outlined at the start of this chapter, developing a PROM begins with involving the patient population and PROM users in establishing a conceptual model of what the PROM is intended to measure.[13, 45, 48, 49, 51, 68, 69] Two theoretical frameworks, the

Canadian Model of Occupational Performance and Engagement (CMOP-E) and the ICF, informed the development of a conceptual model for the draft version of a pediatric hand PROM, named the Upper Extremity Life Impact Measure – Youth (UE LIM-Y).

2.5.1 The Canadian Model of Occupational Performance and Engagement (CMOP-E)

Several theoretical models inform pediatric occupational therapy practice.[130] One such model of practice that applies across the various realms of occupational therapy practice is the CMOP-E.[24] The CMOP-E depicts the relationship between individuals, their engagement in occupations, and the environmental factors that interplay with occupational engagement. The person is at the center of the model, the person level. An individual's cognition, affect, physical factors and spirituality are encompassed at the person level. The individual engages in occupations which comprise the surrounding occupation level. The CMOP-E sets forth that self-care, productivity (e.g., school, work, and volunteering), and leisure activities comprise a person's occupations. External to the occupation level, is the environmental level. The physical, cultural, social, and institutional factors in which the person's occupations occur make up the environmental level. Engagement is the fourth dimension of the CMOP-E. Enablement is a central tenant of engagement. Occupational therapists engage in a client-centered partnership with the goal of enabling clients to optimize their occupational performance.[24] Through this partnership, the occupational therapist applies therapeutic interventions to address impairments at the person level, enabling clients to achieve maximal performance in their areas of occupation within the environments they perform their occupations.

The COPM is an individualized PROM developed from the theoretical perspective of the CMOP-E. The COPM has been established as a valid[27] and reliable[28]

PROM for measuring changes in an individual's perception of their performance and satisfaction with goals which a patient identifies through a semi-structured interview with the occupational therapist.[29] The framework for the semi-structured interview aligns with the CMOP-E's occupational constructs of self-care, productivity, and leisure. Thus, the COPM allows therapists to tailor treatment intervention to enable clients to achieve optimal occupational performance and satisfaction in client-identified goals. Consequently, the COPM allows the therapist and client to partner in tailoring a treatment plan that is targeted at addressing impairments at the person level to maximize the client's participation in and satisfaction with their meaningful occupations in the context of the environments in which they occur. The design of the COPM allows outcomes assessment based upon goals which are uniquely tailored to individual patients. Thus, the design of the COPM provides a lens on the patient perspective of desired treatment outcomes rather than measuring treatment outcomes against an item bank of set standards. Because the COPM provides the perspective of client derived treatment outcomes, in Chapter 4, the COPM goals of children and adolescents receiving hand therapy intervention are used as qualitative data to inform the UE LIM-Y's conceptual model.

2.5.2 The International Classification of Functioning, Disability and Health (ICF)

Widening the lens to view healthcare from a broader perspective than that of occupational therapy alone, the ICF is an internationally accepted framework for understanding health and disability.[6] It was established by the World Health Organization to provide a universal framework for describing health and disability across all sectors of healthcare.[35] The ICF is comprised of two dimensions: Functioning and

Disability and Contextual Factors. These dimensions are expanded further such that two domains, 1) Body Functions & Structure, and 2) Activities & Participation, comprise Functioning and Disability, and the two additional domains, Environmental factors, and Personal factors, make up Contextual Factors.

The profession of hand therapy includes occupational therapists and physical therapists.[8] Additionally, hand therapy professionals commonly practice in multidisciplinary settings working closely with hand surgeons, physicians assistants, nurses, and other healthcare professionals.[8] As such, the perspective of the ICF is valuable in informing the conceptual model of the UE LIM-Y. Furthermore, alignment of the CMOP-E and ICF[42] make them complimentary tools for informing UE LIM-Y's conceptual model.

The ICF and CMOP-E are well aligned. All theoretical constructs of the CMOP-E link to the ICF (Figure 2.5).[42] Three out of four of the CMOP-E's person level constructs (i.e., affective, cognitive, and physical) link to the ICF's Body Function and/or Body Structures domains. The fourth CMOP-E person level construct, spirituality, links to a chapter in the ICF's Activity and Participation domain. The entire occupation level of the CMOP-E (i.e., self-care, productivity, and leisure) links to chapters in the ICF's Activity and Participation domain. Constructs at the environmental level of the CMOP-E (i.e., physical, institutional, cultural, and social) correspond to chapters in the ICF's Environmental Factors domain. Stamm et al.[42] suggested the alignment of the CMOP-E

with the ICF underscores the value of the ICF as a common language across health care sectors.

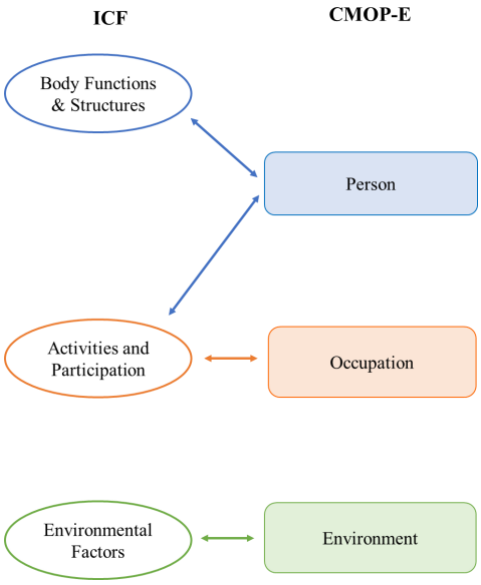

Figure 2.5: Relationship of CMOP-E levels and ICF domains

In Chapter 4, this dissertation draws upon an established ICF linking process[36-38] to align the qualitative concepts derived from pediatric hand therapy patient's COPM goals with the ICF. Through this process the CMOP-E and ICF are brought together to inform the conceptual model upon which the draft UE LIM-Y was derived. In Chapter 5, a conceptual model for the draft UE LIM-Y is introduced. This conceptual model is derived from interpreting findings from the studies outlined in Chapters 3 and 4 and from the theoretical perspectives of the CMOP-E and ICF. To complete the content validation of the UE LIM-Y Chapter 5 utilizes cognitive interviewing[52] to refine the PROM's content.

CHAPTER 3. PEDIATRIC HAND THERAPISTS' EXPERIENCES WITH OUTCOMES ASSESSMENT: AN INTERPRETIVE DESCRIPTIVE STUDY

This chapter is the first step in the content validation of a novel patient reported outcome measure (PROM) for the pediatric hand population, the Upper Extremity Life Impact Measure (UE LIM-Y). Pediatric hand therapists are key stakeholders in the development and utilization of the UE LIM-Y. Therefore, this qualitative interpretive study has two aims which both contribute to the UE LIM-Y's development and content validation. First, therapists' experiences with outcomes assessment and PROM utilization are explored. These findings inform two parts of this dissertation: 1) the PROMs currently used in practice, and 2) the design of the draft UE LIM-Y. Knowledge of which PROMs are used in practice informed the literature review in Chapter 2 of this dissertation. Additionally, therapists' preferences for PROM design elucidated in the current study informed the conceptual model for the UE LIM-Y's draft content (Chapter 5). The second aim of the current study was to discover therapists' perceptions of the treatment outcomes that pediatric patients desire from hand therapy. In Chapter 5, the findings from the current study of therapists' perceptions of pediatric patients' desired treatment outcomes are merged with Chapter 4 findings, which are patient-identified outcomes, to inform the conceptual model of the UE LIM-Y draft content. The following chapter has been accepted for publication in the *Journal of Hand Therapy.*

3.1 Introduction

The reimbursement landscape for occupational therapy and physical therapy services is shifting to a value-based reimbursement system.[131] Beginning in 2019, occupational therapy services delivered in skilled nursing facilities and inpatient

rehabilitation settings transitioned from time-based reimbursement to payment contingent on treatment outcomes[55, 131] As the Centers for Medicare and Medicaid Services (CMS) continue to expand value-based reimbursement, outpatient therapy services will be impacted. Therefore, reimbursement for hand therapy services will be dependent on therapy documentation demonstrating evidence of patients' improved health and quality of life outcomes. Thus, measures of therapy outcomes are essential in therapy documentation to ensure reimbursement and prevent elimination of hand therapy services.[131]

Traditionally, in hand therapy practice, therapists have employed measurements of upper extremity function (e.g., strength, sensation, range of motion and dexterity) to assess a patient's progress in therapy.[4, 5, 132] These impairment measures, which have become recognized as treatment outcome measures,[133] are limited in quantifying patients' activity participation and quality of life.[9] With value-based reimbursement, emphasis on using patient reported outcome measures (PROMs) in healthcare delivery emerged.[134] Thus, more recently, PROMs are being employed in addition to impairment measures in hand therapy[17] and pediatric orthopaedic[43, 135] practices. PROMs are measurements of patients' health status for which the outcome variable is derived directly from the patient's or the caregiver's rating of the patient's current health status.[65] Therefore, PROMs quantify outcomes which clinicians cannot physically measure, such as patients' perceived participation in education, work, leisure interests and activities of daily living (ADLs).[15] In doing so, PROMs underscore therapy's contribution to improving patients' health and quality of life outcomes.[136] By utilizing PROMs, therapists gain insight into how a patient's hand impairment impacts their activity participation and quality of life.

This level of understanding facilitates patient-centered care[12, 66, 137, 138] allowing therapists to tailor therapy intervention towards producing patient-desired outcomes.

In adult hand therapy practice, 92.5% of respondents in a survey of the American Society of Hand Therapy members indicated they utilize PROMs.[17] However, this study does not provide insight into hand therapists' consistency using outcome assessments. Furthermore, Valdez et al.[17] found barriers to using PROMs, including perceived limitations in the usefulness of PROMs, patient factors, constraints within the clinic, and administration difficulties.[17] These findings echo similar reports of barriers to using PROMs among other adult[139-142] and teen/young adult populations.[143] With the scope of their study evaluating practice patterns within the broad context of hand therapy, it is unknown if Valdes et al.'s [17] findings apply to therapists practicing in pediatric hand therapy settings. To our knowledge, no published studies have evaluated outcome assessment practices and the use of PROMs in pediatric hand therapy settings. This study contributes to a more comprehensive understanding of PROM utilization in hand therapy by evaluating practice patterns among hand therapists working in pediatric settings.

Because the use of PROMs during an episode of therapy is dependent upon therapists administering them in many settings, the purpose of this interpretive descriptive qualitative study was to broadly understand pediatric hand therapists' experiences using outcome assessments with children and adolescents, including utilization of PROMs. Specifically, this study aimed to investigate the main research question: How do pediatric hand therapists describe their experience measuring treatment outcomes and using PROMs? Secondarily, this study aimed to explore what therapists perceive children and adolescents desire as treatment outcomes from hand therapy.

3.2 Methods

We employed an interpretive descriptive qualitative methodology[144] to address the study aims. Following approval from the Institutional Review Boards at two universities and one medical center, study participants were recruited using purposive sampling.[145] Twenty-five hand therapists practicing in pediatrics known to the study primary investigator (PI) through the Pediatric Hand Study Group[2] were invited to participate in this study through an email announcement. Interested therapists contacted the PI via email or telephone to express interest in study participation. All interested participants were screened to ensure they met inclusion criteria of 1. Holding a current license to practice occupational therapy or physical therapy in the United States, 2. Delivering hand therapy services for fifteen hours a week or more to pediatric (i.e., age < 21 years old) patients with upper extremity impairment, and 3. Possessing two or more years of experience in a pediatric hand therapy setting. All screened participants (n=10) met inclusion criteria. Agreement to participate in the interview served as consent for study participation.

After obtaining verbal consent from participants to record the interview, interviews were performed using a Zoom© video conference format and recorded in their entirety. Interviewees were located either in their home or place of work. All interviews were performed by the PI who was either in her private work or home office and lasted sixty to ninety minutes. The PI completed interviews between June 9, 2020, and July 21, 2020. An interview guide was used for all interviews (Table 3.1). The interview guide remained unchanged throughout the study. Interviews were transcribed verbatim in their entirety and imported into NVivo 11 Software (QSR International, Melbourne, Australia) for data analysis.

Table 3.1: Interview Questions and Probes

- What meaning does measuring outcomes have in your practice?
    - How do you use these measures?
    - How do you determine what measures you will use to assess a patient's treatment outcomes? (Ex. range of motion, the Canadian Occupational Performance Measure, the PROMIS Measures, strength measurements, etc.

- Explain what you view as successful and unsuccessful outcomes for an episode of care?
    - How do you set goals for an episode of therapy?
    - How do you identify what the patient and family are wanting as outcomes for the episode of care?
    - How do you evaluate whether a patient is making progress towards their goals (e.g., the desired outcomes they have) for treatment?

- Describe your experience using PROMs during an episode of care?
    - Do you find PROMs valuable or burdensome? In what way(s)?
    - Describe what you find as beneficial to using PROMs?
    - What drawbacks or negative experiences do you have using PROMs?
    - What role do PROMs plan in your evaluation of the patient's progress?
    - In what way does the information obtained through PROMs affect your clinical decision making?

- What are the occupations and activities that you find children and adolescents most frequently report as desired functional outcomes from participation in therapy?
    - What life roles or occupations do patients express their injury is impacting?
    - What activities do patients express they wish to return to or have improved function performing?

Multiple trustworthiness measures were employed during data collection and analysis. The PI maintained a reflexivity journal and journaled prior to and directly following each interview.[146] The PI met weekly with the collaborating senior author for peer debriefing. An audit trail also was maintained throughout the study. In addition,

member checking and triangulation of study findings with existing literature were used.[147, 148]

3.2.1 Data Analysis

An iterative approach to data analysis was used so that data collection could continue until saturation. The PI performed all coding using NVivo 11 Software (QSR International). Transcripts were first read in their entirety and then line-by-line to abstract codes.[147] Then codes were compared and categorized using constant comparison. Themes were developed by linking categories to develop rich, thick descriptions.[148] All data analysis was cross checked and corroborated by the senior author.

3.3 Results

3.3.1 Demographics

Ten therapists responded to the initial recruitment announcements sent to 25 therapists (response rate = 40%). All 10 participants that expressed interest in study participation completed interviews. Saturation of themes was met with eight interviews; however, two additional interviews were completed to achieve a study sample that was more geographically diverse. All participants were practicing in outpatient clinic settings of pediatric hospitals within the United States during their participation in this study.

Nine participants were occupational therapists (OT), and one was a physical therapist (PT). Participants had a median of 26 years (range, 6-37 years) of experience practicing in their profession and median 13 years (range, 2-25 years) of experience practicing in pediatric hand therapy. Eight of the participants were certified hand

therapists (CHTs) with a median of 9 years (range, 5-26 years) as a CHT. Additional participant characteristics are in Table 3.2. Pseudonyms were assigned to all participants.

Table 3.2: Participant Characteristics

Participant	Discipline	Years practicing in discipline	Years practicing in pediatric hand therapy	Hours/week practicing in pediatric hand therapy	Certified Hand Therapist (CHT)	Years as a CHT	State of practice
CB	OT[+]	25	25	15	No	_	PA
JP	OT	29	11	28	Yes	6	CA
MB	OT	27	19	36	Yes	20	TX[**]
TD	PT[++]	13	10	32	Yes	7	TX
VG	OT	16	16	26	Yes	6	MD
DK	OT	34	14	19	Yes	10	CA
GL	OT	6	2	30	No	_	TX[**]
JM	OT	12	8	40	Yes	5	TX[**]
GN	OT	19	12	22	Yes	8	CO
WD	OT	37	15	35	Yes	26	MO
Median (Range)		26 (6-37)	13 (2-25)	29 (15-40)		9 (5-26)	

[+] Occupational Therapist; [++]Physical Therapist, **Same employer, but different clinic locations

3.3.2 Outcome Measurement and Current Practice

Four participants reported having workplace guidelines or state Medicaid requirements that mandated using PROMs. One of the therapists indicated her institution required therapists to use at least one PROM and one standardized assessment tool in initial therapy evaluations. Another therapist reported her institution required therapists to utilize outcome measures in therapy evaluations and that this practice standard was a criterion in therapists' annual performance reviews. Two additional participants reported that Medicaid in their states of practice (Colorado and Maryland) required documentation of at least one outcome measure in therapy evaluations. In all instances where therapists were bound by some regulation to use outcome measures, therapists reported they could choose the specific tools they used for outcome measurement. Beyond these practice parameters, therapists described autonomy in choosing which outcome measurement tools and PROMs to use. Participants described using patients' diagnoses and ages as the primary guides to choosing which outcome measures and/or PROMs they used.

In total, 52 unique outcome measurement tools were used among the study participants (Table 3.3). All reported measurement tools were categorized as either impairment measures or PROMs. The 32 reported impairment measures included assessment data collected using a standardized assessment or a measurement tool, such as a goniometer. Participants reported using impairment measures for assessing strength, range of motion, sensation, edema, dexterity, upper extremity function, global function, and hand-writing skills. Within the impairment measures, a variety of standardized assessments were utilized. The specific standardized evaluation tools used varied among participants. The number of PROMs (n=20) therapists reported using was fewer than

impairment measures. Practice patterns with PROM utilization also varied among therapists. Some therapists reported using several different PROMs within their caseload, dependent on factors such as the patient's diagnosis or age. Other participants reported consistently using the same tool(s), and some reported no routine PROM use. The range of PROMs therapists used included region-specific measures, such as the Shoulder Pain and Disability Index (SPADI); measures with set item banks to assess domains such as upper extremity function, pain, or psychosocial factors; and measures that derive patient-identified outcomes through an interview, such as the Canadian Occupational Performance Measure (COPM).

Table 3.3: Outcomes Assessments Participants Report Using

Name of Assessment	**Impairment measure**	**Patient reported outcome measure**		
		R.S.*	D.O.**	I.B.***
Range of motion measures				
Goniometry	X			
Active Movement Scale (AMS)	X			
Mallet Classification	X			
Strength measures				
Manual muscle testing	X			
Dynamometric grip strength	X			
Pinchometer	X			
Myometery	X			
Dexterity				
Nine-hole peg test	X			
Box and Blocks	X			
Functional Dexterity Test	X			

Table 3.3 Continued

Purdue Pegboard	X			
Sensation				
Hot and cold sensibility	X			
Two-point discrimination	X			
Semmes Weinstein Monofilaments	X			
Stereognosis testing	X			
Other impairment measures				
Edema measurements	X			
Patient and Observer Scar Assessment Scale (POSAS)	X			
Upper extremity functional assessments				
Shriner's Hospital Upper Extremity Evaluation (SHUEE)	X			
Jebsen Taylor Hand Function Test (JHFT)	X			
Peabody Developmental Motor Scales (PDMS-2)	X			
Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)	X			
Brachial Plexus Outcome Measure (BPOM)	X			
Assisting Hand Assessment (AHA)	X			
Quality of Upper Extremities Skills Test (QUEST)	X			

Table 3.3 Continued

Hand Assessment for Infants (HAI)	X			
Disabilities of the ARM, Shoulder and Hand (DASH)		X		
Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH)		X		
ABILHAND			X	
PROMIS Upper Extremity Short Form			X	
PROMIS Upper Extremity Form			X	
Prosthetic Upper Extremity Functional Index (PUFI)			X	
Kerlan-Jobe Orthopaedic Clinic (KJOC)		X		
Functional Arm Scale for Throwers (FAST)			X	
Global functional abilities				
Functional Independence Measure for Children (WeeFIM)	X			
Pediatric Evaluation of Disability Inventory (PEDI)			X	
Pediatric Evaluation of Disability Inventory Computerized Assessment Tool (PEDI-CAT)			X	

Table 3.3 Continued

Sensory processing skills				
The Sensory Profile	X			
Handwriting skills				
Berry-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI)	X			
Wold Sentence Copy Test (WSCT)	X			
Evaluation Tool of Children's Handwriting (ETCH)	X			
Prosthetic Upper Extremity Functional Index (PUFI)	X			
Thumb Grasp and Pinch assessment (T-GAP)	X			
Pain				
Pain Quilt			X	
PROMIS Pain Interference			X	
Visual Analog Scale (VAS)			X	
Other patient reported outcome measures				
Canadian Occupational Performance Measure (COPM)				X
Pediatric Outcomes Data Collection Instrument (PODCI)			X	
Shoulder Pain and Disability Index (SPADI)		X		

Table 3.3 Continued

Patient-specific Functional Scale (PSFS)				X
Goal Attainment Scaling (GAS)				X
PROMIS Pediatric Mobility			X	
PROMIS Peer Relations			X	

*R.S. = Region specific PROMs – contain questions focused on an upper extremity body region
**D.O. = Domain oriented PROMs – include questions centered around a domain, such as pain, upper extremity function, or psychosocial function
*** I.B. = Interview based PROMs – utilize a semi-structured interview with the patient to derive patient – identified goals to serve as outcome measures

3.3.3 Themes

Four themes specific to outcomes assessment and the utilization of PROMs in pediatric hand therapy emerged from the study. These themes include:

1. Complexity and variability in pediatric hand therapy practice and outcomes assessment
2. Barriers to PROM use
3. Value of PROM utilization
4. Desired characteristics of an optimal PROM for pediatric hand therapy.

All four themes address our first research question pertaining to pediatric hand therapists' experiences measuring treatment outcomes and using PROMs. The first and fourth theme also inform our secondary aim by elucidating what therapists perceived children and adolescents desire as treatment outcomes from hand therapy.

3.3.3.1 Theme 1: Complexity and variability in pediatric hand therapy practice and outcomes assessment

3.3.3.1.1 Complexity

Pediatric hand therapy practice is complex. The patient population is diverse in age, ranging from newborn to twenty years old. Furthermore, a variety of diagnoses affecting the upper extremity are seen, including traumatic injuries, congenital impairments, motor dysfunction resulting from neurological pathology, and conditions associated with overuse or underlying musculoskeletal conditions, such as juvenile idiopathic arthritis and joint hypermobility spectrum disorders. Therapists described this diversity in patient population as making it difficult to find a tool that is a universal fit. The pediatric hand therapy population is also diverse in cultural and socioeconomic backgrounds. As such, some therapists reported that language barriers limit PROM use. Therapists also described the perception that children's diverse backgrounds make it challenging to find a PROM that measures outcomes that are universally desired across a diverse population. Additionally, with the pediatric population the therapist is working with both the child and the child's caregiver(s). Therapists shared experiences of the patient and caregiver having different perspectives on the impact of the child's condition on the child's life. Also, therapists discussed experiences of incongruence between the child's and the caregiver's willingness to follow therapy protocols. Differences between the child and caregiver treatment goals and engagement in therapy is reported to add complexity to administering PROMs with pediatric hand patients. Therapists stated:

"But the difference between an 18-year-old and an 8-year-old and what their roles are is so different. So, I think that's what's hard about PROMs in pediatrics." (TD)

"You can have a kiddo that has a fractured elbow that's two and you have someone that's fourteen with a fractured elbow. Well, what you're going to do is very different in how you're assessing them and the information you're getting back." (GN)

"[We] have a huge Arabic population. That is also a limitation. We have a huge Hispanic population. If the document is not in another language, then that limits our ability to use it." (JP)

"A lot of times our kids think one way and the parent is in the background going no that's not right. And so having that disconnect between the parent and the child." (TD)

3.3.3.1.2 Variation in Goal Setting Practices

When determining therapy goals, therapists described different approaches for identifying patients' desired therapy outcomes. Some therapists relied on their patient interview during the initial evaluation to reveal what patients desire for treatment outcomes. Other therapists use specific PROMs to facilitate discovery of patient-identified therapy goals. In contrast, some therapists expressed they use impairment measures in their therapy goals and do not find a benefit to using PROMs for identifying

patient-specific therapy goals, especially for children who are receiving therapy for an acquired hand impairment. Perspectives on how therapists established patient goals included:

> ". . .by [the] interview process at the initial evaluation. Those are always standard questions that I ask everybody. . .. even if it's an infant, I ask the parents 'What is your goal? Why are you here?' . . . It's just my subjective interview process." (WD)

> "I would think for instance with the COPM or with the GAS. . . those help us to really get to the heart of what occupational limitations a patient might have and so we can then create a goal around that. (GN)

> "I think our kids with acute injuries just want to get back to normal. . . So, I don't value that [identifying the patient's goals for therapy] as much in that population because I feel like they're going go back to where they were before." (CB)

3.3.3.1.3 Inconsistency in PROM Utilization

Therapists' practice patterns varied with respect to using PROMs. Some therapists did not use PROMs. Other participants reported trying to use PROMs and abandoning them. Conversely, other therapists described routine use of PROMs. Finally, other therapists reported either inconsistent use of PROMs or only using PROMs with specific patient populations, such as children with a chronic condition affecting their upper

extremity function. Some therapists routinely used only PROMs with a set item bank of questions, such as the PROMIS® (Patient-Reported Outcomes Measurement Information System) measures.[125] Other therapists were more apt to use an interview-based measure, like the COPM.[29] Some participants who reported using the COPM did so for specific patient populations, such as those patients who had a chronic condition (e.g., a congenital limb malformation or cerebral palsy) underlying their hand impairment. Finally, some therapists reported using multiple PROMs with each patient, such as measures with set item banks and interview-based PROMs to derive patient-specific outcome measures. Perspectives ranged as follows:

> "I went to a course or a conference and there was a lot of talk about using patient reported outcomes, and I totally agree with that in my mind. So, I came back to hand clinic. . . [and] spoke with the physicians I work with, and I said 'okay let's try this' and did the PODCI. it just seemed like it didn't work out." (DK)

> "Well, as part of our standard evaluation we utilized outcome measures to give us a baseline and also to help identify goals specific to the patient populations and occupation performance." (GN)

> "I just don't think we have utilized it [referring to PROMs] as much as I think we can." (GL)

How therapists use the data collected with PROMs also varied. Some therapists described administering PROMs at the initiation of treatment without evaluating the responses or readministering them later in treatment. In contrast, other therapists reported using the information collected with PROMs to guide treatment planning and assess patient's progress during a course of therapy. Reflecting on their approaches to using PROMs, therapists noted:

> "I'll say 'Well in the last seven days you haven't been eating. . . tell me a little bit about that.' That lends itself to another goal or another issue where I might have to send somebody to social work or whatever it was." (CB)

> "I think that they are doing much better and then when I actually do the retesting it's not where I thought it was. So, then it may change my thought of how many sessions." (JP)

Overall, a diverse caseload was consistent among the therapists participating in this study. The variation in patient diagnoses and age was expressed as a challenge to having a PROM with a universal fit for the pediatric population. Practice patterns varied with respect to how pediatric hand therapists approached goal setting. While some therapists find PROMs as useful tools for facilitating patient-centered goals, others expressed their patient interview is adequate to identify the treatment outcomes the patient desires. Moreover, practice patterns varied with respect to PROM utilization. While some therapists reported routine use, others reported abandoning PROM use. Even

among therapists who reported using them, the degree to which therapists incorporated the data from PROMs into writing goals and ongoing assessment of patients' progress differed among therapists.

3.3.3.2 Theme 2: Barriers to PROM Use

3.3.3.2.1 Operational Barriers

Therapists identified operational barriers to using PROMs in a pediatric hand therapy practice. They described their days as being filled with patient care and having inadequate time to complete their patient care documentation. Thus, the time needed to score and document the data obtained from PROMs is limited. Additionally, they reported insufficient time to utilize PROMs during their treatment sessions. Therapists also expressed that incorporating PROMs routinely into practice requires effort. Some therapists discussed inadequate exposure to PROMs and uncertainty with which ones to use in their practice. Therapists stated:

> "You know when you only have a certain amount of time. . . I think that's my downfall. . . taking that time to do it. So, I think it's important and I think I want to make the time, but I think I have struggled with that in the past." (MB)

> "I think a lot of it is exposure and comfort level and I think sometimes PROMs can be overwhelming." (TD)

3.3.3.2.2 Limitations of PROMs

Limitations of the PROMs themselves were a reported barrier to using them with pediatric hand therapy patients. Some therapists described feeling as though the PROMs they had tried using were not "sensitive enough" to measure change in the pediatric population. The fit of questions on specific PROMs with the pediatric population was a noted concern. Therapists expressed that some PROM questions, such as a question about participation in sexual activities on the Disabilities of the Arm, Shoulder and Hand (DASH)[149], are inappropriate for the pediatric population. Additionally, therapists reported children express that they do not engage in some of the activities referenced in some PROM questions. Examples include:

> "We have tried an outcome measure in the past and it's been hard to find one that's really sensitive enough. So as a result, we have used them and stopped using them." (DK)

> "I don't think that the QuickDASH is . . . the best representation of what our patients are doing, or are capable of doing, or the activities that they do." (TD)

> "I think the Ablihands and the PROMIS® do an okay job. Um, but I think they are probably outdated now." (JM)

3.3.3.2.3 Therapists' Beliefs

A variety of therapists' beliefs impacted PROM utilization. Some therapists expressed a belief that children cannot reliably complete a PROM. Additionally,

therapists held opinions that children want to perform well and may not answer the questions accurately to reflect their actual abilities. Others reported beliefs that children have difficulty understanding the questions. One therapist stated:

> "I don't find kids who are not adolescents or older rate their pain very well or, obviously, can't really figure out their ADL status." (VG)

> "Do they always understand what that means? I think that's part of it too. They are trying in their mind to relate it to an activity. . . that's not always something that they do they do. I get asked. . . 'what does it mean when it says this?'" (TD)

Some therapists reported that patients and/or their families do not value PROMs. Other therapists stated they believed that the referring providers either lack familiarity with PROMs, making them limited in clinical utility, or only value PROMs when utilized within a research study. When reflecting on the value referring providers place on PROMs, one therapist remarked:

> "I don't know that we have really been able to show it for our therapeutic gains. You know obviously the patient goes back after they see us, and they are better and they [referring providers] just say "oh great job working with that you know person." I think they [referring providers] see the overall improvement, but I don't know that they glean any input from that patient reported outcome that we administered throughout their care." (MB)

In summary, both operational barriers and limitations of the PROMs themselves affect pediatric hand therapists' utilization of PROMs. Having the time to administer PROMs and develop comfort with using them were expressed barriers. Similarly, having the time and resources to access available PROMs and discern the fit of various measures with the pediatric hand therapy caseload was a reported barrier. Furthermore, therapists reported limitations in PROMs fitting with the pediatric hand therapy population. Additionally, therapists' beliefs about children's abilities to accurately rate their health status and the value that patients and/or their families and referring providers attribute to PROMs impacted PROM utilization.

3.3.3.3 Theme 3: Value of PROM utilization

While we found barriers to using PROMs exist in pediatric hand therapy practice, benefits to using PROMs were also reported. In fact, even therapists who reported inconsistent use of PROMs in their practice indicated a desire to use them more and/or favorable opinions of PROMs. Therapists remarked:

> "I feel like I can glean some information that I wouldn't on certain other tests - just about what is important to them and how to work on it." (VG)

> "I think it just brings up a lot of really good conversation to really have buy in on both sides, the parents and the kids." (MB)

> "I feel like it [i.e., using PROMs] teases out some things that you might not have done- that I might not have thought about like five or six years ago. . . I think they're very valuable and we just need to be better at using them constantly." (CB)

3.3.3.3.1 PROMs ADD BENEFICIAL DATA

Therapists expressed that PROMs allow them to quantify aspects of patients' abilities in areas of performance which therapists are unable to directly measure in the clinic. Patients' abilities to participate in leisure activities, school related activities, and ADLs were cited examples. Having quantifiable measures on these performance areas was valued not only in terms of reimbursable documentation, but also to motivate patients and communicate the child's progress with the patients and their caregivers. Furthermore, therapists who reported using PROMs routinely indicated that reassessment of a patients' progress with PROMs helps to better evaluate if the gains in impairment measures, such as range of motion and strength, equated to functional gains.

> "But I think you can motivate patients by tapping into what interests them and what they are excited about and help tie into their reasoning why behind what it is that we're doing." (GN)

> "But being able to compare . . . That's the kicker. That information I think really helps a kid stay on board and realize like 'Wow you're right. That really, you know a couple of months ago, I wasn't able to do this and now I can and that's

really meaningful.' So, to be able to tie that in can be very powerful for kids." (VG)

3.3.3.3.2 PROMs Facilitate Patient-Centered Care

Some therapists expressed that PROMs add value by facilitating patient-centered care. Therapists who utilized interview-based PROMs, such as the COPM or Patient-Specific Functional Scale (PSFS),[150] indicated that they gained better knowledge of patients' treatment priorities and were able to tailor treatment goals to patients' desired outcomes. Some therapists described using both the patient report and caregiver proxy report scales for PROMs, such as the PROMIS® Upper Extremity Form. Therapists expressed gaining both the patient and the caregiver perspective helped them to bring alignment in the treatment plan between the therapist, child, and caregivers. Participants stated:

"I may assume . . . they want to do, they probably can't do this, and they need to do this, and they need to do that. But that's just my perceptions. When I bring them into that session and ask them? Yeah, I absolutely can get an indication and better concept of what's important to them and their goals." (MB)

"Sometimes I'm just like this middle-man between the kid and the parent. They're communicating things that they maybe never really communicated before." (GL)

Additionally, facilitating improved care coordination for the patient and family was an expressed benefit. Other cited advantages to using PROMs include identifying the need for additional care resources and providing patient performance data useful to other providers.

> "For my colleagues, like the physical therapists I work with, or speech therapy, they might be interested in the outcomes. . .. they might want to use it for their purposes too. So, I could see it being a good collaborative tool." (DK)

As an example of enhanced care coordination, one therapist described using PROMs to evaluate children and make recommendations to referring hand surgeons about the child's level of function as beneficial in informing surgical decision-making.

> "I think there's a lot. . . that we as OTs can incorporate in through our patient reported outcomes to assist with planning for surgical intervention or not surgery. 'Now actually let's *not* do surgery; let's just continue. This child may have a radial longitudinal deficiency, but have you seen how functional she is? She's amazing with how she uses her hand and family doesn't really care that her wrist doesn't look straight. . .' We therapists can use that patient reported outcomes and . . . our opportunities to build a rapport with those patients and families to come back to providers and … advocate, I suppose, for the families in that way." (MB)

3.3.3.3.3 PROMs Elevate The Evidence Base of Pediatric Hand Therapy

Finally, some therapists cited PROMs as beneficial in establishing more evidence of therapy's value for children and adolescents with hand impairment. Therapists expressed a belief that the profession would benefit from more published evidence to establish pediatric hand therapy's merit. They noted using PROMs allows the profession to add to the limited body of evidence pertaining to pediatric hand therapy practice currently available.

> "I think it's going to be great for research. I think that occupational therapy really needs to have these outcome measures." (JP)

> "Does it validate the orthopedic surgery when they do the PROMIS® on everybody? When they write a paper it certainly does. So, I think when we [therapists] do that next level of proving ourselves, that next level 'I'm going to publish on this therapy technique.' That, I believe makes a difference." (WD)

Overall, therapists reported PROMs have value in pediatric hand therapy practice. The identified benefits to using PROMs were multifaceted. PROMs quantify measures of health status that therapists cannot measure in the clinic. These measures provide therapists greater knowledge of the patient's overall health status, as well as provide data which are necessary for reimbursable treatment documentation. PROMs contribute to patient-centeredness, both by allowing greater understanding of patients and through

fostering coordinated care. Furthermore, utilizing PROMs can lead to more published outcomes of pediatric hand therapy's merit in improving patient outcomes.

3.3.3.4 Theme 4: Desired Characteristics of an Optimal PROM for Pediatric Hand Therapy

3.3.3.4.1 Desire for a PROM With Broad Application In Pediatric Hand Therapy

Therapists articulated a desire for a PROM that has broad application in a pediatric hand therapy practice and a belief that one does not currently exist. Therapists were looking for a PROM that can be utilized across their patient population. One therapist stated:

> "The QuickDASH is sort of the gold standard. . . I'd love to have a QuickDASH that was more pediatric focused or something like that you know." (GN)

> I would love to have one or two [PROMs] that we can utilize with most of our patients because I also value my time and my patient's time and we only have so much time in a session." (GN)

3.3.3.4.2 Attributes of the Ideal PROM

Characteristics that therapists desire in a PROM for pediatric hand therapy practice were noted. Therapists desired a PROM that can be administered and scored efficiently. Participants also indicated that a PROM must be easy to use within the clinic setting. While some therapists reported using PROMs in an electronic format, others

indicated technology resources are limited and they need PROMs that can be administered with pencil and paper. The ability to obtain and use scores at the point of care was desired.

> "I want something that is not going to take a huge chunk of my session to administer. I also don't want to have to spend a lot of time scoring it and analyzing it when I'm done, especially for just my day-to-day patients. (GN)

> "[Something that] I can look at the current score. I can go back to the previous one and compare it. . . I think as a clinician that's nice." (TD)

Not surprisingly, therapists expressed the need for a PROM that contains questions that are relevant to the functional and quality of life outcomes their patient's desire, such as participation in sports and school activities. Gaining greater understanding of the patients' and families' goals were expressed benefits to PROMs. Therapists indicated that understanding how the patient's condition is impacting their life allows them to better align therapy to the needs of the child and deliver patient-centered care. Thus, it is necessary for the information derived from PROMs to be specific to what is most meaningful to the child to best facilitate patient-centered care. Furthermore, therapists expressed that it is beneficial when the patients can complete the PROMs with little assistance from the therapist. One therapist described an ideal PROM for pediatric hand therapy:

> "I think having . . . questions based on their likes and dislikes can be very helpful. Teasing things out specific to things that are important, like gaming and musical instruments and different sports. I think are important. Then. . . we . . . as therapists really figure out how we can help the patient either adapt or. . .work on skills that will get them to those goals of being able to play a flute or kick a ball or whatever they [desire]." (VG)

3.3.3.4.3 Desired Content for a Pediatric-Specific PROM

All participants discussed content they believe a pediatric hand therapy PROM should include based upon what they perceive their pediatric patients routinely report as functional priorities. This content should include participation in play, sports, playing musical instruments, and participation in school-related activities. Additionally, using the upper extremity in specific ways, such as grasping or bearing weight (e.g., doing a push-up), were identified as priorities. Therapists had differing opinions about whether pediatric patients prioritize participation in ADLs. Some therapists remarked that a PROM for the pediatric hand population should include questions about patients' ability to complete ADLs, while others reported they do not experience children reporting concerns with performing ADLs. Some therapists discussed how the appearance of the upper extremity is a priority, especially for the congenital hand population.

> "Sports or musical instruments are the two biggest things probably. . . You know what's funny? I rarely have kids who report that any ADL limitations." (WD)

"I think it needs to have subset of ADLS and leisure and work and school tasks that are important to kids." (GL)

Overall, a PROM that is widely applicable to the pediatric hand therapy population is desired. Clinical utility is a priority. Therapists describe the ideal PROM as efficient to both administer and score. Flexibility in format is also desired since practice settings differ in resources to support electronic formats. Therapists had the most agreement that a pediatric hand therapy PROM should have questions addressing school-related and leisure activities. A variety of other outcome priorities were expressed, yet not as consistently among all therapists.

3.4 Discussion

This is the first study to explore outcomes assessment and PROM utilization specifically within the pediatric hand therapy population. The current study elucidates variation in practice patterns and factors which may contribute to diversity in practice. Furthermore, the qualitative design reveals therapists' attitudes and beliefs relative to outcomes assessment, PROMs, and children and adolescents' concerns and functional outcome priorities for hand therapy. The study provides insights that can be utilized to improve the practice of outcomes assessment, thus allowing pediatric hand therapists to more effectively and consistently incorporate measures of patients' function and health status that are demanded in a value-based reimbursement model.[131]

Our finding that pediatric hand therapists use a range of outcomes assessments, including a variety of PROMs, is consistent with previous findings.[4, 17] Valdes et al.[17] found that 45% of hand therapists reported using a PROM not included in their list of 38

unique PROMs used in hand therapy practice. The DASH and QuickDASH are the most commonly reported in hand therapy literature[4] and are the most frequently used PROMs for adults in therapy practice.[17] In the current study, pediatric hand therapists reported limitations with using the QuickDASH and the DASH in the pediatric population, likely precluding widespread use of both PROMs among pediatric hand therapists.

The first theme of complexity provides some context to the variation in outcome measurement practices. The complexity that arises from the variation in patients' diagnoses, ages/developmental stages, and the caregiver/child relationship contributes to therapists drawing upon a range of outcome measures. Also, variation in how therapists derive patient treatment goals reflects which PROMs therapists use. Some pediatric hand therapists find PROMs useful tools to support goal setting, as has been described for other healthcare practitioners,[17, 151] however, others do not utilize PROMs to set treatment goals. Furthermore, of those who use PROMs to inform treatment goals, practice patterns vary. Some therapists described using interview-based PROMs, like the COPM, to derive patients' treatment goals while others found PROMs with established item-banks valuable. With reimbursement shifting to a value-based model for therapy services, treatment goals aligned with patient preferences become critical.[131] As a result, a PROM with high clinical utility in pediatric hand therapy is needed.

Our second theme of barriers to PROM utilization is a recognized phenomenon.[17, 65, 142, 151-153] Consistent with our findings, time constraints [17, 65, 142, 143, 151-153] and limited experience using PROMs[142, 153] are reported barriers to healthcare professionals using them. These barriers likely contribute more to inconsistencies in PROM utilization rather than the absence of PROM use. However, reported concerns with fit between the

questions on PROMs and the target population is also an identified barrier to PROM utilization in prior studies.[17, 142, 143, 153] Therapists' inexperience with questions on current PROMs that do not fit a pediatric application could be another factor that contributes to variation in PROM utilization.

Our finding that therapists' beliefs about PROMs are barriers to using them is not unique to our study.[142, 143, 152] Like some participants in our study who expressed concerns that children may not reliably complete PROMs, others have reported concerns with patients' reliability.[142, 143, 152] In fact, Boyce et al.[152] found healthcare professionals may refrain from using PROMs when they believe patients feel compelled to provide socially acceptable answers or are unable to accurately complete PROMs. In their systematic review of PROM utilization in outpatient rehabilitation settings, Briggs et al.[142] found evidence of clinicians' perceived barriers to PROM utilization that were not expressed in the current study. Briggs et al.'s[142] review reveals the following beliefs as barriers to PROM use: PROMs do not add value to developing a plan of care, do not provide clinically useful information, require too much effort, only benefit research, and are too subjective.[142] In fact, participants in the current study expressed feeling positively towards using PROMs as a research tool to establish evidence of pediatric hand therapy's effectiveness. Further, a barrier to PROM use unique to the current study are participant beliefs that families or referring providers do not value PROMs. All barriers discovered in the current study likely contribute to the inconsistencies in overall PROM utilization in pediatric hand therapy practice. Therefore, it is possible that consistency in utilization may improve if the barriers are lessened.

The third theme in our study, that there is value to using PROMs, further suggests potential opportunity to improve the utility of PROMs in pediatric hand therapy practice. Several benefits to PROMs were found. Therapists in the current study noted that PROMs provide evidence of patients' progress, which is consistent with other studies.[142, 151] Therapists in the current study also valued PROMs for providing measurable data respective to patients' overall quality of life and functional abilities; this finding was also similar to other research.[136, 154] Additionally, consistent with previously reported benefits of PROMs,[142, 151, 152] therapists in the current study found PROMs valuable in revealing patients' treatment priorities. Like our finding that therapists value PROMs as a tool to motivate patients, others[155] have cited providing encouragement to patients as a primary benefit to using PROMs. While differences between caregiver report and child report on caregiver proxy and self-report measures has been reported,[156] our study elucidated that some pediatric hand therapists find PROMs have value in bringing alignment between children and caregivers' treatment priorities. As previously reported, improved care coordination[154] and enhanced communication among healthcare providers[155] is a benefit of using PROMs expressed by some participants in the current study. In fact, some participants expanded on this benefit by underscoring how they use PROMs to demonstrate patients' functional abilities and inform surgical decision-making. Finally, establishing evidence-based practice is a previously reported benefit to using PROMs, like our findings.[4, 17, 152]

With respect to the fourth theme, the attributes of the optimal PROM for pediatric hand therapy, most features that pediatric hand therapists desire in a PROM align with other's findings. As previously noted, the DASH and QuickDASH are the most

frequently used PROMs for adults participating in hand therapy.[4, 17] Since our population is a subset of the greater hand therapy profession and likely aware that the DASH and QuickDASH are established PROMs with adult populations, it is not surprising that pediatric hand therapists desire PROMs with universal fit for a wide range of children and adolescents with hand impairments. Prior studies[152, 155,40] have established that clinical feasibility of PROMs may be either a barrier or facilitator to use. It is not surprising that pediatric hand therapists in this study desire a PROM that is easy to administer and score and can be used during a therapy session. Finally, having relevance to the patient population was a desired attribute of a pediatric hand therapy PROM, which has also been previously reported.[155] In fact, Duncan et al.[153] found that allied health professionals were more likely to utilize PROMs when they provided information that was clinically relevant to therapists, which we also found to be a desired attribute of PROMs among pediatric hand therapists.

In summary, all participants reported using outcomes measures in their delivery of care and treatment documentation. Yet, variation in therapists' practice patterns with outcomes measurement is evident not only by the number of different outcomes measures used, but also with respect to therapists' approaches using them. Furthermore, current practice is marked by inconsistencies with PROM utilization. The range of barriers to PROM utilization contribute to differences in practice patterns among pediatric hand therapists. Yet, despite barriers, PROMs are perceived to add value to pediatric hand therapy practice. The current study not only elucidates both perceived barriers and benefits to PROMs in pediatric hand therapy practice, but study findings also provide

insights into the characteristics which are desired in a PROM for children and adolescents with hand impairment.

3.4.1 Implications

Impairment measures are the most frequently reported outcomes in published hand therapy literature.[4] The current study found pediatric therapists reported using more impairment measures than PROMs to assess treatment outcomes. However, the shift to value-based reimbursement necessitates the use of outcomes measures that demonstrate functional and quality of life improvements.[131] This study provides evidence that while pediatric hand therapists report barriers to using PROMs, they also identify benefits to using PROMs. Evidence that therapists report abandonment of PROMs with the pediatric population, such as the DASH and QuickDASH, because the questions are not perceived to be adequately relevant to the pediatric population suggests PROMs designed for the adult hand therapy population are not adequately aligned with the pediatric population's outcome priorities[43, 135] With value-based reimbursement increasing the emphasis on delivering patient-centered care,[157] our finding that therapists value PROMs for facilitating patient-centered care further suggests a PROM with clinical utility in pediatric hand therapy would be accepted.

The data with respect to PROM utilization in the pediatric hand therapy population not only provides further evidence that this area of practice is limited in relevant PROMs,[58, 158] but it also establishes guidance on design characteristics and content pediatric hand therapists desire in a PROM. Duncan et al[153] discovered that allied health professionals will not use PROMs unless they perceive value in using PROMs. This sentiment was expressed by participants in the current study as well. Thus, findings

from the current study can be used to inform the design of a PROM that is both aligned with the outcomes desired by the patient population and the features that therapists desire in a PROM. A PROM designed in this way would both facilitate patient-centered care and provide evidence of patient progress in functional and quality of life dimensions, thus strengthening evidence of pediatric hand therapy's merit in a value-based reimbursement model.

3.4.2 Limitations

This study is not without limitations. A greater proportion of occupational therapists participated in the study than physical therapists. Yet, the participant ratio of 9:1 is akin to the distribution of CHTs between the disciplines.[159] Additionally, three therapists who participated in the study were employed by the same institution; however, they worked at different satellite locations and two had worked at different hand therapy centers previously. Furthermore, the remaining participants were geographically diverse across the United States. Due to the nature of study recruitment, most participants in the study were known to the researcher who performed all interviews. While no participants had close professional relationships with the researcher, it is possible that participants' responses may have been editorialized in effort to appease the interviewer. However, reflexivity journaling and an interview guide were used with all interviews to limit bias and build consistency between interviews. Furthermore, recruitment was performed beyond saturation and member checking was utilized to control for response and interpretation bias.

3.4.3 Future research

While prior work has found that the percentage of hand therapists reporting they use PROMs is high,[17] the consistency with which PROMs are administered during the course of therapy intervention is not well established. To maximize the efficacy of PROM utilization in pediatric hand therapy, greater understanding of what factors facilitate consistent use of PROMs is needed. This knowledge may reveal strategies to mitigate barriers to PROM utilization and increase more consistent use of PROMs in hand therapy practice.

Furthermore, the discovery that the pediatric hand therapy community desires a PROM that widely applies to the pediatric hand population, suggests that development of a PROM aligned with pediatric hand therapy patients' outcomes priorities is warranted. Given that some participants believed children may have difficulty understanding PROM questions or do not answer questions accurately, it is necessary to investigate children and adolescents' abilities to understand and relate to the questions to establish content validity of a pediatric specific PROM.

3.5 Conclusion

Outcomes assessment is routinely utilized in pediatric hand therapy practice, yet variation exists among therapists as to which tools are used. While pediatric hand therapists have differing beliefs respective to PROMs, the lack of a PROM which aligns with outcomes priorities of children and adolescents with upper extremity impairment is a consistent finding. Opportunity exists for improving PROM utilization in pediatric hand

therapy practice with the development of a PROM that measures the pediatric population's outcomes priorities.

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CHAPTER 4. ICF LINKING OF PATIENT-REPORTED THERAPY GOALS FOR CHILDREN WITH ACQUIRED UPPER EXTREMITY IMPAIRMENT

This study is the second step in the content validation of a patient reported outcome measure (PROM) for pediatric patients and upper extremity impairment, the Upper Extremity Life Impact Measure - Youth (UE LIM-Y). This chapter has dual aims. The first was to identify the treatment outcomes pediatric hand therapy patients most frequently report in their Canadian Occupational Therapy Measure (COPM) goals. This informs the constructs upon which the conceptual model of the UE LIM-Y is developed in Chapter 5. The second aim of the study was to explore the alignment of the study population's most frequently reported outcome priorities with the International Classification of Function, Disability and Health (ICF) framework. The ICF is one of the theoretical underpinnings of the UE LIM-Y's conceptual model, which is elaborated upon in Chapters 2 and 5 of this dissertation. This chapter has been published in the *Journal of Hand Therapy.*

4.1 Introduction

In hand therapy practice, patient-reported outcome measurement scales (PROMs) are used routinely for assessing patients' functional and quality of life outcomes.[17] The Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH)[160] and other upper extremity region-specific PROMs, such as the Patient-Rated Wrist Evaluation (PRWE)[161], are well-established PROMs in the adult population[17]. Yet, evidence of well-established PROMs for children and adolescents receiving hand therapy is lacking. In fact, PROMs used in pediatric studies, such as the Pediatric Outcomes Data Collection Instrument (PODCI) and QuickDASH, are clinician derived[106, 126] and were initially developed for other populations.[117]

An additional limitation among these PROMs in children is a ceiling effect[58, 158], which occurs when a high proportion of subjects achieve the highest possible score on an outcome measure, making discrimination between subjects at the top end of the scale impossible. Indeed clinically, we have found that children report continued functional deficits when they have attained the maximum score on a PROM such as the PODCI, limiting the clinical utility of such PROMs in guiding ongoing care. Conversely, the Canadian Occupational Performance Measure (COPM)[29], a PROM that derives and measures progress towards patient-identified goals for therapy, has less of a ceiling effect.[158] It is plausible that the COPM's ceiling effect is less in this patient population because the PROM measures patient-identified goals unique to individual patients rather than a set item bank of questions.

Thus, it is possible that the current PROMs are limited because they are not measuring the outcomes that are most relevant to children and adolescents. Therefore, we must determine what outcomes the pediatric population desires. Historical data of patient identified goals, such as those elicited with the COPM, can be used to obtain qualitative data specific to the population's desired treatment outcomes.

To systematically evaluate patient-reported treatment goals in a given population, it is helpful to utilize an established framework, such as the International Classification of Function, Disability and Health (ICF). This framework has been used in a prior study of adults with shoulder pathology to identify the population's primary functional limitations.[41] The ICF framework, a taxonomy of over 1,400 categories of function, is grouped into the following domains: *b body functions, d activities and participation, e environmental factors and s body structures.*[6] It provides an organizational structure that

allows uniformity across medical disciplines.[162] Thus, a systematic process of evaluating PROMs, referred to as ICF linking, has been developed and refined.[36-38] With ICF linking, the constructs within the item banks of PROMs are referred to as meaningful concepts.[38] Once identified, the meaningful concepts are then linked to the ICF taxonomy (Figure 4.1). Studies that use patient-derived data for ICF linking assign meaningful concepts to the patient's reported functional limitations.[41] Drawing on this approach, we applied ICF linking to COPM goals to determine what treatment outcomes are most desired among children and adolescents receiving hand therapy, using a subset of patients with acquired upper extremity impairments.

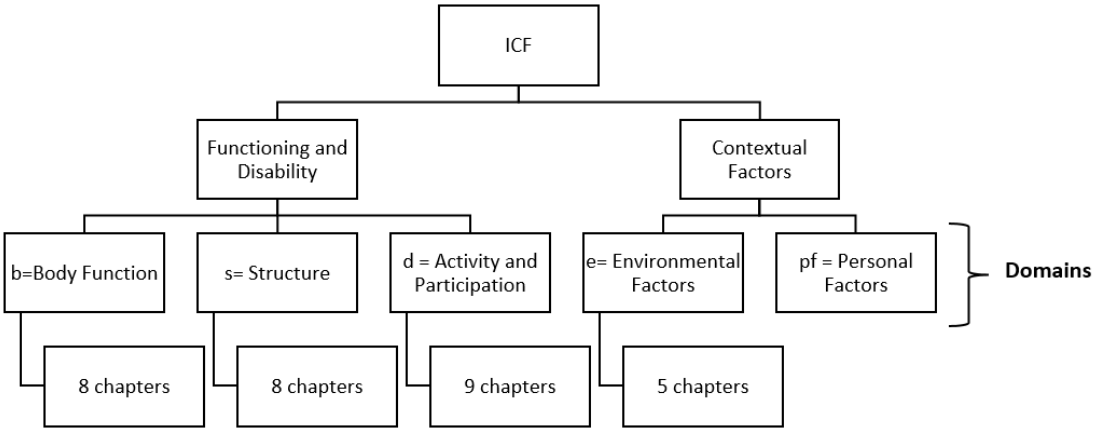


Figure 4.1: Taxonomy of the ICF

Each of the above chapters is further detailed into categories. These categories become more detailed as they unfold into 2nd level, 3rd level and 4th level categories. The level of the category is indicated by the code itself. The code breaks apart as follows:

b28014, where b= domain, 2 = chapter (level 1), 80 = level 2, 1 = level 3, 4= level 4

4.1.1 Study Objective

The objective of this ICF linking study was two-fold. First, we aimed to identify what outcomes are the most frequently reported as treatment goals on the COPM among children participating in hand therapy for acquired hand impairment. Additionally, we identified how these priorities align with the domains of the ICF framework.

4.2 Methods

4.2.1 The Instrument

The COPM is an outcome measure administered through a semi-structured interview that facilitates identification of one to five patient-derived goals for therapy intervention.[29] Patients rate their perceived performance and their satisfaction for each goal to derive performance and satisfaction scores. The measure is utilized at the initiation of therapy services to generate the patient-derived goals and baseline scores. Reassessment during a therapy episode yields a measure of change in performance and satisfaction towards the patient-derived goals. In the current study, the COPM goals derived at the initiation of treatment reflected the outcomes that the patients desired at the completion of the therapy episode reflecting their priorities for return to premorbid functional abilities. The COPM goals were obtained from interviews with the patients during their therapy appointment. Routinely, it is clinical practice in our facility to obtain the goals stated by the child allowing for parent participation when the child looks to the parent to assist them in identifying their treatment goals.

The COPM has established responsiveness and content validity for all ages and the broad range of conditions encompassing occupational therapy practice.[163] Inter-rater

reliability of the COPM is moderate[28, 164]. Construct validity of the COPM has also been established[27], and it has been validated as an outcome measurement tool for children with disabilities[164] and in the adult hand therapy population.[33] In the pediatric population, the COPM was found to identify functional limitations and client-reported goals for therapy that are not measured in current standardized assessments.[164] In adults with acquired upper extremity impairment, improvements in COPM scores correlated with changes in the patients' scores on the Disabilities of the Arm, Shoulder and Hand (DASH).[33] Yet, Case-Smith[33] did not compare the specific functional limitations identified with the COPM directly with the item-bank content of the DASH.[33] Thus, there is limited evidence even within an adult hand therapy population as to the alignment of current PROMS with patients' desired treatment outcomes.

Subjects

The Cincinnati Children's Hospital Institutional Review Board approved this retrospective chart review for children receiving hand therapy services for acquired upper extremity impairments between January 2014 and December 2018. One-hundred and fifty-one subjects met the following inclusion criteria: 1. Subject were 6 to 18 years old at the initiation of therapy, 2. The upper extremity impairment was acquired, 3. The condition was affecting the elbow, forearm, wrist, or hand, and 4. COPM goals were documented at the initiation of therapy intervention. Subjects were not included if the subject's upper extremity impairment was a congenital hand condition or resulting from a central nervous system disorder, such as hemiplegic cerebral palsy. The demographic characteristics of the 151 children included in this study are outlined in Table 4.1.

Table 4.1: Demographics of the Study Population

Characteristic	*n*
Sex	
Male	61
Female	90
Age	
6-9 years old	13
10-12 years old	29
13-15 years old	61
16-18 years old	49
Diagnostic categories*	
Fractures and dislocations:	
Hand	37
Wrist	18
Forearm	6
Elbow	7
Pain NOS**	
Hand	10
Wrist	33
Soft Tissue Injury***	
Hand	15
Wrist	21
Peripheral Nerve Injury	4

* Four patients had multiple diagnoses, such as a fracture and nerve injury and were included in counts for both categories for which their diagnoses fell within

** Not otherwise specified: includes acute and chronic pain presentations without clinical findings of fracture of soft tissue injury

***Includes ligamentous, tendon, epidermal and TFCC injury

4.2.2 Procedure

In the present study, meaningful concepts were identified within the patient identified COPM goals and linked to the ICF. To accomplish this, two researchers, an occupational therapist certified as a hand therapist (OT-CHT) and a pediatric hand surgeon (MD), who performed the ICF linking in this study reviewed all relevant ICF linking literature[36-39, 165] and met with our third researcher who has expertise in ICF linking[165] to achieve consistent familiarization with the ICF linking process. Then, an alternate set of 55 goals derived from 15 patients with acquired upper extremity impairment that did not fall within the study inclusion parameters were used to derive inter-rater agreement with the ICF linking process. Before analysis of the study set, the two raters independently applied the ICF linking rules[10-12] to the set of 55 goals used for developing inter-rater agreement. The OT-CHT, MD and a researcher who is a physical therapist and athletic trainer (PT/AT) with prior ICF linking experience met to bring consensus to the linked codes for this test set. From this process the research team derived additional linking rules for the study population. The team-derived linking rules (Table 4.2) were established to achieve more consistency in linking among the research team.

The research team used an iterative ICF linking methodology. The OT-CHT and MD independently applied established ICF linking rules[10-12] and team identified linking rules (Table 4.2) to the 151 subjects' COPM goals. After independent linking, the OT-CHT (Rater 1) and MD (Rater 2) met to bring consensus to the meaningful concepts and ICF linking for the entire study set. In establishing inter-rater agreement, we compared both raters' codes and arrived at consensus on which raters' coding to use. The process used to

reach consensus in coding is outlined in Table 4.3. The PT/AT was available as an arbitrator for instances when consensus with established ICF linking rules[10-12] was not possible between the OT-CHT and MD. However, arbitration was not required during consensus building of the ICF linked study set.

Table 4.2: Research Team Rules for Linking to ICF Codes

1. Include the upper extremity demand (ex. manipulate) and context (ex. painting) if both are documented in the patient reported goal.
2. Be as specific as possible, but do not infer more that the patient states in their goal.
    a. Unless specified by the patient, avoid inserting specific activities (ex. push/pull/grasp/twist with a goal of "open door") and/or body functions (ex. joint stability/mobility) even if those activities and functions could be components of the patient's stated goal.
    b. When a patient describes specific activities (ex. push, pull, grasp, etc.) and/or body functions (ex. joint stability/mobility) in the context of a more general activity, use the respective code for the specific and general activities (ex. for goal "perform a pull up" the codes for pull, fitness and strength are used).
3. If the activity stated in the patient goal does not fit within a specific ICF activity code (d) but involves hand and arm use, then use hand/arm use (d445). The same applies for activities involving fine hand use. With fine hand use when this occurs, use fine hand use (d440).
4. Do not use codes related to the patient's stated activity if the description of the ICF code differs from the patient's stated goal (e.g., do not use the exercises tolerance code (b445) for weightlifting because the b445 code is specific to cardiovascular function).
5. If the goal refers to a specific body structure, include the body structure code for that goal in addition to the activity or body function code.

Table 4.3: Approach to Establishing Inter-Rater Agreement for the Final List of Linked ICF Codes.

	Rater 1	
Rater 2	A	B
	C	D

Cell A indicates that Rater 1 and Rater 2 had agreement in their ICF linking of meaningful concepts
Cell B indicates initial disagreement between Rater 1 and Rater 2 in their assigned ICF codes with agreement to use Rater 2's coding
Cell C indicates initial disagreement between Rater 1 and Rater 2 in their assigned ICF codes with agreement to use Rater 1's coding
Cell D indicates that there was no agreement between Rater 1 and Rater 2 in their assigned ICF codes and neither of the initial codes was accepted

4.2.3 Data Analysis

All de-identified data was entered into Microsoft Excel 2013 for the coding and linking process. Descriptive analysis was performed in Microsoft Excel 2013. Inter-rater agreement was evaluated by calculating the percentage of observed agreement and the proportion of positive agreement in Excel and a Kappa statistic in IBM SPSS Statistics 25.0, respectively. Frequency distributions of the linked ICF codes were derived in SPSS.

4.3 Results

Each subject had between one and five goals yielding 501 patient-identified goals that were used in this linking study. The linking process for these 501 patient-identified goals yielded 914 meaningful concepts linked to 99 ICF codes in all four ICF domains. Among these 914 meaningful concepts Rater 1 and Rater 2 had initial agreement in their coding of 666 meaningful concepts. Initially, the raters had disagreement with 248 meaningful concepts. For the goals lacking initial agreement between raters on the assigned meaningful concepts or ICF codes, consensus was reached using the linking rules[36-38] (Table 4.2). Through consensus building the raters agreed to use Rater 1's coding for 70

meaningful concepts and Rater 2's coding for 85 meaningful concepts. For 93 of the coded meaningful concepts the raters either choose alternate codes or found the meaningful concepts were unable to be linked to the ICF (Table 4.3). Thus, after consensus the total meaningful concepts for all 501 patient goals was 894. In total, 92 unique ICF codes were linked to these 894 meaningful concepts. The frequencies of the 92 ICF linked codes and meaningful concepts are in Table 4.4.

Table 4.4: Frequencies of all 92 ICF Linked Codes

ICF Limitation Description	ICF Code	Frequency	Percent	Cumulative Percent
Pain in upper limb	b28014	100	11.2	11.2
sports	d9201	95	10.6	21.8
hand and arm use	d445	49	5.5	27.3
strength	b7300	46	5.1	32.4
grasping	d4401	45	5.0	37.4
writing	d170	42	4.7	42.1
lifting	d4300	42	4.7	46.8
mobility of joint functions	b710	33	3.7	50.5
wrist	s73011	29	3.2	53.7
arts and culture	d9202	23	2.6	56.3
throwing	d4454	21	2.3	58.7
caring for hair	d5202	19	2.1	60.8
managing fitness	d5701	19	2.1	62.9
turning or twisting the hands or arms	d4453	18	2.0	64.9
drinking	d560	17	1.9	66.8
manipulating	d4402	16	1.8	68.6
structure of the hand	s7302	15	1.7	70.3
carry, unspecified	d4308_carry	14	1.6	71.8
pushing	d4451	12	1.3	73.2
using writing machines	d3601	9	1.0	74.2
catching	d4455	9	1.0	75.2
hand and arm use, unspecified	d4458_weight bear	9	1.0	76.2
play	d9200	9	1.0	77.2

Table 4.4 Continued

movement functions, other specified	b789	8	0.9	78.1
washing body parts	d5100	8	0.9	79.0
dressing	d540	8	0.9	79.9
putting on clothes	d5400	8	0.9	80.8
maintaining a job	d8451	8	0.9	81.7
structure of the hand, other specified	s73028_finger	8	0.9	82.6
eating	d550	7	0.8	83.4
general products and technology for education	e1300	7	0.8	84.1
putting on footwear	d5402	6	0.7	84.8
school education	d820	6	0.7	85.5
carrying in the hands	d4301	5	0.6	86.0
swimming	d4554	5	0.6	86.6
driving motorized vehicles	d4751	5	0.6	87.2
structure of the upper extremity	s730	5	0.6	87.7
general tasks and demands, unspecified	d228_activity endurance	4	0.4	88.2
producing drawings and photographs	d3352	4	0.4	88.6
fine hand use	d440	4	0.4	89.1
structure of the hand	s7302	4	0.4	89.5
socializing	d9205	4	0.4	89.9
structure of the forearm	s7301	4	0.4	90.4
producing body language	d3350	3	0.3	90.7
pulling	d4450	3	0.3	91.1
driving human powered transportation	d4750	3	0.3	91.4
preparing meals	d630	3	0.3	91.7
taking care of animals	d6506	3	0.3	92.1
education, other specified	d838_class	3	0.3	92.4
recreation and leisure	d920	3	0.3	92.7
muscles of the hand	s73022	3	0.3	93.1
structure of the hand, other specified	s73028_thumb	3	0.3	93.4
touch function	b265	2	0.2	93.6

Table 4.4 Continued

using telecommunication devices	d3600	2	0.2	93.9
changing basic body position, other specified	d4108_functional transfer	2	0.2	94.1
lifting and carrying objects	d430	2	0.2	94.3
carrying in the arms	d4302	2	0.2	94.5
running	d4552	2	0.2	94.7
washing the whole body	d5101	2	0.2	95.0
caring for skin	d5200	2	0.2	95.2
doing housework	d640	2	0.2	95.4
disposing of garbage	d6405	2	0.2	95.6
food	e1100	2	0.2	95.9
friends	e320	1	0.1	96.0
pain in a body part	b2801	1	0.1	96.1
additional sensory functions, other specified	b279	1	0.1	96.2
caring for teeth	d5201	1	0.1	96.3
mobility of a single joint	b7100	1	0.1	96.4
mobility of joints generalized	b7102	1	0.1	96.5
tone of isolated muscles and muscle groups	b7350	1	0.1	96.6
muscle endurance functions	b740	1	0.1	96.8
control of voluntary movement functions	b760	1	0.1	96.9
sensation of muscle spasm	b7801	1	0.1	97.0
communicating with and receiving written messages	d325	1	0.1	97.1
writing messages	d345	1	0.1	97.2
lying down	d4100	1	0.1	97.3
sitting	d4103	1	0.1	97.4
standing	d4104	1	0.1	97.5
carrying on shoulders, hip and back	d4303	1	0.1	97.7
picking up	d4400	1	0.1	97.8
reaching	d4452	1	0.1	97.9
walking	d450	1	0.1	98.0

Table 4.4 Continued

climbing	d4551	1	0.1	98.1
jumping	d4553	1	0.1	98.2
using private motorized transportation	d4701	1	0.1	98.3
using transportation, other specified	d4708	1	0.1	98.4
caring for teeth	d5201	1	0.1	98.5
toileting	d530	1	0.1	98.7
maintaining one's health	d5702	1	0.1	98.8
cleaning the living area	d6402	1	0.1	98.9
assisting others with movement	d6601	1	0.1	99.0
basic interpersonal skills	d710	1	0.1	99.1
muscles of the hand	s73022	1	0.1	99.2
sibling relationships	d7602	1	0.1	99.3
general products and technology for personal use	e1150	1	0.1	99.4
general products and technology for communication	e1250	1	0.1	99.6
structure of the hand	s7032	1	0.1	99.7
elbow joint	s73001	1	0.1	99.8
muscles of the upper arm	s73002	1	0.1	99.9
	Total	894	100.0	

Note: The codes highlighted in light gray represent the top 23 codes (77.2%).

With respect to inter-rater agreement, the percentage of observed agreement between the OT-CHT and MD independently linked ICF codes was 0.80 for the study set. The Kappa coefficient was 0.32, indicating a fair level of agreement.[166] However, with the high percentage of observed agreement and low Kappa coefficient, we observed a Kappa paradox. A Kappa paradox is the phenomenon of calculating a low Kappa statistic despite a high level of observed agreement between raters.[167, 168] Thus, the proportion of positive

agreement, 0.88, is a more accurate measure for interpreting the inter-rater agreement[167, 169] in the present study.

Figure 4.2 depicts the distribution of all 894 meaningful concepts among the ICF chapters. Meaningful concepts linked to two chapters in the *b body functions* domain: *b2 Sensory functions and pain* and *b7 Neuromuscular skeletal and movement-related functions*. All chapters of the *d activities and participation* domain were linked to meaningful concepts. Two chapters of *e environmental factors* domain (*e1 Products and technology* and *e3 Support and relationships)* and only one chapter (*s7 Structures related to movement*) of the *s body structures* domain were represented in the data.

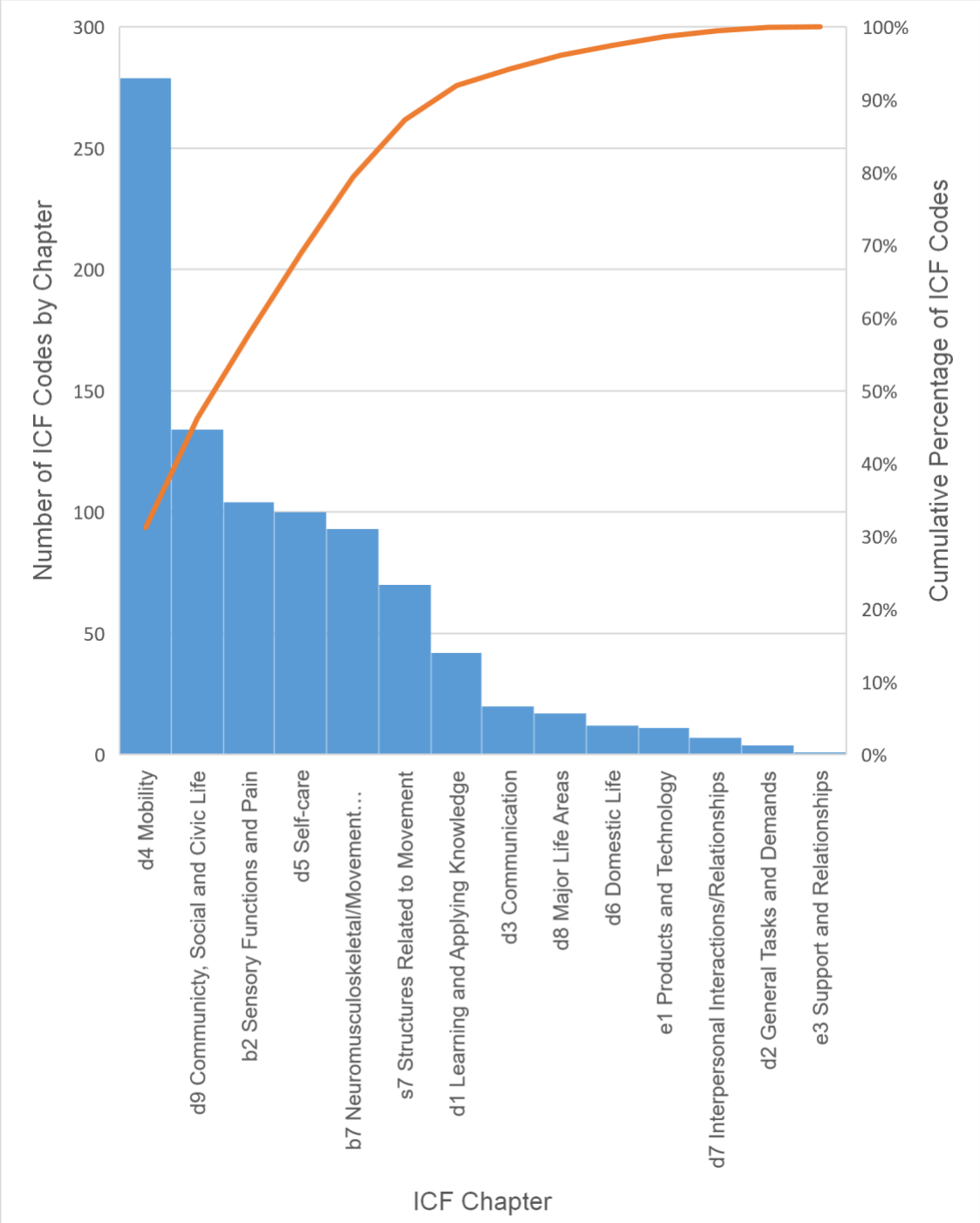


Figure 4.2: Cumulative Percentage of Linked Codes by Chapter for the Complete 894 Meaningful Concepts

Twenty-three ICF codes (highlighted in gray in Table 4.4) comprise the top 77.2% of the most frequently linked codes. Figure 4.3 displays the distribution of these top 23

codes among the ICF chapters. The greatest percentage (51.4%) of these top codes are within the *d4 Mobility chapter* (Figure 4.4). These codes in the *d4 Mobility chapter* all represent some aspect of upper extremity use ranging from the broad concept of *d445 Hand and arm* use to six specific functional patterns of upper extremity use (*d4401 Grasping, d4453 Turning or twisting the hand or arms, d4402 Manipulating, d4451 Pushing, d4455 Catching, and d4458_Weightbearing*). The second largest proportion (14.2%) of linked codes are within the *d9 Community, society, and civic life* chapter (Figure 4.5). Children expressed goals of returning to participation in a wide array of sports which is reflected in *d9201 Sports*, accounting for the largest proportion (74.8%) of the d9 chapter. Goals of improved function playing instruments, dancing, or participating in creative arts are represented in the 18.1% of d9 codes falling within *d9202 Arts and culture* and goals specific to participation in *play (d9200)* account for 7.1% of the d9 codes. The other codes in the *d Activities and participation* domain that fell within this subset of most frequently linked codes were in the *d5 Self-care* (Figure 4.6), the *d1 Learning and applying knowledge* and *d3 Communication* chapters. The distribution of codes within the *d5 Self-care chapter* was spread between *d5202 Caring for hair* (34.5%), *d5701 Managing fitness* (34.5%) and *d560 Drinking* (30.9%). *Writing* (*d170*), with a frequency of 4.7% of the top codes, was the only code in the d1 chapter, and *d3601 Using writing machines* (1.0%) the one code from the d3 chapter within this set of 23 codes.

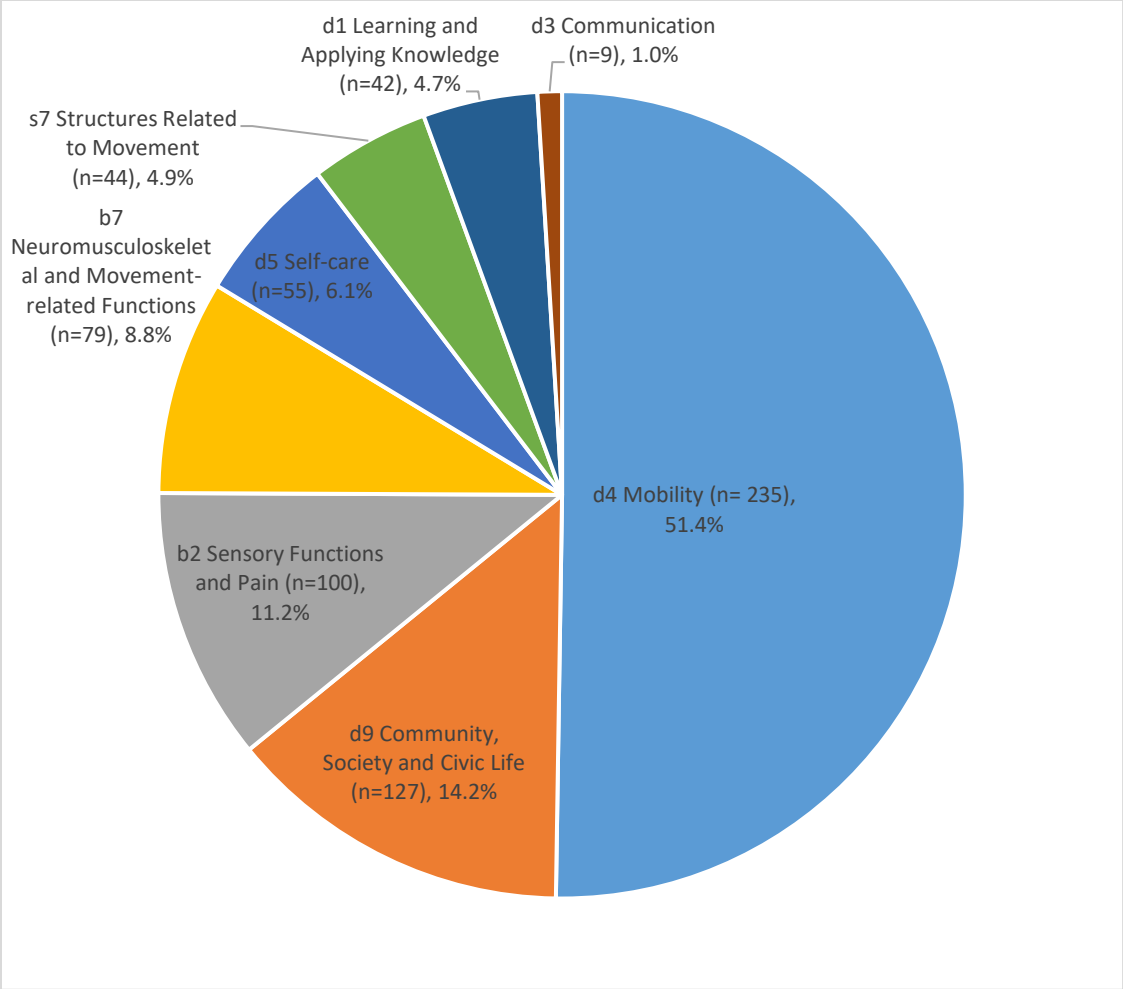


Figure 4.3: Distribution of the top 77.2% of Codes by Chapter. This Includes all Codes that were 1% or Greater of the Entire Set of Linked Codes

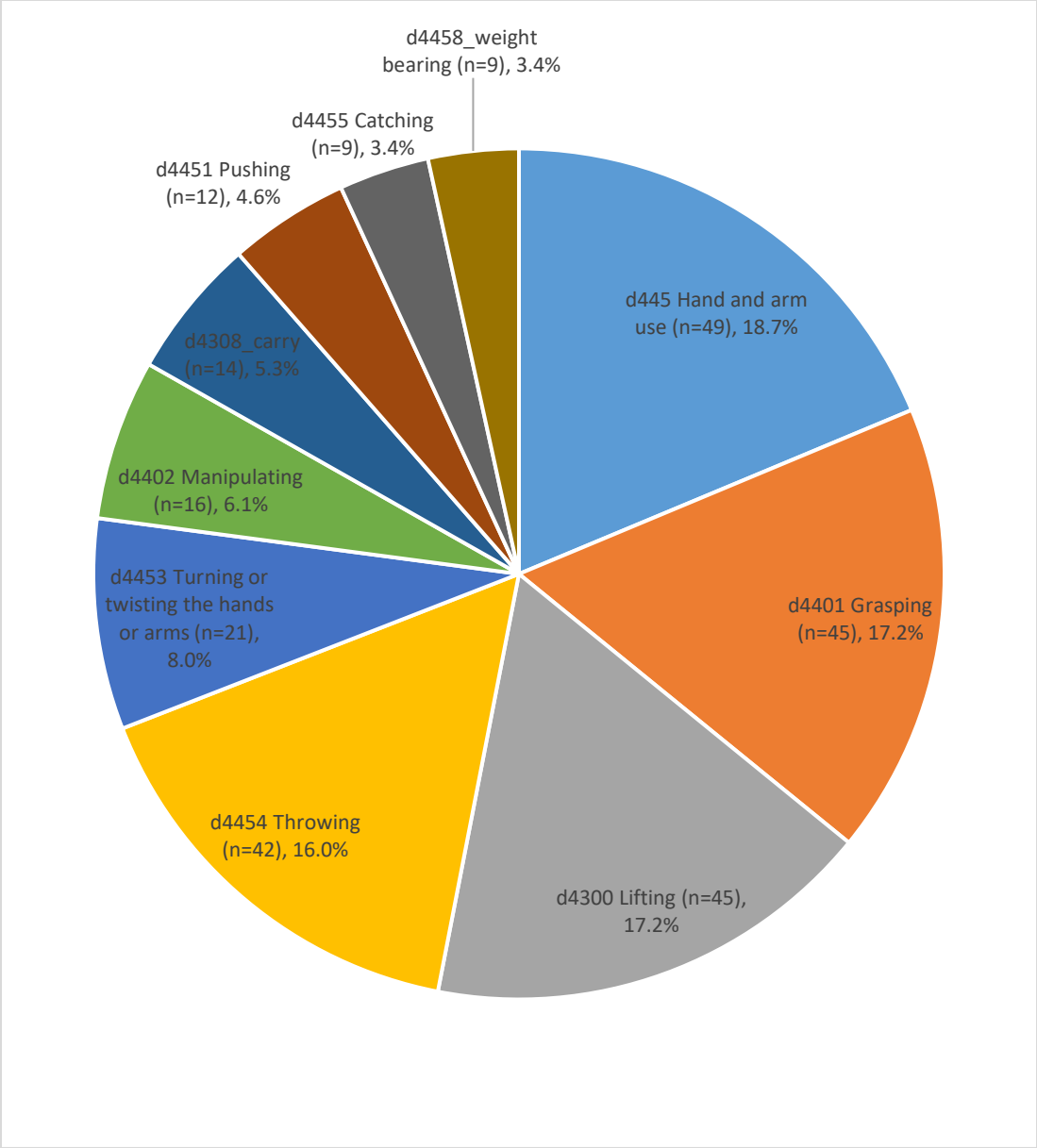


Figure 4.4: Distribution of the d4 Mobility Chapter Codes in the Top 77.2% of Linked Codes

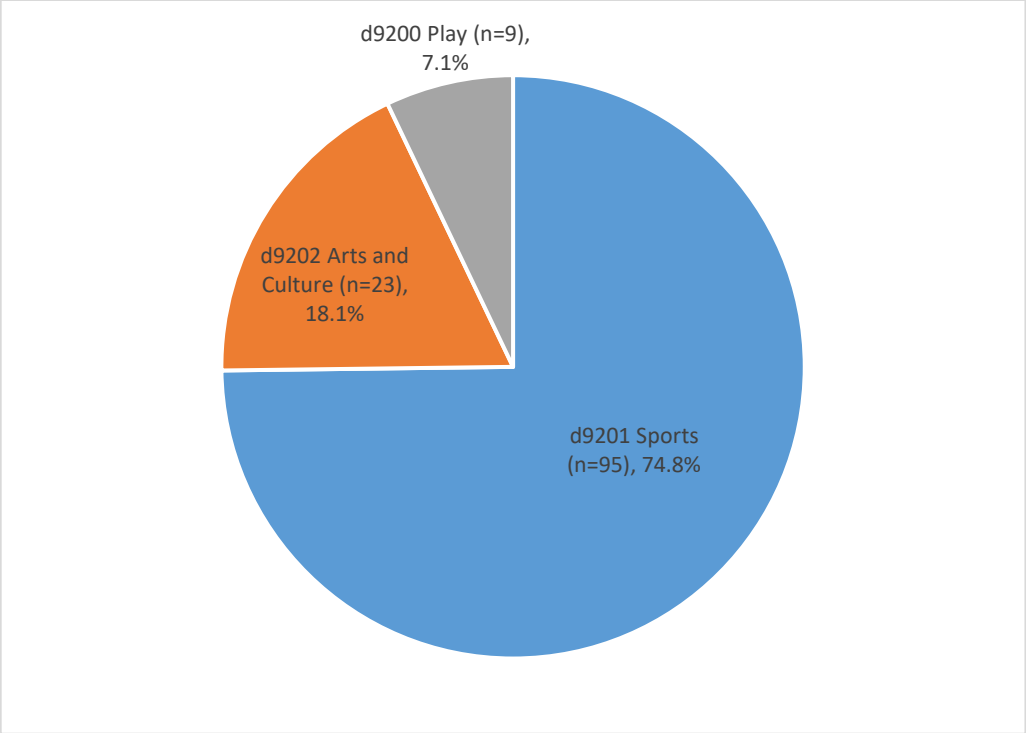


Figure 4.5: Distribution of the d9 Community, Society, and Civic Life Chapter Codes in the Top 77.2% of Linked Codes

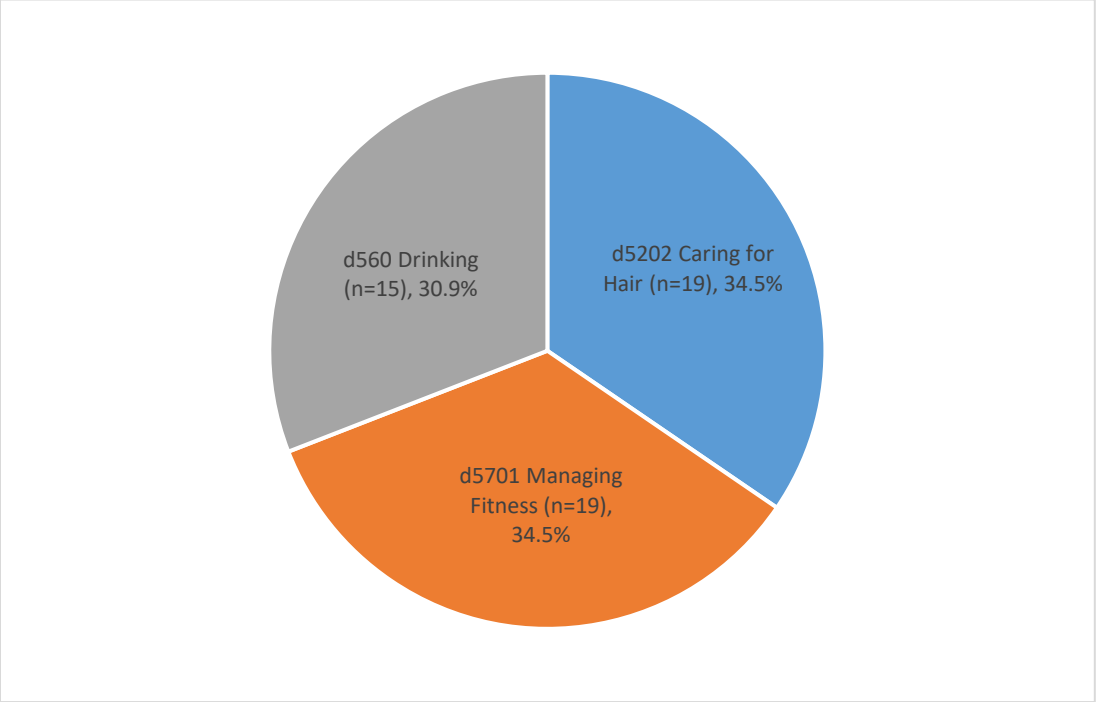


Figure 4.6: Distribution of the d5 Self-care Chapter Codes in the Top 77.2% of Linked Codes

The top 23 most frequently linked codes also included codes from within two chapters of the *b body functions* domain (*b2 Sensory functions and pain* and *b7 Neuromusculoskeletal and movement-related function*) and one chapter of the *s body structures* (*s7 Structures related to movement*). *Pain in the upper limb* (*b28014*) was the only code in the *b2 Sensory functions and pain* chapter representing 11.2% of these top 23 codes. The two codes in *the b7 Neuromusculoskeletal and movement-related functions* chapter accounting for 8.8% of the top 23 codes were *b710 Mobility of joint functions* (pertaining to joint range of motion) and *b7300 Power of isolated muscles and muscle groups* (reflecting strength). The *s7 Structures related to movement* chapter codes, 4.9% of this subset of most frequently linked codes, were *s73011 Wrist joint* and *s7302 Structures of the hand*.

4.4 Discussion

Prior studies have established that children can effectively identify relevant goals for therapy, yet disparity was found between the caregiver and the child's treatment priorities.[170] Furthermore, the COPM previously has been found to have less of a ceiling effect than the PODCI[158] suggesting children's treatment priorities for hand therapy may not be adequately represented in the item banks of currently used PROMs. Thus, in the current study our aim was to identify the most desired treatment outcomes among children receiving therapy services for acquired upper extremity impairment. To do so, we identified the meaningful concepts in the study population's COPM goals and linked the meaningful concepts to corresponding ICF codes. While the entire study population desired treatment outcomes linked to 92 unique ICF codes, twenty-three ICF codes correspond to the most frequently identified meaningful concepts in patient-identified goals for therapy

outcomes and accounted for 77.2% of the desired outcomes. This finding of a diverse array of meaningful concepts within a population's self-identified goals narrowing into a concentration of the most commonly represented meaningful concepts aligning with a more defined group of ICF codes is similar to ICF linking study of patient desired functional outcomes for patients with shoulder pathology.[165] Thus, suggesting a commonality exists among the most frequently identified outcomes that populations desire for therapy intervention even when taking into account variation among individuals within the population.

When considering the twenty-three most frequently desired outcomes, the prevalence of *d4 Mobility* codes (51.4%) is not surprising since the study population was receiving therapy to address upper extremity impairments. The codes in this chapter all reflect various aspects of hand and arm use ranging from the comprehensive concept of *d445 Hand and arm use* to more refined level three ICF codes (Figure 4.1) that reflect specific upper extremity movements, such as grasp and manipulation. This finding is consistent with the finding that goals pertaining to upper limb function were the greatest percentage of treatment priorities identified with Goal Attainment Scaling in a population of children with cerebral palsy participating in therapy.[171] Similarly, because our population reflects school-aged children, the prevalence of goals specific to improvements with writing and typing (coded as *d3601 Using writing machines*) skills also aligns with expected occupational priorities for this age range.[170] Missiuna and Pollock (2000)[170] found that children prioritized writing skills as a top priority for their therapy goals.

Similar to studies in other pediatric populations,[170] these data highlight the importance this population places on participation in the occupations of sports, music and

performing arts, and play. All these activities are reflected in the *d9 Community, society and civic life* chapter which accounts for the second largest proportion (14.2%) of codes in the top 23 codes. Furthermore, the code *d5701 Managing fitness* (Figure 4.6) was linked to the patient goals that include the concepts of "weightlifting" and performing "push-ups". Thus, our findings suggest that PROMs used for this population should measure outcomes specific to performance in sports and fitness, music and performing arts, and play.

Some patient-derived goals could not be classified in specific ICF codes, requiring more general codes to be used. For instance, the *d445 Hand and arm use* code was employed when the stated goal reflected a dimension of hand and arm that was not adequately reflected by the more refined level three ICF codes. For example, "dribble a basketball" or "serve a volleyball" was linked to "sports" and "hand and arm use" as the definitions of the level three ICF codes (Figure 4.1) in the *d4 Mobility* chapter did not reflect dribbling or serving a ball. This phenomenon suggests that PROMs questioning specific task performance may overlook the specific tasks that matter to patients. For instance, traditional activity-specific functions such as "put on a coat" found in the Upper Extremity Function Scale of the PODCI or "use a key to unlock a door" in the PROMIS Upper Extremity Function Computer Adapted Test (CAT) were not goals in this study. Further study is necessary to evaluate whether or not using item banks with broader concepts of upper extremity use for patients to rate their functional performance on a PROM would limit the ceiling effect found when using PROMs such as the PODCI Upper Extremity Function scale with this population[158].

Furthermore, it is unknown if the PROMs currently used in studies evaluating functional outcomes for children and adolescents with acquired upper extremity

impairment include all the dimensions of upper extremity function reflected in these data. Recent studies evaluating treatment outcomes in this population have employed the QuickDASH[172-179], the DASH[180, 181], the Pediatric Patient-Reported Outcomes Measurement Information Systems (PROMIS) scales[182, 183], and the Pediatric Outcomes Data Collections Instrument (PODCI).[176, 184, 185] Yet, how item banks of these validated PROMs align to what children are reporting as desired treatment outcomes has not been explored. Gaps may exist between the functional outcomes desired by this population and the functional outcomes being measured with current PROMs. For example, with respect to participation in *d9 Community, society, and civic life* (Figure 4.5) these data reflect that participation in occupations such as dance and playing musical instruments, represented by the *d9202 Arts and culture* code, are occupations of greatest importance to this population. Of these four PROMs, only the "Optional Sports and Performing Arts" of the DASH and QuickDASH includes questions about participation in performing arts. In recent studies evaluating functional outcomes within pediatric populations, only one[179] out of the ten that used the quickDASH[172-179] or DASH[180, 181] employed this optional module. With respect to the occupations aligned with self-care (Figure 4.6), all three PROMs include items that correspond to some aspect of dressing, which was not found among the study population's top self-care concerns. Additionally, bearing weight through the upper extremity (*d 4458_Weight bearing*) was within the cohort's top 23 codes, yet no items on the PODCI or PROMIS upper extremity scales reflect this task demand. One item on the QuickDASH does address the ability to participate in activities that "require the ability to take some impact or force" through the upper extremity. A more systematic comparison of study findings with current PROMs is necessary to accurately evaluate alignment of current

PROMs with the outcomes desired by this population. Additionally, an opportunity remains to compare study findings to the ICF comprehensive and brief hand core sets.[186, 187] Whereas Vincent et al. (2015)[188] linked the item banks of two PROMs to the ICF coresets, both of which were derived from the perspective of healthcare professionals,[186, 187, 189, 190] the current work draws on patient-derived treatment outcomes. Thus, future work comparing study findings to the ICF hand coresets would add a perspective of alignment between the ICF hand coresets and patient-desired treatment outcomes.

When considering the 23 most frequently desired outcomes, these data do support that child have goals for improvement in range of motion *(b710 Mobility of a joint functions)* and strength (*b7300 Power of isolated muscles and muscle groups),* and reduction in pain (*b28019 Pain in the upper limb*). Therefore, traditional measures of body functions, such as range of motion and strength measurements and pain scale measures, have value in measuring changes towards the outcomes the pediatric population desires with respect to the b *body functions* domain.

Less than 1% of all codes (0.8% in d7 "Interpersonal interactions and relationships" and 0.1% in e3 "Support and relationships") are specific to interpersonal relationships. Prior studies have employed using scales such as the PODCI Happiness subscale[176, 184] and the PROMIS Pediatric Peer Relationships CAT[182, 183] to evaluate outcomes with similar patient populations. Additional study is necessary to explore the relevance of assessing outcomes specific to psychosocial factors in this population. It is possible that the nature of the patient interviews for obtaining COPM goals did not elucidate concerns specific to psychosocial function within this cohort.

The strong agreement by the OT-CHT and MD who performed the ICF linking was likely derived from the study methodology. Applying the linking rules to a test set of data[165] allowed refinement of the rules for this study likely yielding the high inter-rater agreement for linking the study set.

4.4.1 Study Limitations

The ICF framework and linking process allowed for systematic evaluation of patient desired outcomes for hand therapy intervention in the context of global health. Having data from patients' reported goals for treatment allowed for the exploration of outcomes from the patients' perspective. However, when linking some documented goals, the authors were limited by the nature of chart review and using what the therapists documented as the patient stated goals. We were unable to gain greater specificity than what was reported in the medical record. Therefore, for goals such as "perform a cartwheel" we could not infer what component of the activity was underlying the impairment in participation. Because numerous factors, such as pain, range of motion limitations, and weakness, could be making participation in the activity difficult but were not recorded in the chart, we had to use fewer specific codes (e.g., *d789 movement* in our linking process). Consequently, we may have missed meaningful concepts that aligned with the client concerns but were not recorded.

For some concepts derived from the patient-stated goals, the ICF had a level of specificity that prevented us from using certain codes. For example, the concept of "endurance" was expressed by patients in the context of being able to sustain participation in an activity (e.g., "Throw a ball for 20-30 minutes"). The ICF codes for endurance were either specific to muscle endurance falling within the *b7* Neuromusculoskeletal and

movement-related functions or within *b4 Functions of the cardiovascular, hematological, immunological, and respiratory systems*. These codes, indicating either muscle endurance functions or cardiovascular and respiratory endurance, were a level of specificity beyond what we could ascertain from the stated goal. In such cases, we applied the previously established linking rules[37] and used an "other-specified" code.

The population in this study includes a wide range of children and adolescents, from 6-18 years old, at differing developmental stages. Additionally, the diagnoses represented in this study population encompass the elbow, wrist and hand and range from nonspecific pain to specific acute injuries (e.g., flexor tendon lacerations and fractures). While the study population's heterogeneity could be considered as a limitation, it reflects the breadth of age ranges and diagnoses that comprise a pediatric hand therapy practice. Therefore, study population's heterogeneity enhances the generalizability of the study findings to the defined population.

4.5 Conclusions

The study results highlight that the ICF domain of *Activities and participation* is the greatest global health concern in this population. Specifically, children and adolescents participating in hand therapy for acquired upper extremity impairment are reporting top functional priorities in a various dimensions of hand and arm use and in participation in sports and fitness, music and performing arts, and play. These findings suggest there is a need to consider areas of activity participation that may not be measured by current PROMs used with this population. Further research is needed to identify agreement between the outcomes children and adolescents with acquired upper extremity impairment desire and

the items measured with current PROMs. Study findings suggest that children and adolescents do value improvement in outcomes that align with current body functions measures, such as measures of pain, range of motion and strength. Finally, additional research may elucidate whether PROMs need to include measurement of psychosocial factors for this population.

4.6 Conflict of Interest

Conflicts of interest: none.

CHAPTER 5. THE CONCEPTUAL MODEL AND CONTENT VALIDATION OF THE UPPER EXTREMITY LIFE IMPACT MEASURE -YOUTH (UE LIM-Y)

5.1 Introduction

Occupational therapists and physical therapists practicing in hand therapy have adopted routine use of patient reported outcome measures (PROMs) in their delivery of care.[17] Yet, for hand therapists providing care to pediatric patients, the PROMs currently utilized in pediatric hand care are limited in clinical utility.[34, 58] Furthermore, pediatric hand therapists desire a PROM that is widely applicable to and better aligned with their patient population.[102] The Canadian Occupational Performance Measure (COPM),[29] is a PROM which therapists use a semi-structured interview to derive individualized patient-identified treatment goals to measure as treatment outcomes. The COPM's design allows for individualized treatment goals for pediatric hand therapy patients facilitating alignment of the measured treatment outcomes with the patient population. However, the COPM's individualized design limits comparisons between specific pediatric hand therapy populations. A PROM with a set item bank of questions that align with the pediatric hand therapy population's outcomes priorities is desired among pediatric hand therapists[102] to allow for population comparisons. Furthermore, the design of the COPM requires greater administration time than a PROM with a set item bank of questions. This time required to administer the COPM is an identified barrier to PROM utilization in the pediatric hand therapy population.[102] Thus, establishing the need for a PROM with a set item bank of questions tailored to the pediatric hand therapy population. Chapter 2 of this dissertation presented evidence that a PROM with well-established psychometrics for application in a pediatric hand therapy population is lacking. Thus, a need to develop a PROM tailored to the pediatric hand therapy population exists.

The standards which inform PROM development have evolved over the past two decades.[13, 45, 48-52, 68, 69] At the same time, mixed methods research applications have expanded,[73] and scholars have asserted that PROMs should be developed using mixed methods research (MMR).[66] It is accepted by both MMR scholars[74] and experts in measurement science[51, 52, 69] that PROM development begins with qualitative methods. The qualitative phase of creating a PROM involves two steps. In the first stage of the qualitative phase, the developer derives a conceptual model to inform the draft PROM content. This conceptual model is informed by data from the target patient population and PROM users. Next, refinement of the PROM is accomplished through cognitive interviewing to establish content validity is the second stage of the qualitative phase. Once the draft PROM's content validity is established the qualitative phase is completed. Following a sequential mixed method approach,[75] the quantitative phase of PROM development then begins. The quantitative phase includes further studies to establish structural validity, construct validity, reliability, and the minimal important change.[46, 48, 50, 71] This dissertation's focus is completing the entire qualitative phase of PROM development to establish the UE LIM-Y's content validity.

During the qualitative phase, a conceptual model is derived through qualitative inquiry with the patient population for which the PROM is intended to be used.[51, 52, 69] Patrick et al.[51] recommended using focus groups with members of the target population to elicit data for informing the conceptual model of the PROM. Additionally, PROM development standards[70] advise that stakeholders who will be administering the PROM should be included in qualitative inquiry designed to inform the conceptual model. Once

the conceptual model is derived, the draft PROM is developed from the conceptual model.

The second phase of the qualitative stage establishes the draft PROM's content validity. Once the instructions, response scale and the item bank of questions is drafted, cognitive interviewing[76] is used to refine the PROM so that the content aligns with the patient population it is intended to be used with.[52] Cognitive interviewing is a qualitative method that allows researchers to identify potential sources of error in PROM content and make refinements.[76] An iterative process of data analysis following a small subset of interviews and PROM refinement is completed until there is sufficient evidence of no remaining comprehension concerns with the PROM.[52]

This study has two aims. First, a conceptual model will be proposed and applied to develop the draft PROM for children receiving hand therapy for upper extremity impairment, named the Upper Extremity Life Impact Measure – Youth (UE LIM-Y). Then, the draft UE LIM-Y will be refined to establish the content validity of this novel PROM for pediatric hand therapy patients. Secondarily, participant evaluation of the UE LIM-Y will be evaluated qualitatively to evaluate the target patient population's impressions of the measure.

5.2 Methods

5.2.1 Conceptual Model and Draft PROM

Following a MMR approach to PROM development, the results of two prior studies [102, 191] were applied to derive the conceptual model and draft PROM for the pediatric hand therapy population, the UE LIM-Y. (Figure 5.1). Drawing on PROM

development standards,[51, 52, 69] qualitative data was obtained from stakeholders who will administer the PROM (e.g., pediatric hand therapists)[102] and representatives of the target patient population.[191] Findings from the qualitative study with representatives of pediatric hand therapists[102] primarily informed the conceptual structure for the UE LIMY, including the target patient population and the PROM's format. Secondarily, stakeholder data informed the constructs the UE LIM-Y should measure (Appendix 1). Informed by the International Classification of Functioning, Disability, and Health (ICF)[6] and the Canadian Model of Occupational Performance and Engagement (CMOP-E)[24] directed through the COPM as the data collection tool informed the UE LIM-Y's conceptual model. Qualitative study with representatives of the target patient population primarily informed the constructs the UE LIM-Y should measure (Appendix 1) Secondarily, these study findings informed the five categories of questions in the UE LIM-Y's conceptual structure. The conceptual structure and constructs were merged to inform the conceptual model for deriving the UE LIM-Y's draft instructions, response scale and questions. (Appendix 2).

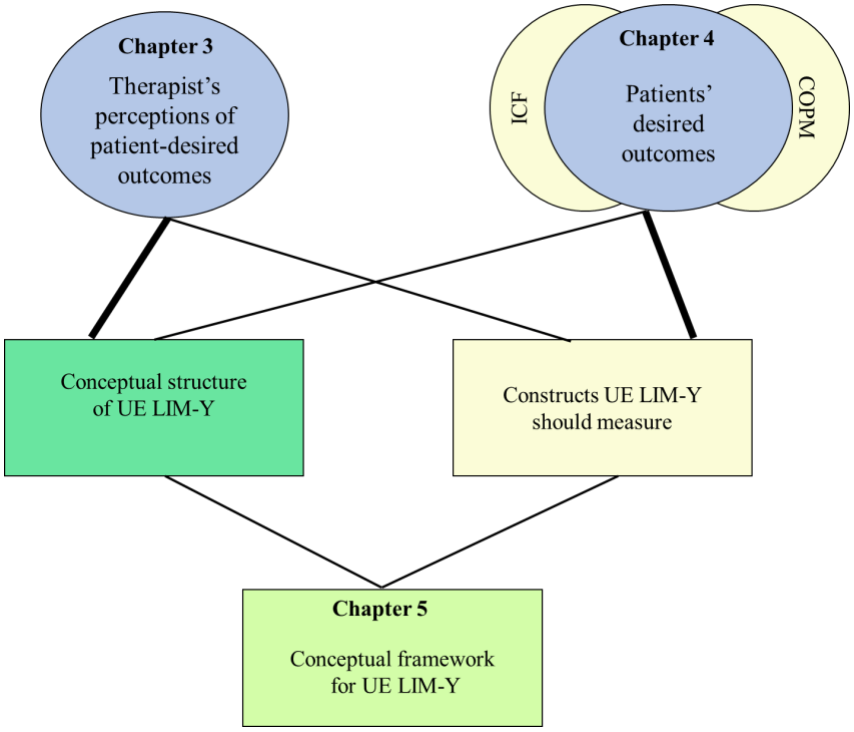


Figure 5.1: Schematic of the Derivation of the UE LIM-Y's Conceptual Model

5.3 Development of the UE LIM-Y

The UE LIM-Y draft instructions, response scale, and questions were then derived from a subset of the PROMs currently used in pediatric hand therapy which have evidence of some psychometric application in a pediatric population (Chapter 2). Questions from the PROMIS® Upper Extremity Function (Short From), Pediatric Outcomes Data Collection Instrument (PODCI), and QuickDASH were mapped onto the conceptual model for the UE-LIM-Y. The ABILHAND-Kids and PUFI were excluded because the questions in these PROMs were developed for narrowly defined patient populations.[108, 121] Thus, questions in these two PROMs were determined to be too specific as compared to the questions from the three included PROMs which were developed for broader applications.[106, 107, 160] Additionally, the COPM's design precludes

it from having a set item bank of questions, so it was excluded as well. Since the Michigan Hand Outcomes Questionnaire (MHQ), Patient Specific Functional Scale (PSFS), and Upper Limb Functional Index (ULFI) have no established psychometrics for application in a pediatric population, these measures were also excluded.

In this process of developing the initial instructions, response scale, and questions for the draft UE LIM-Y when no questions from these existing PROMs aligned with the conceptual model, a novel question for the UE LIM-Y was developed. ICF language and findings from qualitative study with the target patient population (Chapter 4) informed the wording of these novel questions. Once a first version of the UE LIM-Y was complete, the principal investigator (PI) refined questions and instructions until a Flesch-Kincaid reading level consistent with a sixth grade reading level was achieved using Microsoft Word. Then the first version of the UE LIM-Y (Appendix 3), which included 29 questions, was used in the first round of cognitive interviews with representatives of the patient population.

5.4 Content validation of the UE LIM-Y

5.4.1 Subjects

The Cincinnati Children's Hospital (CCHMC) and University of Kentucky Institutional Review Boards (IRB) approved this study. Following IRB approval, study participants were recruited from the CCHMC Hand and Upper Extremity Center via an informational flyer distributed to patients receiving care for an upper extremity condition. Interested patients were referred to the PI who screened them for study inclusion, either in person or over the phone. Participants were selected from among eligible patients

using a maximum variation sampling plan to ensure diversity in the study sample (Table 5.1). Participants selected for participation were invited to participate in one direct face-to-face interview at CCHMC. All participants received a $20 gift card to Target© for study participation. All participants only participated in one round of data collection.

To achieve diversity while keeping the study sample to a customary[76] and manageable size for data analysis our maximum variation sampling plan focused on five demographic variables. Because the researchers anticipated that different age groups may have unique experiences with respect to living with their condition and the activities that they participate in, as well as their reading and comprehension abilities, we prioritized having at least 2 participants for each age group for each round of data collection. With content revisions occurring between each round, it was deemed necessary to continue this priority of diversity in age across each round of data collection to ensure achievement of content validity. Other priority variables across the entire study sample were diagnostic category, region of affected upper extremity, biological sex, race, and ethnicity. We sought to have diversity in diagnosis and region of the affected extremity to ensure generalizability of study results. While these variables could influence participant responses, they are less likely to impact the UE LIM-Y's overall comprehension and readability. Therefore, the researchers determined diversity across the entire sample was adequate for these variables. Similarly, biological sex, race and ethnicity were priorities for participant diversity across the entire sample to achieve a balance among male and female participants and the greatest amount of participant diversity possible within the available participant pool.

Table 5.1: Parameters for Maximum Variation Sampling

Parameters for each round of data collection

• Recruit at least two participants from each of the following age groups for each round of data collection:
  o 8-12 years old
  o 13-16 years old
  o 17-20 years old

Parameters guiding selection for the entire study sample

• At least two participants from each diagnostic category
  o Acquired pathology
  o Chronic musculoskeletal condition
  o Congenital anomaly
  o Neuromotor pathology
• At least two participants with pathology affecting each of the following regions
  o Shoulder
  o Elbow
  o Wrist
  o Hand
• Equal proportion of male and female participants
• Diversity in race and ethnicity

5.4.2 Inclusion and exclusion criteria

Eligibility for study participation required participants to be greater than or equal to 8 years old and less than 21 years old. Additionally, study participants had to be receiving medical or therapy care for a hand and/or upper extremity impairment at the time of recruitment or within the preceding two months. Potential participants who were not fluent in reading and speaking English were excluded from study participation because the researcher performing the cognitive interviews was only English fluent.

Children younger than eight were excluded since eight is the youngest age children are able to reliably rate their health on five-point Likert scales.[192] At pediatric hand centers, care is typically provided to patients who are less than 21 years of age. Therefore, we limited our study sample to patients under 21 years old.

5.4.3 Cognitive interviewing

Cognitive interviewing is an established method for refining PROM content to achieve content validity.[52, 193, 194] Once a draft PROM is developed, 1:1 interviews are performed with members of the target population the PROM is designed to be used with. Cognitive interviewing uses two techniques, thinking aloud and verbal probing, to elucidate the alignment between the participants' understanding and the developer's intended meaning of the questions.[195, 196] Additionally, asking participants to define terms, comment on the perceived accuracy of responses, and/or respond to general questions about the PROM may be utilized.[77, 197] During the interviews the participants read aloud the content of the draft PROM and indicate their responses to all questions. The researcher uses probes to elicit the participant's interpretation of the instructions, questions, and response scale. The interviews are recorded in their entirety and transcribed verbatim for data analysis. Prior authors have successfully utilized cognitive interviewing techniques in pediatric populations as young as 7 years old in questionnaire development.[194, 198, 199]

While pioneers in cognitive interviewing methods recommend multiple rounds of cognitive interviews to inform iterative refinement of the questionnaire,[76] the practice has not been routine in studies involving pediatric populations.[194, 198, 199] Additionally, published studies[197, 200] which use the established coding scheme[201] applied in the current

study only utilize one round of cognitive interviews to inform measure refinement. Thus, an established method of applying cognitive interviewing methods to refine draft PROMs for the pediatric population is lacking.

5.4.4 Procedure

Following verbal consent from the participant's legal guardian and the participant's verbal assent, participants completed a demographics questionnaire (Appendix 4) and participated in a 1:1 semi-structured interview with the PI in a private room. Participant's guardians were permitted to remain in the room and were seated away from the table at which the interview was performed. An interview guide (Appendix 5) was used to structure all interviews. The interviews were audio recorded in their entirety.

The interview involved the participant reading aloud the UE LIM-Y's content (e.g., instructions, response scale, and questions) and marking his/her answers to the questions on the draft PROM. Using the interview guide, throughout the interview the PI probed participants to think aloud and explain their understanding of the measure's instructions, response scale, and their responses to questions. Upon completion of the draft UE LIM-Y questionnaire, participants were engaged in responding to additional questions to identify the participants' overall impressions of the PROM's questions and their recommendations for any revisions. The PI took field notes throughout each interview to record participant behaviors during the interviews. Specifically, the PI recorded when any of the following were observed: delay or uncertainty answering the question, qualification of their response, inconsistent or changed responses, rewording of the question when thinking aloud, and challenges with answering questions. Additionally, the PI noted if caregivers participated in the interviews to assist their child.

Each interview audio recording was transcribed verbatim. The PI reviewed complete recordings of each interview. Then, transcripts were read in their entirety and then line by line to perform content analysis.[202] Data analysis was organized in Microsoft Excel (Microsoft Corporation, Version 2112) so that content analysis[202] was performed individually on each set of instructions and each question in the draft PROM. Additionally, the PI referenced field notes for each participant when performing data analysis. A previously established coding scheme[201] was adapted and used to identify and quantify problems in the instructions, questions, and response scale (Table 5.2). This coding scheme categorizes six types of problems, which may be discovered with the draft PROM's content during cognitive interviewing. In the current study, the seventh code, other concerns (OC), was added a priori to capture any identified comprehension problems which did not fall within the previously established coding scheme.[201] For each participant, this coding scheme was applied to the draft PROM's instructions, response scale,, and all questions. The PI tabulated any instances of these codes occurring within a question across participants for both the instructions and questions and made reflexivity notes for any of these instances. This analysis occurred following three separate rounds of interviews. Each round included 9 to 11 interviews. The PI repeated rounds of data collection iteratively with data analysis occurring between each round of interviews for PROM refinement.

After all interviews were completed, the PI merged interview transcript data pertaining to participants' impressions of the UE LIM-Y. This data was obtained at the end of the interviews from the PI's probe, "How well do you feel these questions capture your experience with your hand/arm problem?" Descriptive analysis of these qualitative

data was performed to identify categories of participant responses. Compiled responses were read in their entirety and then line-by-line to abstract codes.[147] Next, using constant comparison, codes were compared and grouped into categories. Then categories were grouped into categoriess.[148]

Table 5.2: Coding Scheme for Data Analysis

Code	**Description**
Clarity/comprehension (CC)*	The participant displays difficulty with understanding the meaning or intent of the question
Relevance (R)*	The question is irrelevant to the participant
Inadequate response definition (IRD)*	One of the following three situations: 1) misalignment of participant response with the question, 2) absence of potentially applicable responses for the posed question, 3) concerns with the participant's logic or assumptions made when formulating the response
Reference point (RP)*	The participant demonstrates difficulty with determining his/her response because recall is unclear, or the question boundaries are vague
Perspective modifier (PM)*	Participant personal factors, experiences or environmental factors influence responses that would result in difference between participants
Other Concerns (OC)	Any additional concerns noted with the participants' interpretation of instructions, response scale, or questions that did not fall within the six defined codes

Table 5.2 Continued

Calibration across items*	The response to one question influences responses to other questions

*Note: *Adapted from MacDermid.*[201]

At the end of each round of data collection, the PI reviewed the tabulation of codes, all additional notes, and all reflexivity notes which occurred for the instructions and each question. To increase rigor, the PI met with a pediatric hand surgeon (RC) to review all instruction segments and questions with codes and field notes. The two researchers used the data analysis to inform revisions to the UE LIM-Y for the subsequent round of data collection for each individual question, the instructions, and response scale. Then tabulated problems across all participants in the data collection were reviewed. Occurrences of the same problem across multiple participants were grouped together to inform revisions to draft PROM. Thus, while a specific item may have had twelve tabulated problems for the entire dataset, collective groups of like problems reduced the number of revisions needed for that item. After the first round of data collection, the researchers looked at the codes for each question from the prior rounds of data analysis. In instances where prior coding did not meet the threshold for a revision, if new instances of the same code emerged in subsequent rounds, then revisions were made. The researchers used the following criteria for revisions: 1) Instances of two or more unique problems (after grouping of like problems) warranted revision, and 2) For problems discovered in interviews with participants younger than 10, the threshold for revision was reduced to one problem instance resulting in a revision. Whenever available, patient wording was used to inform the language used in item revisions.

This study used a variety of trustworthiness measures. Cognitive interviewing methods employed in the current study were triangulated with the literature.[147] Before data collection began, the PI practiced cognitive interviewing techniques in the form of a mock cognitive interviewing session with the draft UE LIM-Y and a healthy ten-year-old child. A faculty advisor experienced in cognitive interviewing reviewed the audio recording and provided feedback for training prior to data collection. Throughout the study the PI engaged in reflexivity journaling[146] and maintained an audit trail to ensure reliability. The participation of a second researcher (RC) in the evaluation of coded problems and PROM revisions throughout iterative data analysis rounds increases credibility.[148] Additionally, the PI engaged in peer debriefing with faculty advisors who are experts in qualitative research techniques to minimize bias.[148] Member checking of study findings was not performed in the current study secondary to the cognitive interviewing methods. During each interview the PI used probing throughout to elicit understanding of the participants responses.[76, 195, 196] Furthermore, at the end of the interviews the PI engaged in additional probing on questions where the PI identified that clarification of the participants' thinking aloud was necessary to ensure the PI was accurately understanding the participants' statements. In these instances, the PI and participant engaged in discussion until mutual understanding was achieved.

5.5 Results

Data collection occurred from September 7, 2021, through December 6, 2021. In the first round of data collection, nine participants consented and completed interviews. In the second round of data collection, eleven participants consented and initiated participation, with ten of these participants completing a full interview. One participant in

round two withdrew participation after reading the instructions and the first question stating she did not want to continue. In the third round of data collection, eleven participants consented and completed interviews. The median interview duration was 22.37 minutes (range 16.38 to 37.07 minutes).

5.5.1 Participant Demographics

In total, thirty children and adolescents aged 8-20 participated in the study. Eighty seven percent (*n*=26) of the participants were white/Caucasian and 15% (*n*=4) were Black/African American. Ten percent (*n*=3) were Hispanic (90% non-Hispanic, *n*=27). A summary of demographics with respect to age, biological sex, region and laterality of the affected extremity, and type of condition is in Table 5.3.

Each round of data collection included children across the full age range set for study inclusion. In the first round of data collection the participants were predominantly female; however, the proportion of females to males was more evenly split in subsequent rounds with the overall percentage of female participants (57%, *n*=17) just over half that of males (43%, *n*=13). In each round of data collection, the number of participants with their dominant upper extremity being their affected was almost evenly split. While each round did include at least one participant with proximal upper extremity (e.g., elbow or shoulder) involvement, throughout the data collection, most participants had conditions affecting either their wrist or hand.

Table 5.3: Summary of Patient Demographics

	Round 1 ***n*=9**	**Round 2** ***n*=10**	**Round 3** ***n*=11**	**Total** ***n*=30**
Mean age (years)	14	13	13	13
Age range	9-20	8-20	8-18	8-20
Female	8 (89%)	4 (40%)	5 (45%)	17 (57%)
Male	1 (11%)	6 (60%)	6 (55%)	13 (43%)
Dominant affected	4 (44%)	5 (50%)	5 (45%)	14 (47%)
Affected region				
Shoulder	0 (0%)	2 (20%)	2 (18%)	4 (13%) †
Elbow	1 (11%)	1 (10%)	0 (0%)	2 (7%) †
Wrist	3 (33%)	6 (60%)	5 (45%)	14 (47%)
Hand	6 (66%)	3 (30%)	5 (45%)	14 (47%)
Type of condition				
Acquired pathology	8 (89%)	8 (80%)	9 (82%)	25 (83%)
Chronic musculoskeletal condition	0 (0%)	1 (10%)	1 (9%)	2 (7%) *
Congenital anomaly	1 (11%)	0 (0%)	1 (9%)	2 (7%) *
Neuromotor pathology	0 (0%)	1 (10%)	1 (9%)	2 (7%)

Note: *one participant had a chronic musculoskeletal condition and congenital anomaly; †one participant had pathology affecting both the elbow and shoulder

Ninety seven percent of participants (*n*=29) were students. Three (10%) were college students, twelve (40%) were in high school, seven (23%) were in middle school, and seven (23%) were grade school students. Seven (23%) participants reported they are

employed. Thirty percent (*n*=9) of the participants reported regular engagement in performing arts activities, including dance, drama or playing an instrument. Eighty percent (*n*=24) of participants were involved in sports. Reported sports included golf, cheer, baseball, basketball, volleyball, football, soccer, karate, weightlifting, lacrosse, gymnastics, and track.

5.5.2 UE LIM-Y Revisions

5.5.2.1 First round of data collection

The first round of data collection on Version 1 of the UE LIM-Y elucidated problems with the instructions, response scale, and 17/29 questions (Table 5.4). In total, 49 problems were coded among all questions, the instructions and response scale. Concerns with clarity/comprehension was the most frequently coded problem. Seventeen instances of clarity/comprehension were elicited from among twelve items. Ten problems coded as perspective modifier were found among eight questions. All nine problems coded as "other concern" occurred within the instructions and were the same problems among nine participants. The nine instances of reference point problems occurred among four questions. Only four instances of inadequate response definition were elucidated, each occurring in a unique question. No problems with relevance were elucidated in round one of data collection. Figure 5.2 provides a summary of the coded problems, their grouping into categories to inform scale revisions and the number of revisions to the scale.

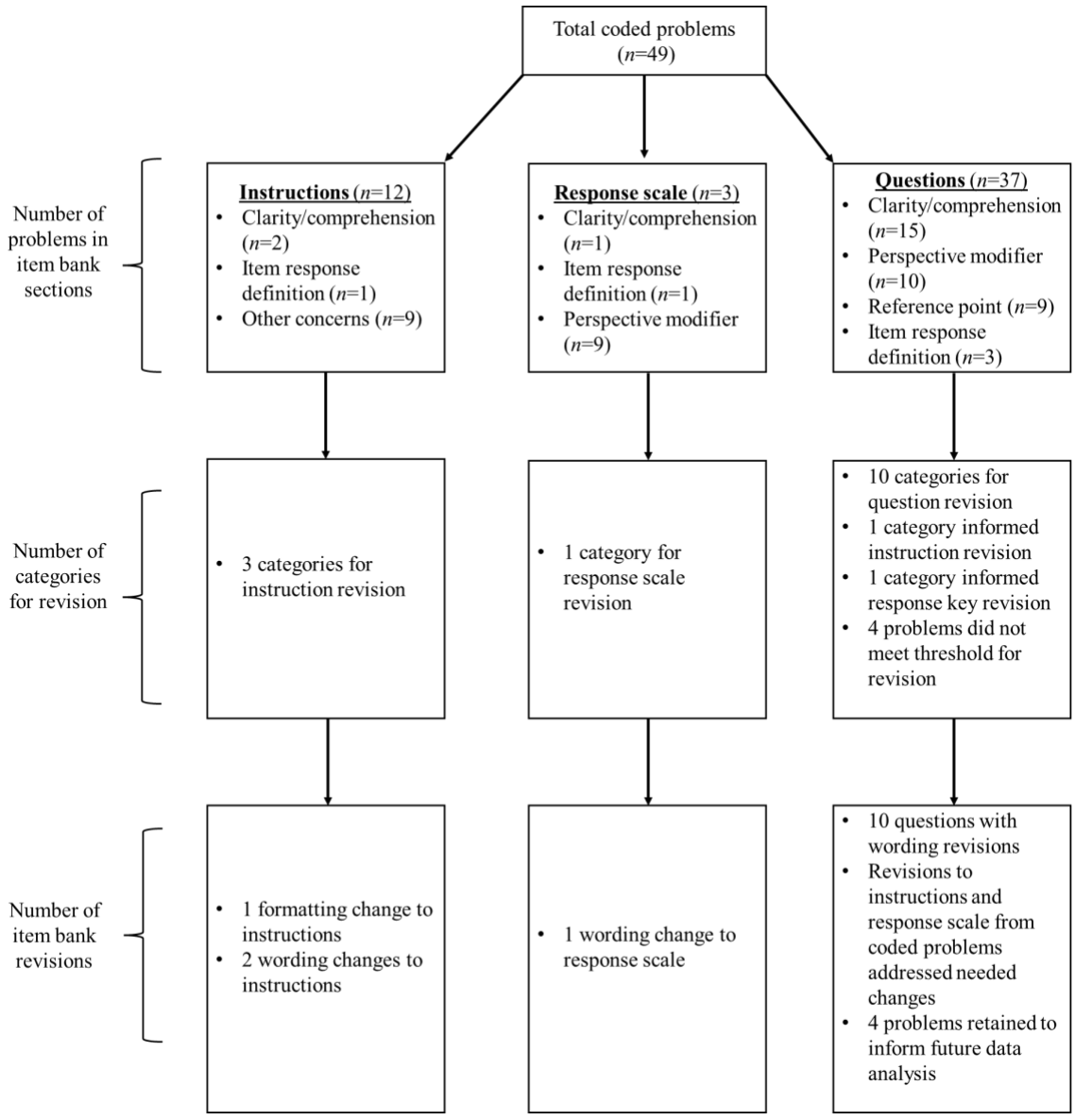


Figure 5.2: Summary of UE LIM-Y Revisions from the First Round of Data Collection

Two Occurrences of the Comprehension/Clarity Code, One of the Inadequate Response definition code, and nine of other concerns code were elucidated for the instructions. Thus, three revisions were made to the instructions. In Version 1 of the UE LIM-Y instructions, the language for the timeframe participants should reference (i.e., "in the past 7 days") was placed at the start of each section of the UE LIM-Y. Most participants did not read "in the past 7 days" aloud at the start of each section and

reference point errors were observed with questions 12, 14, 15 and 23. Therefore, all instructions were moved to the top of the questionnaire rather than having any instructions at the beginning of sections, including language for the timeframe reference point. One participant in round one of data collection had comorbidities to her upper extremity condition. She expressed uncertainty with answering the questions about the limitations she experienced specific to her upper extremity condition or in relation to her comorbidities as well. Therefore, the instructions for Version 2 were revised by adding language to clarify that participants should calibrate their responses to how their upper extremity condition impacts them. The final revision to instructions for round two was to add language specifying that if the respondent does not typically perform the activity referenced in the question, he/she should choose the response "does not apply." Participant responses indicating that they do not typically use their affected extremity for the tasks referenced in questions 13 and 19 prompted this revision.

Table 5.4: Coding Summary of Problems in the UE LIM-Y – Version 1

Round 1							
Item	**CC**	**RP**	**IRD**	**RP**	**PM**	**OC**	**Total**
Instructions	2		1			9	12[§]
1							
2							
3	1						1
4	2						2[*]
5							
6							
7			1				1
8	1						1
9							

Table 5.4 Continued

10							
11	2				1		3*
12	2			1	1		4*
13	1				1		2§
14				1	1		2*
15	1			4			5*
16							
17	2						2*
18	1		1				2†
19					3		3§
20							
21	1		1				2*
22	1				1		2*†
23				3			3*
24					1		1*
25							
26							
27							
28					1		1
29							
Total Problems	17	0	4	9	10	9	49

Key: CC = Clarity/Comprehension; R = Relevance; IRD = Inadequate Response Definition; RP = Reference Point; PM = Perspective Modifier; OC = Other Concerns

*question revision due to problems with question; †response scale revision; §revision to instructions

The response scale was also revised after the first round of data collection. For question 18, one participant expressed that “frequently” and “occasionally” were unclear to them. Additionally, probing for question 22 revealed inconsistencies with the response a participant chose with respect to his/her report of his/her ability to perform the task referenced in the question. Thus, “frequently” and “occasionally” were replaced with “more than half the time” and “less than half the time” respectively in UE LIM-Y Version 2.

Among the questions, concerns with comprehension/clarity were the most frequently coded problem. Fifteen instances of concerns with comprehension/clarity were found among eleven questions (Q 3, 4, 8, 11-13, 15, 17-18, 21-22). Analysis also revealed ten occurrences of perspective modifier code among eight questions (Q 11-14, 19, 22-24), nine of the reference point code among four questions (Q 12, 14-15, 23), and three of the inadequate response definition code among three questions (Q 7, 18, 21). The researchers grouped like problems for individual questions into problem categories for each question to inform question revisions. Ten questions underwent wording revisions (Table 5.5). Seven questions (Q 3, 7-8, 13, 18-19, 28) had problems coded but did not undergo wording revisions in this round. Of these seven questions, four (Q 3, 7-8, 28) only had one instance of a problem coded so revision was withheld to assess if further data collection elucidated more problems, problems coded for two questions (Q13, 19) informed revisions to the instructions, and the problem coded for question 18 informed the response scale revisions.

Table 5.5: Summary of Revisions to UE LIM-Y-Version 1 questions

Round 1		
Question	**Revision**	**Rationale**
4	Changed “appearance” to “look”	Concerns with comprehension/clarity
11	Changed items in the example from “coins, clothing fasteners, shoelaces, pencils, a fork” to “buttons, zippers, shoelaces, pencils”	Concerns with comprehension/clarity; perspective modifier
12	Changed “grasp” to “hold” and removed “bike” before handle	Concerns with comprehension/clarity; perspective modifier
14	Added “everyday” before things	Reference point; perspective modifier
15	Added “everyday” before things	Reference point
17	Changed “interfered with” to “has gotten in the way of”	Concerns with comprehension/clarity
21	Changed from “arts and crafts” to “arts activities”	Concerns with comprehension/clarity; inadequate response definition
22	Changed from “my hand and arm limits participation in sports” to “I could do sports and exercise”	Concerns with comprehension/clarity
23	Changed “at work” to “in my job”	Reference point
24	Changed wording in the example from “car or bike” to “bike or car”	Perspective modifier

No questions were eliminated from UE LIM-Y during revisions after the first round of data collection. Additionally, no new questions were added. UE LIM-Y-Version 2 (Appendix 6) was the resultant draft from changes made from round one data analysis. UE LIM-Y-Version 2 was used in the second round of data collection.

5.5.2.2 Second Round of Data Collection

The second round of data collection on Version 2 of the UE LIM-Y elucidated problems with the instructions and 18/29 questions (Table 5.6). The total number of problems coded within this round (n=48) was only reduced by one in comparison to the first round of data collection. In this second round of data collection, concerns with clarity/comprehension remained the most frequently coded type of problem. Twenty-five total instances of concerns with clarity/comprehension occurred across the instructions and twelve questions. Ten of these instances occurred in the instructions. Nine problems coded as inadequate response definition were elucidated among five questions. Seven perspective modifier concerns occurred among four questions. Six reference point problems arose across six questions. Only one problem was assigned to the other concern code in this round, occurring in question 4. No problems were coded as relevance in this round. Figure 5.3 summarizes the coded problems, their grouping into categories to inform scale revisions, and the number of revisions to the scale following this second round of data collection and analysis.

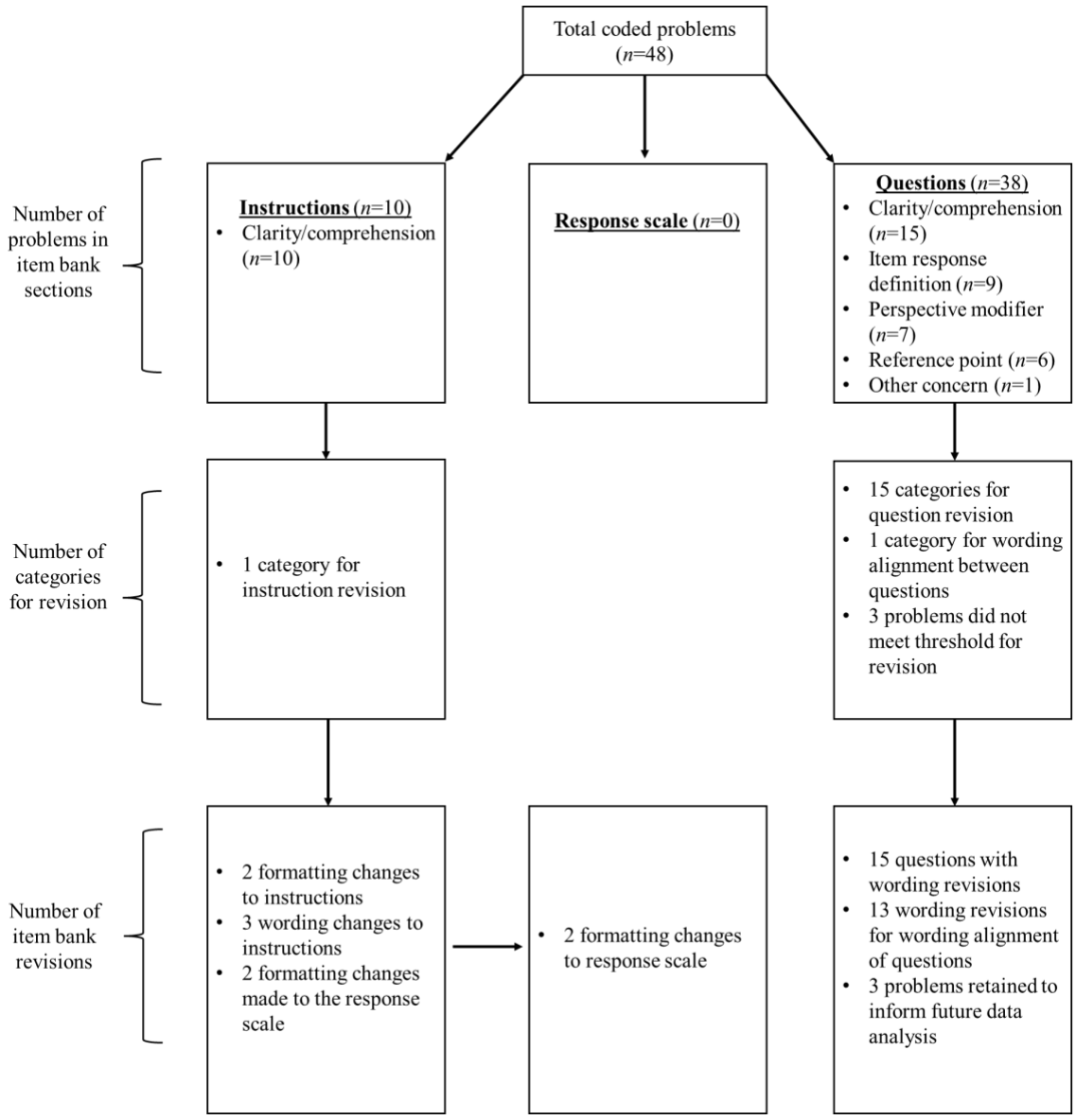


Figure 5.3: Summary of UE LIM-Y Revisions from the Second Round of Data Collection

Ten Occurrences of the Comprehension/Clarity Code were Elucidated for the Instructions. Overall, data indicated the question wording was too cumbersome. Therefore, the instructions were reduced to one line at the start of the PROM. The wording in this one line of instructions was also changed to add clarity. Revision included replacing “think about” to “answer the following questions below with.” Additionally, the following text was bolded: “hand and/or arm” and “over the past seven

days." The following text added from round 1 data analysis was removed: "If you have other injuries or health conditions, please respond to the questions below about how your hand and/or arm problem affects you." To further simplify the instructions, the text describing the response scale rating system was embedded into the response scale for each question. Specifically, the language that explains the scaling was embedded into the response scale for each item. Additionally, the instructions about choosing the response option "does not apply" was placed within the response scale. Finally, the following instructions that followed were removed from the introductory text, revised, and embedded into question 19: "If the activity in question is typically only performed with your arm or hand that does not have a problem, choose "does not apply" for your response to that question."

Table 5.6: Coding summary of problems in the UE LIM-Y – Version 2

Round 2							
Item	**CC**	**R**	**IRD**	**RP**	**PM**	**OC**	**Total**
Instructions	10						10[§†]
1	1			1			2[*]
2	1						1[*]
3	1						1[*]
4	1					1	2
5				1			1
6							
7	2		1				3[*]
8				1			1[*]
9				1			1[*]
10	3			1			4[*]
11					2		2[*]
12							

Table 5.6 Continued

13	1			1			2*
14							x
15							x
16	1						1*
17	1						1*
18					1		1x
19			3				3*
20							x
21	1				1		2*
22	2		1				3*x
23			3		3		6*x
24			1				1x
25							x
26							x
27							x
28							x
29							x
Total Problems	25	0	9	6	7	1	48

Key: CC = Clarity/Comprehension; R = Relevance; IRD = Inadequate Response Definition; RP = Reference Point; PM = Perspective Modifier; OC = Other Concerns

*question revision due to problems with question; †response scale revision; §revision to instructions; x wording of question revised to achieve alignment with other questions in the respective section of questions

Revisions performed to the response scale were made because of problems discovered with the introductory instructions. As already noted, to simplify the instructions the scaling information for the response scale was embedded within the

response scale for each question. With this revision, the design of the response scale was also revised to place the options for the participants could chose for responses into blue boxes (except for the response option "does not apply" for questions 18-24) to add clarity to which text represented response options.

Among the questions, concerns with comprehension/clarity were the most frequently coded problem. Fifteen instances of concerns with comprehension/clarity were found among eleven questions (Q 1-4, 7, 10, 13, 15, 16-17, 21-22). Analysis also revealed twelve occurrences of the inadequate response definition code among eight questions (Q 7-10, 19, 22-24), eight of the perspective modifier code among five questions (Q 4, 11, 18, 21, 23), and three of the reference point code among three questions (Q 1, 5, 13). No instances of the relevance code were found. After theming of coded problems for each question, twenty-five questions underwent wording revisions (Table 5.7). Fifteen questions (Q 1-3, 7-11, 13, 16-17, 19, 21-23) were revised because of coded problems and thirteen questions (Q14-15, 18-20, 22-29) to align the question wording more questions with other questions in the associated section of the draft PROM. Three questions (Q 4, 18, 24) had coded problems in this round and did not undergo wording revisions for these respective findings since they did not meet the *a priori* threshold for revisions. These three problems were flagged to review after round 3 of data collection to evaluate if round 3 data collection elucidated additional instances of like problems for these questions.

Table 5.7: Summary of Revisions to UE LIM-Y-Version 2 Questions

Round 2		
Question	**Revision**	**Rationale**
1	Changed from "I had difficulty doing my regular daily activities" to "My hand or arm problem has made doing my regular daily activities difficult"	Concerns with comprehension/clarity; reference point
2	Changed from "My hand or arm problem has made me unhappy" to "I have not been happy because of my hand or arm problem"	Concerns with comprehension/clarity
3	Changed from "I have been happy with how I can use my arm and hand" to "I have liked how well I can use my hand and arm"	Concerns with comprehension/clarity
7	Changed from "It has been easy to move my arm and hand" to "Moving my arm and hand has been easy"	Concerns with comprehension/clarity; inadequate response definition
8	Changed from "I could move my arm and hand without having pain" to "It has been painful to move my hand and/or arm"	Inadequate response definition
9	Changed from "I had the strength in my arm and hand to do my regular daily activities" to "My hand and arm have been strong enough to do my regular daily activities"	Inadequate response definition

Table 5.7 Continued

10	Changed from “I had the strength in my arm and hand to do the activities I enjoy most” to “My hand and arm have been strong enough to do the activities I enjoy most”	Concerns with comprehension/clarity; inadequate response definition
11	Removed “pencil”	Perspective modifier
13	Removed “screwdriver” and changed “rotate” to “twist”	Concerns with comprehension/clarity; reference point
14	Changed from “I have been able to. . .” to “I could use my hand and arm to. . .”	Change made for wording alignment with other questions in the Hand and Arm Functions section
15	Changed from “I have been able to. . .” to “I could use my hand and arm to. . .”	Change made for wording alignment with other questions in the Hand and Arm Functions section
16	Changed “through my hands” to “through my hand and arm;” changed “from a chair” to “up out of a chair”	Concerns with comprehension/clarity
17	Changed “has gotten in the way of” to “has limited”	Concerns with comprehension/clarity
18	Changed from “I could use my arm and hand for play” to “My hand or arm problem has limited play”	Change made for wording alignment with other questions in the Activity Participation section

Table 5.7 Continued

19	Changed from “I could write with a pen or pencil” to “My hand or arm problem has limited writing with a pen or pencil”	Change made for wording alignment with other questions in the Activity Participation section
	Added * at the end of question to reference the following wording moved from instructions to the response scale options for this question: “If you hand or arm that has a problem is not the hand you typically write with, chose “Does not apply”	Change made for concerns with comprehension/clarity of the instructions section
20	Changed from “I could use a. . .” to “My hand or arm problem has limited. . . “	Change made for wording alignment with other questions in the Activity Participation section
21	Changed from “I could participate in. . .” to “My hand and arm problem has limited. . .”	Concerns with comprehension/clarity; perspective modifier
22	Removed “other kids my age”	Concerns with comprehension/clarity; inadequate response definition
	Changed from “limits my participation in. . .” to “has limited doing. . .”	Change made for wording alignment with other questions in the Activity Participation section

Table 5.7 Continued

23	Added “household chores”	Inadequate response definition; perspective modifier
	Changed from “I could use my arm and hand in. . .” to “My hand or arm problem has limited doing”	Change made for wording alignment with other questions in the Activity Participation section
24	Changed from “I could use my hand and arm to drive vehicles” to “My hand or arm has limited driving vehicles”	Change made for wording alignment with other questions in the Activity Participation section
25	Changed from “I could” to “My hand and arm has limited my ability to”	Change in wording made for alignment of question wording with other questions in the item bank
26	Changed from “I could” to “My hand and arm has limited my ability to”	Change in wording made for alignment of question wording with other questions in the item bank
27	Changed from “I could” to “My hand and arm has limited my ability to”	Change in wording made for alignment of question wording with other questions in the item bank

Table 5.7 Continued

28	Changed from "I could" to "My hand and arm has limited my ability to"	Change in wording made for alignment of question wording with other questions in the item bank
29	Changed from "I could" to "My hand and arm has limited my ability to"	Change in wording made for alignment of question wording with other questions in the item bank

No questions were eliminated from UE LIM-Y during revisions after the second round of data collection. However, two new questions were added based upon participant feedback. In this round of data collection one participant had expressed that she experienced impaired sensation that impacted her tactile sensation and manual dexterity. Additional participants in round two data collection reported this phenomenon. Therefore, question 30 was added to measure patients' experience with their tactile sensation. Additionally, two participants in round 2 data collection had shoulder involvement and expressed they had trouble with reaching overhead. Thus, question 31 was added to assess patients' report of their overhead reach. UE LIM-Y-Version 3 (Appendix 7) was the resultant draft PROM from changes made from round two data analysis. UE LIM-Y-Version 3 was used in the third round of data collection.

5.5.2.3 Third Round of Data Collection

The third round of data collection on Version 3 of the UE LIM-Y revealed problems with the instructions, response scale, and 10/31 questions (Table 5.8). The total number of coded problems decreased to 26 in the third round of data collection. In this

round, ten inadequate response definition occurred among five questions. Six instances occurred in question nineteen and all reflected the same problem. Six instances of clarity/comprehension problems were elucidated from three questions. Five problems coded as other concern occurred among the instructions (*n*=4) and question 2. The four instances of other concern in the instructions were all the same category of problem. Three problems were coded as perspective modifier among three questions. No relevance or reference point problems were coded in the third round of data collection. A summary of the coded problems, their grouping into categories to inform scale revisions, and the number of revisions to the scale following the third round of data collection and analysis follows (Figure 5.4).

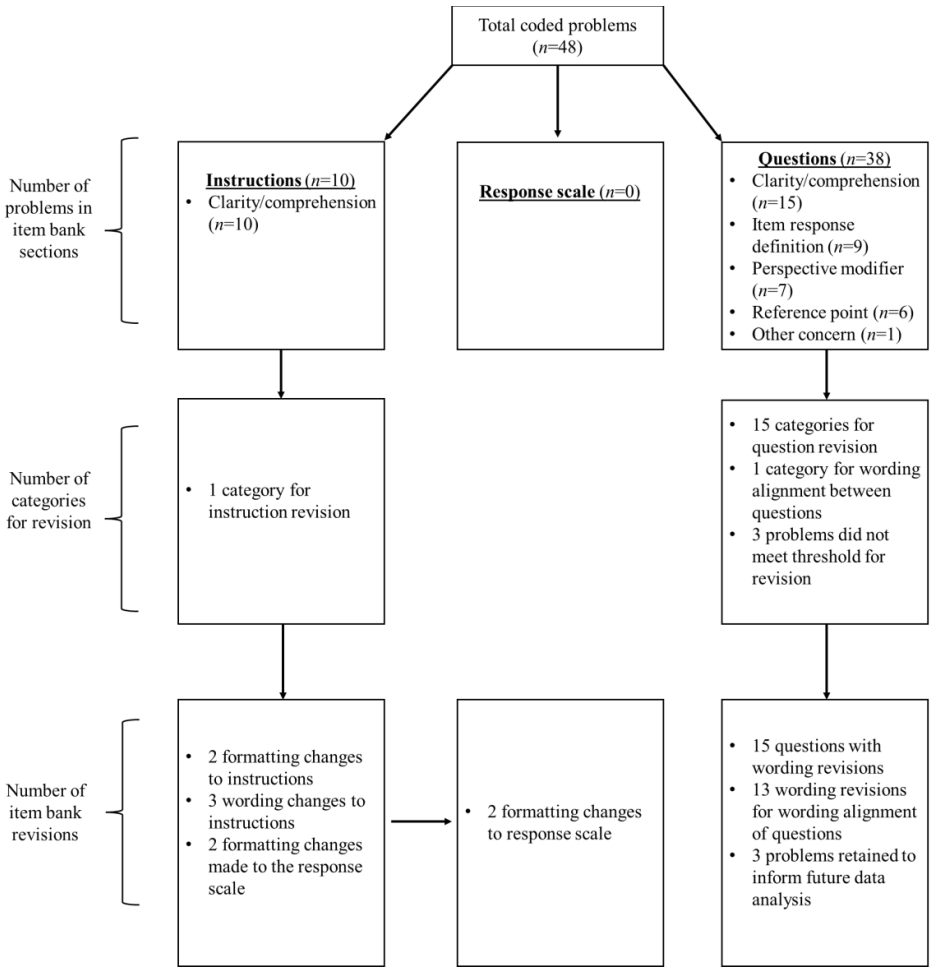


Figure 5.4: Summary of UE LIM-Y Revisions from the Second Round of Data Collection

Two occurrences of the comprehension/clarity code and four of other concerns code occurred in the instructions. Thus, three revisions were made to the instructions. First, the instruction wording at the start of the PROM was further simplified by removing the words "how" and "has been" from the first sentence. Second, the text "over the last 7 days was underlined." Third, based upon coded concerns with question 2, the following sentence was added to provide more clarity in how participants should indicate responses: "Circle your response in the blue box for each question."

Table 5.8: Coding summary of problems in the UE LIM-Y – Version 3

Round 3							
Question	**CC**	**R**	**IRD**	**RP**	**PM**	**OC**	**Total**
Instructions	2					4	6§†
1							
2						1	1§
3							
4							
5							
6							
7	1						1*
8			1				1*
9							x
10	2		1				3*
11							
12							
13							
14							
15							

Table 5.8 Continued

16					1		1
17							
18							
19			6				6†
20							
21			1				1†
22							
23							
24			1		1		2†
25							
26					1		1
27							
28							
29							
30	3						3*
31							
Total Problems	8	0	10	0	3	5	26

Key: CC = Clarity/Comprehension; R = Relevance; IRD = Inadequate Response Definition; RP = Reference Point; PM = Perspective Modifier; OC = Other Concerns

* question revision due to problems with question; † response scale revision; § revision to instructions; x wording of question revised to achieve alignment with other questions in the respective section of questions

The response scale was revised based upon problems coded as inadequate response definition for three questions (Q 19, 21, 24). Two categories of problems emerged among these coded problems. Therefore, the response scale was revised. First, the response option "Does not apply" was moved to the start of the response scale for

questions 18-24 and placed in a blue box to match the other response scale options. This revision was a recommendation made by participants during data collection. Second, for question 19, the following text was removed from underneath the question 19 response scale and placed within the text of the question: *If your hand or arm that has a problem is not the hand you typically write with, choose "Does not apply."* Participants also recommended this amendment.

For the questions, ten occurrences of the inadequate response definition code were elucidated among five questions (Q 8, 10, 19, 21, 24). Six instances of concerns with comprehension/clarity were found among three questions (Q 7,10, 30). One instance of the reference point, perspective modifier, and other concern codes were the found for questions 26, 16 and 2, respectively. No occurrences of the relevance code were elucidated. Four categories of question problems were derived which resulted in format and/or wording revisions to five questions (Q 7-10, 30) (Table 5.9). The problem coded for question 2 resulted in a revision to the instructions and the problems coded for three questions (Q 19, 21, 24) resulted in response scale revisions. Two questions (Q 16, 26) only had one coded problem per question, not enough to warrant revisions according to a priori criteria.

Table 5.9: Summary of Revisions to UE LIM-Y-Version 3 Questions

Round 3		
Question	**Revision**	**Rationale**
7	Bolded "easy"	Concerns with comprehension/clarity
8	Changed from "It has been painful to move. . ." to "I have hand pain moving. . ."	Inadequate response definition
9	Bolded strong enough	Changed to align to revision made with question 10
10	Bolded strong enough	Concerns with comprehension/clarity; Inadequate response definition
30	Changed from "feel things" to "feel things that I touch"	Concerns with comprehension/clarity

No questions were removed, nor were any new questions added following the analysis of round three data collection. Furthermore, the researchers agreed that saturation was met with the third round of data collection since no major content revisions were made in this round. The researchers set reaching a point of no major content revisions as *a priori* criteria for saturation.[203] Major revisions were defined as any revisions requiring more than wording or format revisions which used participant informed wording or format changes. After round three data collection, while minor revisions were made, the question wording for the two questions with revised wording

was provided by participants. Thus, the researchers agreed that wording was fitting for a pediatric patient population. The other question revisions were format changes. Specifically, text in questions 7, 9 and 10 was bolded. This strategy of highlighting text with bolding proved to be an effective strategy used in prior rounds of testing. Thus, the researchers (the PI and RC) agreed an additional round of data collection was not necessary to assess effectiveness of this technique to emphasize question wordings. Furthermore, like the revisions to question wording, the formatting changes for the response scale were also provided by participants. Consequently, the researchers agreed that changes made from round 3 data collection and reflected in UE LIM-Y – Version 4 (Appendix 8) did not require any further testing. Researchers agreed that UE LIM-Y Version 4 is the final version of the draft PROM.

5.5.2.4 Calibration across items

During the first round of data collection no concerns with calibration across items were elucidated. In the second and third data collection rounds calibration concerns did arise. Questions 5, 6 and 8 all pertained to pain and were placed towards the start of the item bank for rounds one and two data collections. During the second round of data collection some participants were noted to continue referring to pain when explaining their responses to subsequent questions. For this reason, in Version 3 of the UE LIM-Y the body function questions section was moved to the end of the item bank with the pain questions moved to be the last three questions. In the third and final round of data collection this calibration concern was not observed. Thus, researchers agreed that moving the pain question to the end of the UE LIM-Y resolved this problem.

During the third round of data collection two participants chose responses for question 7 that did not correspond to their stated experience. Question 7 stated "Moving my hand and arm has been easy." Specifically, in thinking aloud he/she discussed that it was easy to move his/her arm and hand yet chose "less than half the time." Because of moving the body functions questions to the end to address the concerns with calibration for questions 5, 6 and 8 after round two of data collection, question 7 followed a set of questions asking about participants' limitations in their abilities performing activities of daily living. Thus, for the questions preceding question 7, when a participant's experience was responding with few limitations in the activities referred to in the questions preceding question 7, they would choose a response on the left end of the response scale, such as "almost never" or "less than half the time". Therefore, for question 7, because the question wording changes from being negatively stated to positively stated, participants who are having the experience of easy movement would choose "more than half the time" or "almost always". Therefore, to accentuate the shift in question language from the set of question prior to question 7 being negatively stated to question 7 being positively stated the word "easy" was highlighted in bold in UE LIM-Y Version 4.

5.5.2.5 Flesch-Kincaid reading level

The Flesch-Kincaid reading grade level[204] of UE LIM-Y Version 1, the version used for data collection in round one, was 6.9 (i.e., sixth grade). Refinements to the content performed after the first round of data analysis increased UE LIM-Y Version 2's Flesch-Kincaid grade reading level to 8.0 (i.e., eighth grade). The UE LIM-Y Version 2 was used for round two data collection. Revisions following round two data collection

decreased the Flesch-Kincaid grade reading level to 1.9 (i.e., second grade) for UE LIM-Y Version 3 used in round three of data collection. The revisions made following round three data collection increased the Flesh-Kincaid grade reading level to 2.5 (i.e., second grade) in UE LIM-Y Version 4, the final version.

5.5.2.6 Participant evaluation of UE LIM-Y

Three main concepts emerged among participant reflections on their overall evaluation of the UE LIM-Y. These main concepts follow: 1) The UE LIM-Y design and format are favorable, 2) The questions are relevant, and 3) The questions are useful. While participants offered constructive comments to enhance the UE LIM-Y's content, no participants expressed negative feedback. Furthermore, throughout interviews caregivers remained observers rather than participants in the process. Thus, the data evaluating the participants' impressions of the UE LIM-Y is directly from participants and was not influenced by caregivers during the data collection.

Participants' evaluations of the UE LIM-Y reflected three points respective to the first concept, *the UE LIM-Y design and format are favorable*. Participants expressed that the UE LIM-Y content was easy to understand. Some participants remarked they found the examples helpful in the questions with provided examples. Participants also remarked that the response scale was easy to understand. In referring to the UE LIM-Y questions, Participant 4 (age 14, elbow dislocation) remarked "They stuck straight to the points and are really like easy and simple to answer."

Two ideas arose among participants pertaining to concept 2, *the questions are relevant*. Participants reported the questions pertained to topics that were most relevant to them. Sports, hobbies, school, and "everyday things" were examples participants cited

when noting the relevancy of questions. Some participants also expressed the questions were worded so they were relatable. Remarking on this later point, Participant 23 (age 18, hemiparesis secondary to brain tumor) stated, “I like how yours, even though they are about specific topics, they’re still broad enough to apply to anyone.” This participant reported having previous experience completing PROMs and compared the UE LIM-Y questions to her experience with past PROMs. Referring to questions in previously completed PROMs, Participant 23 noted, “Sometimes they’ll say things like, . . . ‘can you throw a baseball?’ You know, it’s way too specific. It’s like that doesn’t apply to my life.”

With respect to the third concept, *the questions are useful*, participants noted two points. Some participants said they found completing the UE LIM-Y useful in evaluating their health status. Participant 17 (age 14, thoracic outlet syndrome) remarked, “These questions definitely helped me think about what my symptoms were. . . I think these are great questions to just kind of help the person think about like what they are feeling.” Other participants reported feeling the UE LIM-Y would provide their medical care team with useful information about their experience with their condition. Remarking on the UE LIM-Y questions Participant 10 (age 11, wrist ligamentous injury) stated, “I think they do a good job because it like helps the doctor or therapist like know what’s happening.”

5.6 Discussion

In this study the conceptual model for the UE LIM-Y was developed drawing upon established methods. [51, 52, 69] While qualitative data to inform the conceptual model was collected from both the patient population and prospective PROM users, the methods employed in this study varied with respect to how qualitative data was derived from the

patient population compared to the norm of focus groups[52] in both adult[205] and pediatric populations.[194, 206] Instead, an ICF linking study (Chapter 4) using patient-identified treatment goals provided data from the patient perspective to inform the conceptual model for drafting the UE LIM-Y. This approach allowed us to access qualitative data from the patients in the form of the meaningful concepts embedded in their COPM goals that were identified by patients in the context of receiving their care (Chapter 4). Rather than a focus group interview that occurred at a time outside the delivery of the patient receiving care, the COPM goals, which were derived at the initiation of the child's therapy treatment, provided data directly from the child and family during the time the child was actively receiving care for their upper extremity condition. Furthermore, the ICF linking allowed for analysis of the child-derived data in the context of the ICF. Thus, it provided a perspective of data interpretation that allowed elucidation of a conceptual model for item bank development that incorporates activity and participation while not losing the perspective of body structures and functions.

Historically, hand therapy draws from a biomechanical model[12] and therapists value measures of body function[102] (Chapter 3). Thus, as the profession is challenged to move towards a more holistic focus of health and therapy intervention[207] the goal was to expand measurement areas without losing what has been valued in the profession. The ICF framework allowed for this expansion into activity and participation without losing the valued perspective of measuring body structures and functions. Additionally, the COPM goals also emphasized activity and participation by its design. This theoretical perspective was necessary since upper extremity impairment does involve body structures and/or function components. Thus, using the COPM goals, which also highlights activity

and participation, and the ICF to discover the constructs for the UE LIM-Y conceptual model placed activity and participation soundly within the UE LIM-Y conceptual model. Utilization of data from 1:1 interviews with pediatric hand therapists broadened the conceptual model to include constructs which are observed in practice but were not discovered in the ICF linking study. Thus, together these data sources provided a comprehensive perspective to develop the conceptual model for drafting the UE LIM-Y's content.

In this study we drew upon prior cognitive interviewing studies[193, 194, 197-200] to develop a novel approach to iterative data collection and analysis for refining the UE LIM-Y's content. The cognitive interviewing used for content refinement was instrumental in refining the UE LIM-Y. Like Silva et al.[199] and Reeve et al.[194] our 1:1 interviews were performed with the pediatric population the UE LIM-Y is designed for. While caregivers were permitted to be in the room during the interviews to put the child and caregiver at ease, we did not include the parent in the interview as prior authors have.[198] Additionally, field notes provided evidence that caregivers did not voluntarily participate in the interviews to assist their child. Thus, the current study adds to the body of literature providing evidence that children eight years old and older can effectively participate in cognitive interviewing studies.

The current study utilized a previously established framework [201] for evaluating cognitive interview data. Prior authors studies that used this framework only used one round of data collection.[193, 200] Other authors who have performed cognitive interviewing studies for PROM refinement in pediatric populations utilized iterative rounds of data collection for PROM refinement. [194, 198] Thus, we drew upon this established practice of

iterative rounds of data collection and PROM refinement with the pediatric population in the current study. Consequently, the current study is the first to blend MacDermid's[201] framework of data analysis with iterative rounds of data collection and PROM refinement, establishing a rigorous method for refining draft PROMs.

With each round of data collection, we elucidated an overall decrease in the number of coded problems within the UE LIM-Y. After the first round of data collection, the instructions underwent three content revisions, the response wording was refined, and ten questions were revised. The revisions decreased slightly after the second round of data collection. The instruction wording was reduced to achieve simplification and clarity. No revisions were necessary for the response scale, and nine questions were revised. The third round of data collection included modifications to further simplify wording and specify how participants should indicate responses. The response scale was redesigned based upon participant recommendations to address the coded problems with inadequate response definition, and five questions underwent minor revisions. The revisions in this final round were minor and were informed by participant recommendations of how to revise the questions. Thus, the decreased return of coded problems, minor nature of revisions and participant data to guide the revisions for the UE LIM-Y Version 4 were adequate to establish content validity. Furthermore, the reading level improved over the course of revision. The initial Flesch-Kincaid level of 6.9 was reduced to a 2.5 grade reading level in UE LIM-Y Version 4. This decrease in overall grade reading level indicates good suitability as a pediatric self-report measure. As a final point, participants evaluated the UE LIM-Y Version 4 favorably. Participants' evaluation

of the UE LIM-Y as relevant and useful in their healthcare experience provides further evidence of UE LIM-Y Version 4's content validity.

This study establishes a method for developing the conceptual model of a PROM which is enhanced by using data derived from the patients at the time they were receiving care. This approach establishes a more natural method of patient generated data to inform PROM development than focus groups with patients outside the time in which they are directly engaged in their care. Furthermore, by linking the patient derived concepts to the ICF, the study further expands on the method for developing a conceptual model in the context of a holistic model for evaluating health and disability which is the universal language across healthcare. Additionally, this study adds to the body of evidence that cognitive interviewing is effective with a pediatric patient population as a method for refining a PROM. Moreover, the current study expands and blends prior methods of data collection and analysis into a method which can be applied for increased rigor in future studies.

In Chapters 2 and 3 the author established that a PROM with psychometric fit for application in pediatric hand therapy is lacking and that pediatric hand therapists desire a PROM that applies to the pediatric hand therapy population. Moreover, concerns with alignment of the questions in item banks of the PROMs which are currently applied in pediatric hand therapy populations were articulated by pediatric hand therapists (Chapter 3). The author's central focus on quality of life in designing the conceptual model and chosen theoretical underpinnings led to the UE LIM-Y being comprised of five sections of questions. These five question groupings cover general quality of life, hand and arm use, activity participation, activities of daily living and body functions respective to the

meaningful outcomes derived from children with hand impairment in Chapter 4. The current PROMs which are applied in pediatric hand therapy lack this breadth of holistically evaluating how a child's upper extremity impairment impacts their quality of life. Thus, the content validation of the UE LIM-Y is significant in establishing an item bank of questions that measures what is meaningful to the patient population and comprehensive with respect to quality of life.

5.6.1 Limitations

The current study is not without limitations. Data collection in the current study only occurred at one institution. However, the study does draw a diverse sample to mitigate concerns with limited generalizability of study findings. The study sample is diverse in age, diagnosis, region of impairment, race, ethnicity, and activities in which the participants engage in. Thus, the breadth of participant diversity aids in generalizability for the pediatric hand therapy population. The revisions made in UE LIM-Y Version 4 have not been tested in a further round of data collection, raising the potential for researcher bias in the determination of achieving content validity at this point. It is noteworthy that in the current study multiple rounds of PROM refinement and repeat testing were utilized. In prior works using the same coding approach,[197, 200] only one round of data collection was used with PROM refinement and no subsequent testing. Thus, the current study includes a level of rigor that has not been previously reported in achieving establishing content validation. Furthermore, 2.5 grade reading level, simplicity and patient informed nature of these final revisions is suggestive of established content validation.

5.6.2 Future Research

While the current study establishes content validation of the UE LIM-Y additional study is necessary for the tool to be a valid and reliable measure. A study using classical test theory and modern test theory methods (i.e., Rasch analysis or item response theory) is necessary to determine if the item bank can be reduced and establish the UE LIM-Y's structural validity.[49, 78, 79] Then, further psychometric study is necessary to establish reliability, validity, and the minimal important change of the UE LIM-Y. These studies will be future work.

5.6.3 Conclusion

The current study drew upon qualitative data from prior qualitative studies with members of the target patient population and potential PROM users[102, 191] to develop a conceptual model which informed the UE LIM-Y draft content. The application of three rounds of cognitive interviewing with representatives of the target patient population resulted in content refinements informed by the participants. With three rounds of iterative data collection and content refinement the UE LIM-Y's content validity was established. Representative members of the patient population had a favorable evaluation of the UE LIM-Y.

CHAPTER 6. QUALITY OF LIFE, PATIENT ENGAGEMENT AND A MIXED METHODS APPROACH TO ACHIEVE THE UPPER EXTREMITY LIFE IMPACT MEASURE'S CONTENT VALIDATION

6.1 Background

Over the last decade, hand therapy clinicians have begun taking a more holistic approach to outcomes assessment incorporating measurements of patients' activity participation and occupational performance, primarily through using patient reported outcomes measures (PROMs), in their practice. As these advancements have occurred in the profession of hand therapy, gaps have emerged. While prior authors have characterized hand therapists' utilization of PROMs both in clinical[17] and research applications[4] these prior works did not explore PROM utilization specifically in pediatric hand therapy applications. Thus, there was a need to characterize PROM use within pediatric hand therapy populations to inform the development of a novel PROM for children with upper extremity impairment. The purpose of this chapter is to provide an overview of how the studies in this dissertation applied mixed methods research to develop the draft content of such a PROM, the Upper Extremity Life Impact Measure – Youth (UE LIM-Y). Moreover, this chapter aims to illustrate how a focus on quality of life and patient engagement underpinned and impacted the UE-LIM-Y's development.

6.2 A Mixed Methods Research Approach to Establishing the UE LIM-Y's Content Validation

The dissertation began with a literature review (Chapter 2) to identify the PROMs used in pediatric hand therapy practice and evaluate evidence of their psychometric fit for a pediatric hand therapy population. In a series of studies evaluating the psychometrics of PROMs currently used with the pediatric hand therapy population,[34, 58, 112, 116, 117]

moderate to significant limitations of the PROMs' fit for broad application in pediatric hand therapy applications was discovered. Thus, the studies in this dissertation expanded MMR within an established MMR model for developing a PROM[66] to complete the qualitative phase of PROM development for the UE LIM-Y. (Figure 6.1)

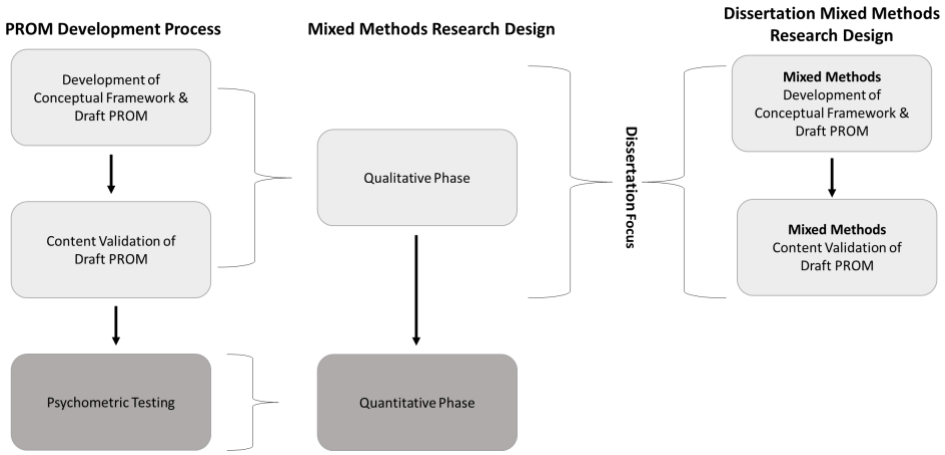


Figure 6.1: Illustration of dissertation's extension of MMR into the qualitative phase of PROM development

6.2.1 Evaluating the need for a pediatric hand therapy-focused PROM

Chapter 3 addresses previously identified limitations through qualitative inquiry evaluating pediatric hand therapists' practice patterns with outcomes assessment and PROM utilization. Study findings revealed pediatric hand therapists currently use a wide range of outcomes assessment tools which include PROMs. Pediatric hand therapists described their patient population as diverse[102] and articulated a desire to have a PROM that is widely applicable to their patient population. The absence of this type of PROM was expressed. Furthermore, therapists stated they desire a PROM that measures

participation in the occupations that the children and adolescents whom they provide care report as most meaningful to them.

6.2.2 Deriving the UE LIM-Y's Conceptual Model

Findings of Chapters 2 and 3 establish that a PROM designed specifically for children and adolescents with upper extremity impairment is needed. Thus, consistent with PROM development standards of using qualitative data from the target patient population to inform PROM content,[45, 48, 51, 68, 71] a study to identify the treatment outcomes pediatric hand therapy patients desire was necessary to inform the conceptual model for developing a PROM for the patient population. Thus, an ICF linking study of pediatric hand therapy patients COPM goals was performed (Chapter 4). This approach brought together the complimentary ICF and CMOP-E theoretical frameworks to inform the constructs included in the conceptual model for deriving the UE LIM-Y. In doing so, Chapter 4 introduces a MMR approach into the qualitative phase of PROM development. Furthermore, this study provided data directly from the patient population the UE LIM-Y is being designed for, which is essential for establishing a PROM's content validity. A MMR approach of applying ICF linking[36-38] to the qualitative data derived from the target population's COPM goals and quantitative analysis of the ICF linked data allowed discovery of the constructs which were most meaningful to the target population to inform the conceptual model for deriving the UE LIM-Y. This methodology revealed the occupations that are top priorities for the patient population, including participation in sports, performing arts, play, academically related activities, and activities of daily living priorities.

A secondary aim of the qualitative study in Chapter 3 was to identify outcomes priorities pediatric hand therapists perceived their patients desire from hand therapy intervention. This was beneficial for two reasons. First, standards for PROM development indicate the individuals who will administer the PROM are considered key stakeholders for informing the constructs a PROM should measure.[45, 68, 71] Second, the design of the COPM focuses on areas of occupation, specifically self-care, leisure, and productivity (e.g., paid and unpaid work and academic activities). Thus, using COPM goals may have limited discovery of outcomes priorities which may not fall within this framework. Therefore, inclusion of what the pediatric hand therapist themselves experience their patients expressing as outcome priorities minimizes the risk that important priorities would be overlooked.

The findings from Chapters 3 and 4 were combined to derive the conceptual model for a PROM for the pediatric hand therapy population. The combined Chapter 3 and 4 data were organized to identify what constructs the PROM should measure (Chapter 5). The ICF and CMOP-E in combination with the author's focus on quality of life informed this organization. The following construct groupings emerged: General Quality of Life, Hand and Arm Functions, Activity Participation, Activities of Daily Living, and Body Functions. In the conceptual model for the PROM, these five concepts organize the constructs that the PROM should measure. To draft an item bank of questions aligning to this conceptual model, the questions in the item banks of the PROMs currently used in pediatric hand therapy were compared to the conceptual model. Questions that matched the constructs were grouped and merged to inform wording for the questions in the novel PROM. For most constructs elucidated in Chapters 3 and 4,

PROMs currently used in pediatric hand therapy lack a corresponding question. Therefore, for these constructs the language used in patients' COPM goals and the ICF language were used to derive novel questions.

6.2.3 Content validation of the UE LIM-Y

To complete the qualitative stage of PROM development the study in Chapter 5 used cognitive interviewing with representatives of the target patient population to refine the UE LIM-Y's content. By applying a coding scheme to analyze and quantify the problems discovered with the iterative rounds of data collection and content refinement, the study also introduces a mixed methods approach to this second stage in the qualitative phase of PROM development. Through a series of three rounds of data collection, two additional questions were added, the PROM's formatting was revised, and question wording was refined to address problems identified with the structure and wording of the instructions, PROM questions, and response scale. Using a mixed methods approach, the cognitive interviewing study completed the qualitative stage of PROM development and established the UE LIM-Y's content validity.

6.3 Quality of Life and Patient Engagement

6.3.1 Theoretical Underpinnings: Their Contribution to a Focus on Quality of Life and Patient Engagement

Throughout this dissertation, the author was guided by a focus on quality of life. As a licensed occupational therapist with over two decades of clinical experience, the author has observed that children's healthcare experiences are intertwined with and can impact their quality of life. Within rehabilitation sciences, quality of life has been

positioned as a participation measure.[21] More specific to occupational therapy practice, enhancing individuals' quality of life through a focus of maximizing their occupational performance is foundational to occupational therapy.[22] In addition to this focus on quality of life, three closely related theories provided the framework to explore the gaps outlined above and build upon study findings.

First, the Canadian Model of Occupational Performance and Engagement (CMOP-E) is a natural framework for the author to draw upon given her training and practice as an occupational therapist. The CMOP-E is a conceptual model of occupational therapy practice which provides perspective of occupational therapy practice and its relationship to the patient (or client).[24] Engagement is emphasized in the CMOP-E, extending the occupational therapist's role beyond facilitating clients' occupational performance to enabling clients' full participation in their lives. This enablement allows clients their maximal quality of life.

Within the CMOP-E's theoretical framework the occupational therapist's role is to collaborate with the client to enhance their occupational performance within the environments that the individual performs their occupations and facilitate the client's engagement. One tool occupational therapists use to facilitate this collaborative process is the Canadian Occupational Performance Measure (COPM).[26] The COPM is an assessment measure which was developed from the CMOP-E.[27] In Chapter 4 of this dissertation, the COPM goals of children with acquired hand impairment were evaluated to inform the conceptual model of a novel PROM for children with hand impairment, the Upper Extremity Life Impact Measure (UE LIM-Y).

The World Health Organization's International Classification of Functioning, Disability and Health (ICF) is a complimentary theoretical framework that underpins this dissertation.[19] The ICF provides a universal language for understanding and measuring health across healthcare sectors and international cultures. The ICF classifies health and health-related factors into four domains: Body Functions and Structures, Activities and Participation, Environmental Factors and Personal Factors. Thus, the ICF extends the perspective of health beyond a condition having bodily impacts to include a focus on an individual's participation. The ICF defines participation as "involvement in a life situation" (p. 10)[35] and includes a spectrum of participation ranging from the individual level to societal participation. In doing so, the ICF expands health care professionals' perspectives of patients to include "understanding of the lived experience of people with disabilities" (p. 393).[208]

A process for evaluating health-related data in the context of the ICF, termed ICF linking, was developed by Cieza et al.[36-38, 162] With the ICF's close alignment to the CMOP-E constructs and its ability to extend data analysis into a more universal language, ICF linking was used to analyze patients' COPM goals in Chapter 4. Thus, Chapter 4 marries these closely aligned theoretical frameworks (e.g., CMOP-E and the ICF) to inform the conceptual model for deriving the UE LIM-Y's draft content.

The Occupational Therapy Practice Framework (OTPF)[11] is the third theoretical framework underpinning this dissertation. The OTPF sets the guide for OT practice. At its center is the guiding principle of OT practice: "Achieving health, well-being, and participation in life through engagement in occupation." Like the ICF, the OTPF is organized into domains, which encompass OT's scope of practice. The OTPF's domains

of practice include client factors, occupations, contexts, performance skills and performance patterns.

6.3.2 Theoretical Underpinnings: Their Contributions to the UE LIM-Y

The following figure (Figure 6.2) depicts the close relationship of these three theories and how they informed the UE LIM-Y. All three theoretical frameworks include concepts related to the person, occupation or participation, and the environment. Drawing on study findings (Chapters 3 & 4), the UE LIM-Y was designed to include five sections of questions. As depicted in Figure 6.2, two of these sections, General Quality of Life and Body Functions, are focused on the person level. Of these two question groups, only the Body Functions section includes questions which are biomechanical in nature. The General Quality of Life questions include items focused on overall happiness and satisfaction with various aspects of the arm. Thus, the General Quality of Life questions expand the PROM to have a more holistic focus on health than a purely biomechanical model. Three of the five question groups (i.e., Hand and Arm Functions, Activity Participation, and Activities of Daily Living) pertain to occupations and participation. Thus, the UE LIM-Y is novel in that most of the PROM questions are centered on participation. As such, the UE LIM-Y extends pediatric hand therapy practice to become more occupation focused as the hand therapy profession has been challenged to do.[7, 9, 30-32] However, the PROM also contains questions about the body function outcomes most relevant to the target patient population making the UE-LIM-Y comprehensive in assessing patient perceived outcomes at the person and participation levels.

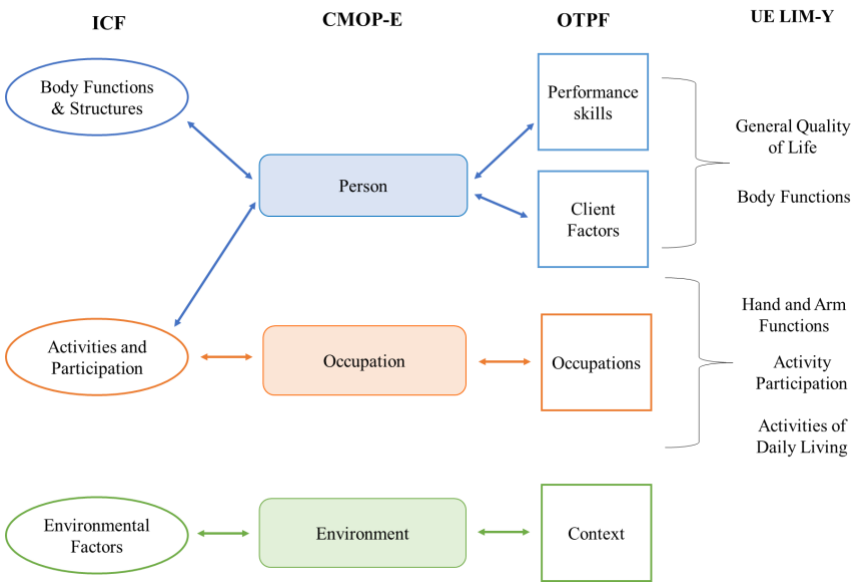


Figure 6.2: Alignment of the UE LIM-Y and Theoretical Underpinnings

What Figure 6.2 does not depict is the common concept of engagement shared across all three theoretical frameworks. While not synonymous, the concepts of facilitating participation (ICF) and occupational performance (CMOP-E and OTPF) within the three frameworks share a common focus on extending the perspective of health from being centered on a condition's impact on the body to being focused on how the condition affects the patient's overall quality of life. In doing so the three theories shift one's perspective to a focus on engaging patients and enabling them to maximize their quality of life through optimizing participation in meaningful activities. As noted above, the design of the UE LIM-Y is such that most of its questions pertain to the occupations most meaningful to the target patient population. As such, the UE LIM-Y is designed to facilitate patient engagement and maximize pediatric hand therapy patients' quality of life through optimizing their participation in meaningful activities.

6.3.3 Quality of Life in the UE LIM-Y Nomenclature

The emphasis of the UE LIM-Y's orientation to a focus on quality of life is even found in the PROM's name. As outlined above, the five sections of the draft PROM reflect the areas of life which the data revealed are meaningful to patients. Thus, the tool is a measure of how the child's impairment is impacting their life in the areas most meaningful to them. Consequently, the name "Life Impact Measure" emerged. "Upper Extremity" was placed at the start of the name, just before "Life Impact Measure," to specify the PROM pertains to a population with conditions affecting their hand and/or arm. Finally, because the PROM is for patients aged 8 to 20 years old, the term "youth" was added to the end, making the full name "Upper Extremity Life Impact Measure – Youth."

The organization of the name was intentional. First, "Life Impact Measure" was chosen to reflect the comprehensive nature of the PROM having questions that measure global quality of life concepts such as happiness, appearance concerns, and general ability to use the affected extremity, as well as questions that measure various aspects of participation (e.g., hand and arm use, activity participation, and activities of daily living) and questions that assess the patient's perception of their upper extremity's body functions. Additionally, the author foresees that the methods used for developing the UE LIM-Y may be scaled to other populations in the future to develop other Life Impact Measures. If such applications for other age groups (i.e., adults or proxy measures for younger children), the "youth" can be replaced with another term which characterizes the alternate population. Additionally, the term "upper extremity" may be removed from the

start of the name and replaced with alternate terms, such as “lower extremity” or “visual impairment.”

6.4 Research Contributions

6.4.1 Infusing MMR into the Qualitative Phase of PROM Development

In addition to establishing the content validity of a PROM designed specifically for a pediatric hand therapy population, this dissertation makes additional contributions to PROM development science. Focus groups with the target population are the established method for obtaining qualitative data to inform the conceptual model for developing a PROM.[52] Focus groups occur outside the delivery of care and rely on patients to recall their experiences. In Chapter 4, ICF linking COPM goals was a mixed methods research (MMR) approach for informing the UE LIM-Y’s conceptual model. This method provided analysis of data that was derived from the patients specific to their desired treatment outcomes at the time they were engaged in their delivery of care. Furthermore, it allowed collection of data from 151 patients providing a larger pool of participants than focus groups for informing PROM development. Because of this larger pool of data, the quantitative analysis of frequency distributions was used making the methodology used in Chapter 5 a mixed methods data analysis. Quantifying the findings allowed for prioritization of the patient-identified outcomes to ensure the conceptual model was built to measure the outcomes which patients most desire. This prioritization allows for comprehensiveness and succinctness to limit the response burden on patients when completing the PROM.

6.4.2 Contributions of the ICF to PROM Development

An additional benefit from our ICF linking methodology for deriving the conceptual model of the constructs the PROM should measure was the perspective the ICF framework allowed. As previously noted, aspects of hand and arm use were the most frequently observed concepts in the patients' COPM goals. Consequently, the UE LIM-Y draft item bank includes questions specific to the various hand and arm use constructs discovered in the ICF linking study. These questions are unique to those in items banks of established PROMs for measuring upper extremity function and may be worded in such a way they apply to patients more inclusively. For example, the question for measuring hand manipulation skills on the UE LIM-Y is "I could use my fingers to handle small objects (For example, buttons, zippers, string small beads)." In the analysis of interview transcripts, no participants stated this question was not applicable to them. However, in the PI's clinical experience using the PODCI's Upper Extremity Function Scale, which attempts to measure manipulation skills with the question "I could button buttons," patients routinely report "I don't wear buttons." Thus, it is possible that the ICF provides a theoretical perspective for deriving the wording of PROM questions that increases the breadth of applicability. Further study comparing the item banks with representatives of the patient population may be used to examine this hypothesis.

6.4.3 Evidence of Cognitive Interviewing's Effectiveness in a Pediatric Population

Few authors have employed cognitive interviewing with pediatric populations.[192, 194, 199] Thus, the cognitive interviewing study in Chapter 5 adds to the body of evidence that children are able to effectively participate in cognitive interviewing. The literature review (Chapter 2) which examined what PROMs are used for the pediatric hand therapy

population and the qualitative study (Chapter 3) examining pediatric hand therapists' outcomes assessment patterns revealed that most PROMs used with the pediatric hand therapy population were developed for adult populations. Furthermore, those PROMs which were developed specifically for pediatric populations did not involve children in the concept elicitation phases of the PROM development. Thus, increased evidence of children's capacity to effectively participate in the qualitative stages of PROM development is needed to make children's involvement a more routine practice.

6.4.4 Content Validation of the UE LIM-Y: A Pathway to Expanding Patient Engagement and Maximizing their Quality of Life

In conclusion the greatest contribution this dissertation makes is establishing UE LIM-Y Version 4's content validity. This work was informed from the author's two decades of clinical experience with a pediatric hand population. Repeated experiences of children expressing they were not satisfied with their recovery when scores were at the ceiling on PROMs with item banks of questions, such as the PODCI, inspired the work in this dissertation. The author aimed to systematically evaluate the literature and examine elucidated gaps to inform this work. This work revealed that pediatric hand therapy professionals shared experiences of existing PROMs not fitting well with the pediatric hand population (Chapter 3). Consequently, the author embraced using a combination of qualitative and quantitative methods to derive data from the pediatric hand therapy population for developing the UE LIM-Y and establishing the measure's content validity.

With its design, the UE LIM-Y provides hand care professionals knowledge of how the child perceives their hand condition is impacting their participation and engagement in their meaningful occupations. With this knowledge of factors which cannot be readily assessed in the clinic setting, hand care professionals gain insight into

the child's overall quality of life as it relates to the child's upper extremity condition. By shifting outcomes measurement to be more aligned with the outcomes the patients desire from care, the UE LIM-Y centers the hand care professional's focus on the patients' overall quality of life. In doing so, the UE LIM-Y can facilitate the hand care professional's engagement with the patient to provide intervention that is impactful in optimizing patients' engagement and quality of life. Thus, the UE LIM-Y can be a tool for facilitating patient-centered care both at the point of care and in research applications. Through its design, UE LIM-Y will transform outcomes focused research because by enhancing hand care professionals' ability to evaluate the effectiveness of our interventions by measuring the outcomes which are most meaningful to the patients.

In addition to the twenty-nine questions in the initial UE LIM-Y item bank being directly aligned with outcomes the pediatric population desired, cognitive interviewing data from Chapter 5 informed the addition of two more questions to the final version of the UE LIM-Y. Thus, the full content of UE-LIM-Y was derived from the patient population. Moreover, participant evaluation of the UE LIM-Y was favorable. Children willingly engaged in the cognitive interviewing process and completed it independently. They expressed they perceived the measure as useful in informing their care, and they engaged in providing thoughtful evaluation of how the PROM could be enhanced. Consequently, the UE LIM-Y Version 4 is a tool created by the members of the patient population for which it is designed to be used with. The author provided the structure and methods, but the children developed its content. As a final point, revisions informed by children's recommendations for wording and format changes resulted in the Flesh-Kincaid grade reading level decreasing from 6.9 in Version 1 to 2.5 in Version 4 of the

UE LIM-Y. This improved readability was achieved through the children's involvement and is further evidence of the PROM's content validity for a pediatric population. Collectively, the methods employed in this dissertation and the children's active engagement in the process established the content validation of the UE LIM-Y Version 4.

6.4.5 Clinical Implications

The UE LIM-Y has applicability for pediatric hand therapy populations across all settings in which the patient population receives hand care. This could include both pediatric focused hand therapy clinics, as well as hand clinics that provide care to patients with hand impairment across the lifespan. In any of these settings the tool has applicability to patients 8-20 years old who are receiving hand therapy intervention to address upper extremity impairment affecting any region of the upper extremity from fingertip to shoulder. Furthermore, the UE LIM-Y is designed for application with the four diagnostic groups commonly seen in hand therapy practice: patients with acquired pathology, congenital hand conditions, chronic musculoskeletal conditions, or neuromotor impairment of their upper extremity.

It is anticipated that the PROM will first be applied by hand therapy clinicians; however, the author's vision is that the tool will be adopted by pediatric hand surgeons for application in their clinics and research as well. Currently, pediatric hand surgeons use the same PROMs that pediatric hand therapists have been using. Thus, they are bound by the limitations in available PROMs discovered in this study (Chapter 2). Since they provide care to the same population that pediatric hand therapists do, the UE LIM-Y will be validated for application in pediatric hand surgery practice as well.

Participant evaluation of the UE LIM-Y (Chapter 5) reflected that the target patient population viewed the UE LIM-Y as being useful in their healthcare experience. Participants reflected on how the UE LIM-Y helped them assess their status in terms of how their upper extremity condition is impacting them. Thus, they expressed they perceived the UE LIM-Y would be helpful in informing hand care professionals about how their condition is impacting them. Consequently, the UE LIM-Y can be used at the initiation of care to assess the child's baseline health related quality of life related to their upper extremity impairment. When used at the point of care, clinicians can utilize the UE LIM-Y to establish a plan of care and treatment goals that align with the healthcare concerns and outcomes most meaningful to the patient. Thus, the UE LIM-Y has usefulness in facilitating patient-centered care. Hand care professionals can then readminister the UE LIM-Y during a patient's episode of care to assess the patient's change in status. Identification of changes in the patient's status will inform how intervention may be adjusted to ensure care is continuing to align with maximizing the child's health related quality of life. It is through this pattern of use that the UE LIM-Y can be best leveraged to engage patients in their care and achieving their desired quality of life outcomes.

6.4.6 Limitations

The studies in this dissertation were not without limitations. The study participants in the qualitative study examining pediatric hand therapists' experiences with outcomes assessment were not diverse in terms of gender, race, and ethnicity. Future studies should utilize additional recruitment methods, such as recruiting from the American Society of Hand Therapist's membership, in effort to include a more diverse

participant pool. The ICF linking study only used COPM goals of patients with acquired hand impairment and did not include patients with congenital hand conditions, chronic musculoskeletal conditions, or neuromotor impairment of their upper extremity. However, the UE LIM-Y is designed for application across the broad spectrum of children with upper extremity impairment, including these types of more chronic conditions affecting the upper extremity. To control for this, in Chapter 5 cognitive interviews were performed with representatives from all four diagnostic categories of patients (e.g., acquired pathology, chronic musculoskeletal condition, congenital anomaly and neuromotor pathology) who receive pediatric hand therapy care. In this dissertation, the qualitative study with pediatric hand therapists (Chapter 3) occurred following the ICF linking study (Chapter 4); therefore, the finding that pediatric hand therapists desired a tool applicable to these four diagnostic groups followed the ICF linking. In future research, qualitative research with the target PROM users should be performed first to inform the target patient population for the PROM, thus informing the inclusion criteria for the ICF linking study. Finally, the ICF linking study (Chapter 4) and cognitive interviewing study (Chapter 5) occurred at one institution, which limits the generalizability of study findings. Future work would be strengthened by including participants from multiple institutions.

6.4.7 Future research

While this dissertation makes the contributions outlined above, future work is essential to this growing area of science and clinical practice. Upon assigning the UE LIM-Y a scoring structure, the author will undertake the quantitative phase of PROM development (Figure 6.3). The quantitative phase of PROM development is necessary to

establish the UE LIM-Y's psychometric fit for the pediatric hand therapy population. The author's next study will be to collaborate with experts in measurement development to establish the structural validity of the UE LIM-Y Version 4. Further research should continue to include elements of both classical and modern test theory methods (i.e., item response theory or Rasch analysis) to strengthen this PROM. Care should be taken to not only reduce the response burden of future research participants, but optimize items, item banks, and subsequent study designs, as well. Once the UE LIM-Y is refined with these methods, a subsequent study involving administration of the UE LIM-Y with members of the target patient population will be used to establish reliability, validity, and the minimal important change. After the UE LIM-Y has been fully developed with established psychometrics for the pediatric hand therapy population, opportunities to apply the UE LIM-Y in evaluating the effectiveness of treatment interventions for specific pediatric hand populations exist.

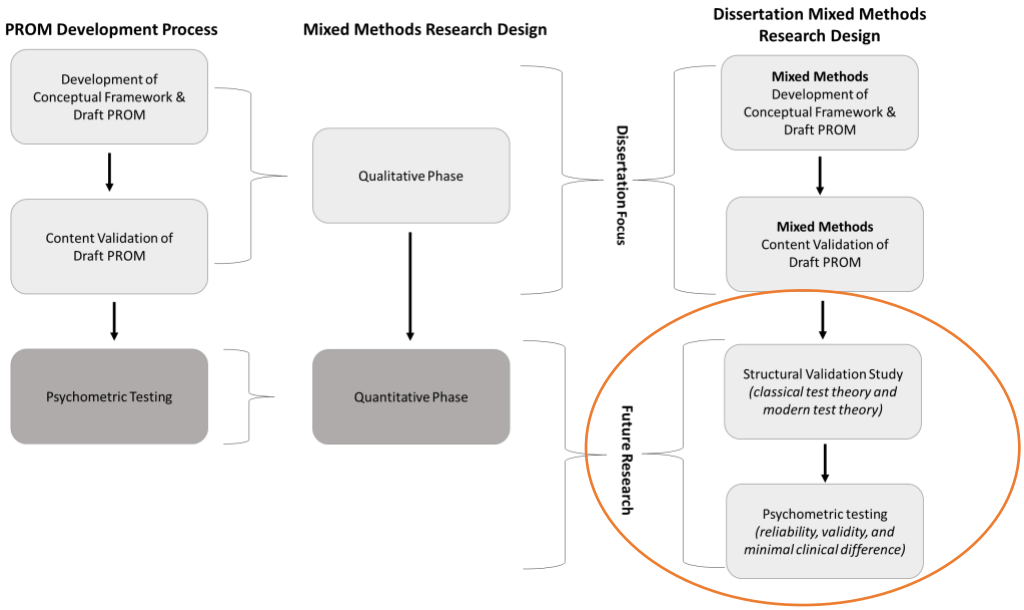


Figure 6.3: Figure of Complete PROM Development Process with Future Research Highlighted

Currently, the body of evidence to guide pediatric hand therapy practice is limited. Application of the UE LIM-Y in outcomes-based research applications will be instrumental in expanding this body of evidence. Some examples of such studies include a prospective cohort comparison of two different post-operative therapy protocols for flexor tendon management, a randomized controlled trail comparing hand therapy intervention to no therapy in the management of idiopathic nonspecific wrist pain, and a cohort study examining the outcomes of the combined surgical and therapeutic management of spastic hemiparesis in children. Additionally, the study in Chapter 3 revealed that practice patterns using PROMs vary among pediatric hand therapists despite therapists stating beliefs that they add value. Furthermore, Chapter 3 revealed that one barrier to using PROMs with the pediatric hand therapy population is the fit of current measures with the population. Therefore, an intervention study with the pediatric hand therapist population examining use patterns with the UE LIM-Y can be useful in elucidating if its design overcomes this barrier and increases PROM utilization among pediatric hand therapists.

As previously noted, the methods for creating the UE LIM-Y were founded on PROM development standards yet are novel in using ICF linking of the patient population's COPM goals in the early qualitative phases of PROM development. These methods may be applied to develop other similar Life Impact Measure PROMs, such as measures for impairments in other body regions (e.g., lower extremities, craniofacial, visual, etc.) and measures for hand therapy populations of other age groups. For example, the UE LIM-Y may be adapted to be applied as a parent proxy measure for pediatric patients who are too young to engage in self-report.

While opportunities for future work abound, this dissertation is evidence that pediatric patients can be placed at the center of research and engaged in the research process to guide healthcare professionals in delivering and measuring care that is truly patient centered. It is this perspective of placing the patients at the center of the research and engaging them in the research process which the author aims to be central to all future work. In doing so, healthcare can be transformed to a level of patient centered care that engages patients to maximize their participation in meaningful activities and optimize their quality of life.

Appendix 1

Constructs Guiding PROM Development	
• Sports participation*†	• The ability to grasp*
• Participation in performing arts (dance, drawing, playing instruments) *†	• The ability to turn or twist the arms/hand*
• Participation in play*†	• Drinking*
• Writing*†	• Pushing *
• Lifting*†	• Driving cars and bicycles†§
• Caring for hair*†	• Dressing†§
• Manipulating items with hands*†	• Eating†§
• Carrying*†	• Bathing†§
• Using computers*†	• Being able to complete work tasks†§
• Weight bearing through the upper extremities*†	• Socializing with peers†
• Decreased pain*	• Concerns with upper extremity appearance†
• Improved strength*	• Happiness with upper extremity function†
• Improved range of motion*	

Note: *constructs from the top 23 most frequently desired patient outcomes;[191] †constructs which pediatric hand therapists perceive pediatric hand therapy patients desire;[102] § constructs pediatric hand therapists perceive pediatric hand therapy patients desire that fall below the top 23 most frequently desired patient outcomes[191]

Appendix 2

Conceptual Model for Upper Extremity Life Impact Measure (UE LIM-Y)

General

- Overall ability to use the affected upper extremity
- Happiness
    - How the condition affects overall happiness
    - Happiness with upper extremity function
    - Happiness with the appearance of the affected upper extremity

Body function

- Pain
    - Generally being free of pain
    - Using the upper extremity without pain
    - Moving the upper extremity
- Range of motion
    - The ability to move the upper extremity without limitations in its mobility
- Strength
    - Possessing the strength necessary for participating in daily activities
    - Having the strength necessary to engage in leisure activities

Hand function

- Manipulating
    - Using the fingers to handle small items
- Grasping
    - Holding onto things in one's hand
- Turning the hand and/or arm
    - Performing tasks that require twisting of the hand or arm (e.g., opening containers and turning doorknobs)
- Lifting
    - Using the hand/arm to pick things up
- Carrying
    - Using the hand/arm to carry things up
- Weight bearing through the hand/arm
    - Supporting one's weight through their hands (e.g., pushing up from a chair or doing a push-up)

Activity participation

- Socializing
    - Being able to engage in activities with friends

- Playing
    - Participating in playing video games, playing with toys, imaginative or outdoor play
- Writing
    - Writing for school
- Using a computer
    - Using a computer, computer equipment and tablets
- Performing and visual arts
    - Participating in dance, acting, drawing, playing an instrument, and creating art and crafts)
- Sports
    - Participating in formal and informal sports activities
- Work
- Driving
    - The ability to drive a car or bike

ADL performance

- Hair care
    - Washing and styling one's hair
- Drinking
    - Pouring a drink, opening the drink container, and holding the cup
- Eating
    - Using utensils, opening food packages, and holding food
- Dressing
    - Putting on and taking off clothes
- Washing
    - Washing one's hands, face, and body

Appendix 3

Upper Extremity Life Impact Measure (Youth)

Draft PROM – Version 1

Please answer the following questions about your hand and/or arm problem.

Use the following scale:

***Almost always** = 90% or more of the time*

***Frequently** = 75% of the time*

***Half the time** = 50% of the time*

***Occasionally** = 25% of the time*

***Almost never** = 10% or less of the time*

General

In the past 7 days:

1. I had difficulty completing my regular daily activities because of my hand or arm problem	Almost Never	Occasionally	Half the time	Frequently	Almost always	
2. My hand or arm problem has made me unhappy	Almost Never	Occasionally	Half the time	Frequently	Almost always	
3. I have been happy with how I	Almost Never	Occasionally	Half the time	Frequently	Almost always	

can use my arm and hand						
4. I have been happy with the appearance of my arm and hand	Almost Never	Occasionally	Half the time	Frequently	Almost always	
Body Functions						
In the past 7 days:						
5. I had arm or hand pain	Almost Never	Occasionally	Half the time	Frequently	Almost always	
6. I had so much pain in my arm or hand that I had to stop what I was doing	Almost Never	Occasionally	Half the time	Frequently	Almost always	
7. It has been easy to move my arm and hand	Almost Never	Occasionally	Half the time	Frequently	Almost always	
8. I could move my arm and hand without having pain	Almost Never	Occasionally	Half the time	Frequently	Almost always	
9. I had the strength in my arm and hand to do my regular daily activities	Almost Never	Occasionally	Half the time	Frequently	Almost always	

10. I had the strength in my arm and hand to do the activities I enjoy most	Almost Never	Occasionally	Half the time	Frequently	Almost always	
Hand and Arm Functions						
In the past 7 days:						
11. I could use my fingers and hand to handle small objects (For example: coins, clothing fasteners, shoelaces, pencils, a fork)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
12. I could grasp things in my hand (For example: a bike handle, cup, ball)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
13. I could use my hand or arm to rotate or turn an object (For example: a lid on a bottle or jar, doorknob, screwdriver)	Almost Never	Occasionally	Half the time	Frequently	Almost always	

14. I have been able to lift things with my arm and hand (For example: pick up something from the ground or a table)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
15. I have been able to move things from one place to another using my arm and/or hand	Almost Never	Occasionally	Half the time	Frequently	Almost always	
16. I have been able to support my weight through my hands (For example: pushing up from a chair or doing push-ups)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
Activity Participation						
In the past 7 days:						
17. My arm or hand problem has interfered with	Almost Never	Occasionally	Half the time	Frequently	Almost always	

my normal social activities with family, friends, neighbors, or groups						
18. I could use my arm and hand for play (For example: video games, and playing indoor and outdoor activities)	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
19. I could write with a pen or pencil	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
20. I could use a computer, tablet, and/or phone	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
21. I could participate in doing arts and crafts (ex. drawing, playing an instrument, dance, or making art or crafts)	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
22. I could do sports and	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not

exercise other kids my age do						apply to me
23. I could use my arm and hand at work	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
24. I could use my arm and hand to drive vehicles (For example: a car, a bike)	Almost Never	Occasionally	Half the time	Frequently	Almost always	Does not apply to me
Activities of Daily Living						
In the past 7 days:						
25. I could care for my hair (For example: wash and style hair)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
26. I could get myself a drink (Including: pouring a drink, opening the drink container, and holding the cup)	Almost Never	Occasionally	Half the time	Frequently	Almost always	
27. I could eat (Including: using utensils, opening	Almost Never	Occasionally	Half the time	Frequently	Almost always	

food packages, and holding food)						
28. I could put on and remove my shoes and clothes	Almost Never	Occasionally	Half the time	Frequently	Almost always	
29. I could wash my hands, face, and body	Almost Never	Occasionally	Half the time	Frequently	Almost always	

Appendix 4

Upper Extremity Life Impact Measure – Youth

Demographics Form

Please answer the following questions:

1. What is your age: _____

2. Your biological sex:

- ☐ Male
- ☐ Female
- ☐ Other, please specify _____
- ☐ Prefer not to say

3.Your race:

- ☐ White/ Caucasian
- ☐ Black/ African American
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Pacific Islander
- ☐ Other, please specify _____
- ☐ Prefer not to say

4. Your ethnicity:

- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Other, please specify _____
- ☐ Prefer not to say

5. Which arm/hand are you receiving care for?

- ☐ Right
- ☐ Left
- ☐ Both

6. Which hand do you use to hold a pencil/pen?

- ☐ Right
- ☐ Left

7. Are you a student?

□ Yes

□ No

If you answered yes, what grade are you in_____

8. Do you have a job?

□ Yes

□ No

If you answered yes, what type of work_____

9. Do you play an instrument or participate in performing arts (e.g., dance, acting, chorus, etc.)?

□ Yes

□ No

If you answered yes, name the instrument or activity_____

10. Do you play a sport?

□ Yes

□ No

If you answered yes, name the sport(s)_____

11. please list any other hobbies or activities you regularly participate in:

_____

_____

_____

Appendix 5

Upper Extremity Life Impact Measure – Youth

Interview Guide

Subject #_____

Instructions for interviewer

- Note the following:
  - Delays/uncertainty when answering a question
  - Answers that were qualified
  - Inconsistent responses
  - Questions the participant reworded when "thinking aloud"
  - Questions that seemed challenging for the participant to answer

- Remind participant to "say out loud what you are thinking"

Introduction:

Thank you for helping us to test our assessment tool questions. At this point, we are not collecting information about you. Instead, we are trying out our instructions and questions with a few people, like yourself, so that we can improve them.

What I would like you to do is read aloud each of the instructions and then tell me what you are thinking, so please try to think aloud. For the questions, read one and then answer it, including marking your answer. I would like to hear about what you are thinking, so please try to think aloud when you read and answer each question. Just tell me everything that comes to mind whether it seems important or not. While you are answering and at the end, I may ask some questions about how you came up with your answer or how you interpret a question.

Saying what you are thinking can be hard, so before we do the survey, I am going to ask you to practice. Please answer this question, thinking aloud as you do.

How many doors are there in the house or apartment where you live?

How did you come up with that answer?

I will be taking notes and recording this so that we capture all you say. Do you have any questions before we start?

Ok. Please begin by reading the instructions at the top of page 1 for completing these questions. Remember to read the instructions aloud. Then, tell me what the instructions mean to you.

Now please read question #1 aloud to me and then repeat it back in your own words. . .. (after they reply): read aloud the answer choices and choose your answer, please think aloud while doing so.

Let's continue the same for the next questions. . .

- If the participant pauses, "I noticed you paused when answering_____. Tell me what you were thinking about

- Questions 18-24: If a participant answers "Does not apply to me" →Tell me why you chose "Does not apply to me."

After completing all the questions:

- How well do you feel these questions capture your experience with your hand/ arm problem?
- Were there questions that you feel did not apply to you? Please tell me about it.
- What was missing from these questions? Would you add anything?

Appendix 6

Upper Extremity Life Impact Measure – Youth

Draft PROM – Version 2

Think about how your hand/or arm problem has been over the past 7 days. Please use the scale below to answer the following questions about your hand and/or arm problem. If you have other injuries or health conditions, please respond to the questions below about how your hand and/or arm problem affects you. If the activity in question is typically only performed with your arm or hand that does not have a problem, choose "does not apply" for your response to that question.

***Almost always** = 90% or more of the time*
***More than half the time** = 75% of the time*
***Half the time** = 50% of the time*
***Less than half the time** = 25% of the time*
***Almost never** = 10% or less of the time*

General

1. I had difficulty completing my regular daily activities because of my hand or arm problem	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
2. My hand or arm problem has made me unhappy	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	

3. I have been happy with how I can use my arm and hand	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
4. I have been happy with how my arm and hand look	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
Body Functions						
5. I had arm or hand pain	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
6. I had so much pain in my arm or hand that I had to stop what I was doing	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
7. It has been easy to move my arm and hand	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
8. I could move my arm and hand without having pain	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
9. I had the strength in my arm and hand to do my regular daily activities	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	

10. I had the strength in my arm and hand to do the activities I enjoy most	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
Hand and Arm Functions						
11. I could use my fingers and hand to handle small objects (For example: buttons, zippers, shoelaces, pencils)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
12. I could hold things in my hand (For example: a handle, cup, ball)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
13. I could use my hand or arm to rotate or turn an object (For example: a lid on a bottle or jar, doorknob, screwdriver)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
14. I have been able to lift everyday things with my arm and hand (For	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	

example: pick up something from the ground or a table)						
15. I have been able to move everyday things from one place to another using my arm and/or hand	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
16. I have been able to support my weight through my hands (For example: pushing up from a chair or doing push-ups)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
Activity Participation						
17. My arm or hand problem has has gotten in the way of social activities with family, friends, neighbors, or groups	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
18. I could use my arm and hand for play (For example: video games, and	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply

playing indoor and outdoor activities)						
19. I could write with a pen or pencil	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply
20. I could use a computer, tablet, and/or phone	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply
21. I could participate in doing arts activities (ex. drawing, playing an instrument, dance, or making art or crafts)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply
22. My hand or arm limits my participation in sports and exercise other kids my age does	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply
23. I could use my arm and hand in my job	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply
24. I could use my arm and hand to drive vehicles (For	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	Does not apply

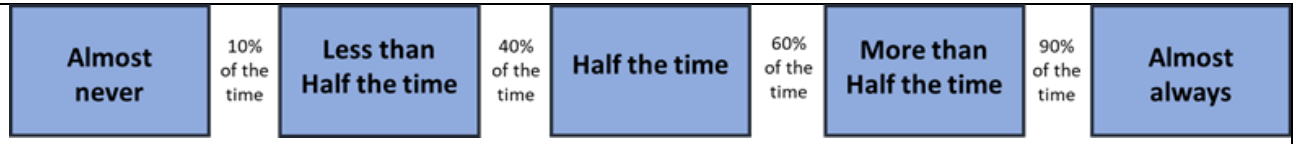
example: a bike or car)						
Activities of Daily Living						
25. I could care for my hair (For example: wash and style hair)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
26. I could get myself a drink (Including: pouring a drink, opening the drink container, and holding the cup)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
27. I could eat (Including: using utensils, opening food packages, and holding food)	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
28. I could put on and remove my shoes and clothes	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	
29. I could wash my hands, face, and body	Almost Never	Less than half the time	Half the time	More than half the time	Almost always	

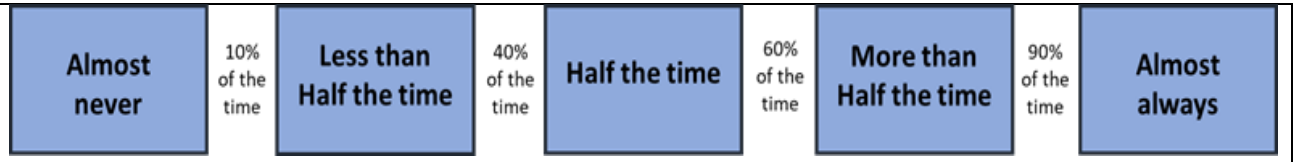
Appendix 7

Upper Extremity Life Impact Measure -Youth

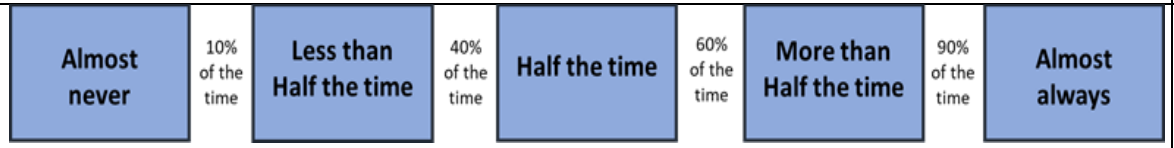
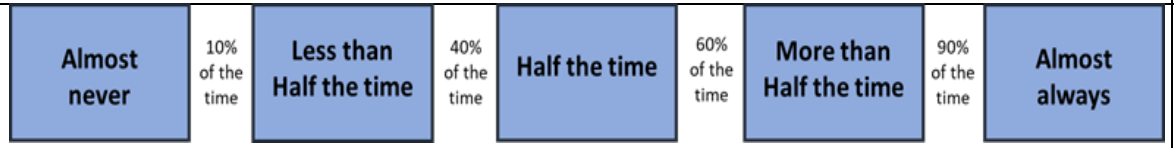
Draft PROM – Version 3

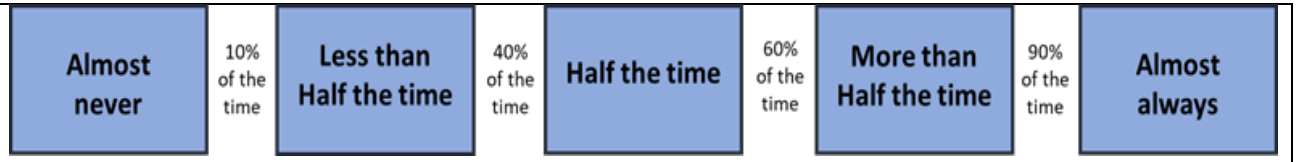
*Answer the questions below about how **your hand and/or arm problem** has been **over the last 7 days**.*	
General	
1. My hand or arm problem have made doing my regular daily activities difficult	
2. I have **not** been happy because of my hand or arm problem	

3. I have liked how well I can use my hand and arm	
4. I have been happy with how my hand and arm look	
Hand and Arm Functions	
11. I could use my fingers and hand to handle small objects (For example: buttons, zippers, string small beads)	
12. I could hold things in my hand (For example: a handle, cup, ball)	
13. I could use my hand or arm to twist or turn an object (For example: a lid on a bottle or jar, doorknob)	

14. I could use my hand and arm to lift everyday things (For example: a bookbag, gallon of milk, box of cereal)	
15. I could use my hand and arm to carry everyday things from one place to another (For example: books, a plate of food)	
16. I have been able to support my weight through my hand and arm (For example: pushing up out of a chair or doing push-ups)	
31. I could reach with my hand and arm to perform overhead activities (For example: take something off	

a shelf above shoulder height, put on a hat)		
Activity Participation		
17. My hand or arm problem has limited social activities with family, friends, neighbors, or groups		
18. My hand or arm problem has limited play (For example: video games, and playing indoor and outdoor activities)		Does not apply
19. My hand or arm problem has limited writing with a pen or pencil*	 **If your hand or arm that has a problem is not the hand you typically write with, choose "Does not apply"*	Does not apply

20. My hand or arm problem has limited using a computer, tablet, and/or phone		Does not apply
21 My hand or arm problem has limited doing arts activities (ex. drawing, playing an instrument, dance, or making art or crafts)		Does not apply
22. My hand or arm problem has limited doing sports and exercise		Does not apply
23. My hand or arm problem has limited doing household chores and/or my job		Does not apply
24. My hand or arm problem has limited driving vehicles (For example: a bike or car)		Does not apply
Activities of Daily Living		

25. My hand or arm problem has limited my ability to care for my hair (For example: wash and style hair)	
26. My hand or arm problem has limited my ability to get myself a drink (Including: pouring a drink, opening the drink container, and holding the cup)	
27. My hand or arm problem has limited my ability to eat (Including: using utensils, opening food packages, and holding food)	
28. My hand or arm problem has limited my ability to put on and remove my shoes and clothes	

29. My hand or arm problem has limited my ability to wash my hands, face, and body	
Body Functions	
7(5). Moving my hand and arm has been easy	
9(6). My hand and arm have been strong enough to do my regular daily activities	
10(7). My hand and arm have been strong enough to do the activities I enjoy most	

30. My ability to feel things with my hand and arm has limited my regular daily activities	
5(8). I have had hand or arm pain	
8(9). It has been painful to move my hand and/or arm	
6(10). I had so much pain in my hand and/or arm that I had to stop what I was doing	

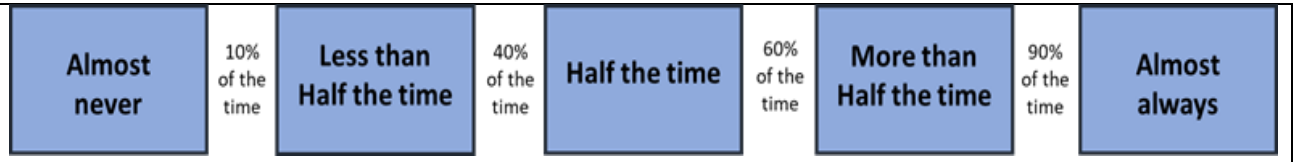
Appendix 8

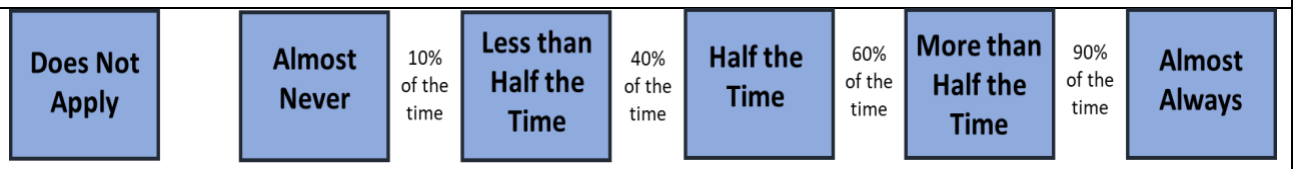
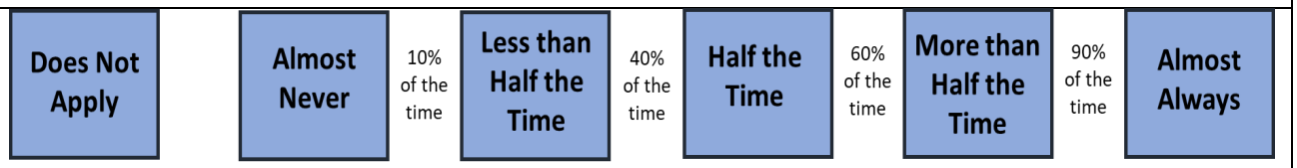
Upper Extremity Life Impact Measure - Youth

Draft PROM -Version 4

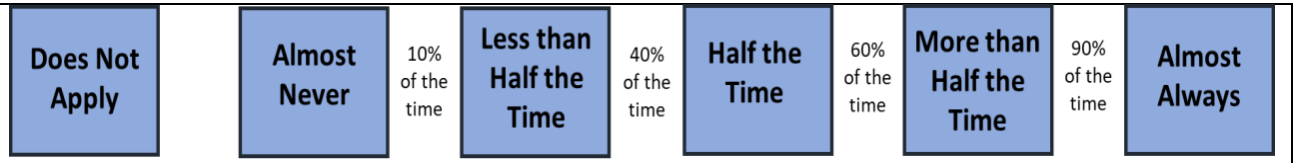
*Answer the questions below about **your hand and/or arm problem <u>over the last 7 days</u>**. Circle your response in the blue box for each question.*	
General	
1. My hand and/or arm problem have made doing my regular daily activities difficult	
2. I have **not** been happy because of my hand or arm problem	

3. I have liked how well I can use my hand and arm	Almost never | 10% of the time | Less than Half the time | 40% of the time | Half the time | 60% of the time | More than Half the time | 90% of the time | Almost always
4. I have been happy with how my hand and arm look	Almost never | 10% of the time | Less than Half the time | 40% of the time | Half the time | 60% of the time | More than Half the time | 90% of the time | Almost always
Hand and Arm Functions	
11. I could use my fingers and hand to handle small objects (For example: buttons, zippers, string small beads)	Almost never | 10% of the time | Less than Half the time | 40% of the time | Half the time | 60% of the time | More than Half the time | 90% of the time | Almost always
12. I could hold things in my hand (For example: a handle, cup, ball)	Almost never | 10% of the time | Less than Half the time | 40% of the time | Half the time | 60% of the time | More than Half the time | 90% of the time | Almost always
13. I could use my hand or arm to twist or turn an object (For example: a lid on a bottle or jar, doorknob)	Almost never | 10% of the time | Less than Half the time | 40% of the time | Half the time | 60% of the time | More than Half the time | 90% of the time | Almost always

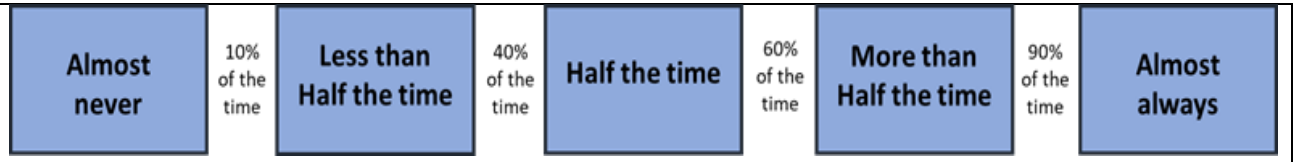
14. I could use my hand and arm to lift everyday things (For example: a bookbag, gallon of milk, box of cereal)	
15. I could use my hand and arm to carry everyday things from one place to another (For example: books, a plate of food)	
16. I have been able to support my weight through my hand and arm (For example: pushing up out of a chair or doing push-ups)	
31. I could reach with my hand and arm to perform overhead activities (For example: take something off	

a shelf above shoulder height, put on a hat)	
Activity Participation	
17. My hand or arm problem has limited social activities with family, friends, neighbors, or groups	
18. My hand or arm problem has limited play (For example: video games, and playing indoor and outdoor activities)	
19. My hand or arm problem has limited writing with a pen or pencil (*If your hand or arm that has a problem is not the hand you typically*	

write with, choose "Does not apply)	
20. My hand or arm problem has limited using a computer, tablet, and/or phone	Does Not Apply · Almost Never · 10% of the time · Less than Half the Time · 40% of the time · Half the Time · 60% of the time · More than Half the Time · 90% of the time · Almost Always
21 My hand or arm problem has limited doing arts activities (ex. drawing, playing an instrument, dance, or making art or crafts)	Does Not Apply · Almost Never · 10% of the time · Less than Half the Time · 40% of the time · Half the Time · 60% of the time · More than Half the Time · 90% of the time · Almost Always
22. My hand or arm problem has limited doing sports and exercise	Does Not Apply · Almost Never · 10% of the time · Less than Half the Time · 40% of the time · Half the Time · 60% of the time · More than Half the Time · 90% of the time · Almost Always
23. My hand or arm problem has limited doing household chores and/or my job	Does Not Apply · Almost Never · 10% of the time · Less than Half the Time · 40% of the time · Half the Time · 60% of the time · More than Half the Time · 90% of the time · Almost Always

24. My hand or arm problem has limited driving vehicles (For example: a bike or car)	
Activities of Daily Living	
25. My hand or arm problem has limited my ability to care for my hair (For example: wash and style hair)	
26. My hand or arm problem has limited my ability to get myself a drink (Including: pouring a drink, opening the drink container, and holding the cup)	
27. My hand or arm problem has limited my ability to eat (Including: using utensils, opening food packages, and holding food)	

28. My hand or arm problem has limited my ability to put on and remove my shoes and clothes	
29. My hand or arm problem has limited my ability to wash my hands, face, and body	
Body Functions	
7. Moving my hand and arm has been **easy**	
9(6). My hand and arm have been **strong enough** to do my regular daily activities	

10. My hand and arm have been **strong enough** to do the activities I enjoy most	
30. My ability to feel things that I touch with my hand and arm has limited my regular daily activities	
5(8). I have had hand and/or arm pain	
8 (9). I have had pain moving my hand and/or arm	
6 (10). I have had so much pain in my hand and/or arm that I had to stop what I was doing	

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Education

Master of Business Administration, Marketing, 2003
University of Cincinnati, Cincinnati, Ohio

Bachelor of Science in Occupational Therapy, 1998
Indiana University – Purdue University Indianapolis, Indianapolis, Indiana

Professional Positions

Cincinnati Children's Hospital Medical Center. Cincinnati, Ohio. *Occupational Therapist III, Certified Hand Therapist*. December 2018-Present

Cincinnati Children's Hospital Medical Center. Cincinnati, Ohio. *Occupational Therapist II, Certified Hand Therapist*. August 2009-December 2018

Clermont County Educational Service Center, Clermont County Schools. Batavia, Ohio. Occupational Therapist, August 2007-August 2009.

Cincinnati Children's Hospital Medical Center. Cincinnati, Ohio. *Occupational Therapist I*, August 2007-August 2009

Cincinnati Children's Hospital Medical Center. Cincinnati, Ohio. *Clinical Programs Manager, Center for Professional Excellence*, August 2006 –August 2007

Cincinnati Children's Hospital Medical Center. Cincinnati, Ohio. *Coordinator, Division of Occupational Therapy and Physical Therapy*. August 2003-August 2006

Bethesda Hand Rehabilitation. Cincinnati, Ohio. *Occupational Therapist, Hand Therapist.* September 1998-August 2003.

Indiana University Medical Center. Indianapolis, Indiana. Rehabilitation Technician. Fall 1996 –Spring 1998.

Scholastic and Professional Honors

Clinical Excellence Award, Division of Occupational Therapy and Physical Therapy. Cincinnati Children's Hospital Medical Center, December 2020.

Outstanding Fieldwork Educator Award. University of Cincinnati Master of Occupational Therapy Program, May 2020.

Highest Orthopaedic Patient Experience. Division of Orthopaedic Surgery, Cincinnati Children's Hospital Medical Center, December 2019

Professional Publications

Dorich, J.M., Howell, D. M., Skubik-Peplaski, C. (2022). Pediatric hand therapists' experiences with outcomes measurement: An interpretive descriptive study. *Journal of Hand Therapy*, In Press.

Dorich, J. M., & Cornwall, R. (2021). Evaluation of a Grip-Strengthening Algorithm for the Initial Treatment of Chronic, Nonspecific Wrist Pain in Adolescents. *Journal of Hand Surgery Global Online*, 4(1), 8-13.

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Dorich, J.M., Cornwall, R. & Uhl, T. "ICF Linking of Patient-reported Therapy Goals for Children with acquired Upper Extremity Impairment," Virtual Pediatric Hand Study Group Annual Meeting, September 29, 2020

Dorich, J.M., Cornwall, R. & Uhl, T. "ICF Linking of Patient-reported Therapy Goals for Children with acquired Upper Extremity Impairment," American Society of Hand Therapy 43rd Annual Conference, Virtual, 2020

Heebner, N., Dorich, J.M., Cascia, N., Eldridge, T. & Uhl, T. "Biomechanical Analysis of Pull-up Tasks to Inform Therapy Progression for Elbow Conditions," American Society of Hand Therapy 43rd Annual Conference, Virtual, 2020

Dorich, J.M., Heebner, N., Cascia, N., Eldridge, T. & Uhl, T. "Biomechanical Analysis of Pull-up Tasks to Inform Therapy Progression for Wrist Conditions," American Society of Hand Therapy 43rd Annual Conference, Virtual, 2020

Dorich, J.M. "The Therapist's Approach to Implementing a Grip Strengthening Protocol for Pediatric Nonspecific Wrist Pain," Pediatric Hand Study Group, 19th Annual Meeting, Denver, CO, February 15-16, 2019.

Dorich, J.M., Skubik-Peplaski, C., Cornwall, R. "Utilization of the Pediatric Data Outcomes Collection Instrument for Functional Outcomes Assessment in Children with Upper Extremity Impairment: A Systematic Review," Pediatric Hand Study Group, 19th Annual Meeting, Denver, CO, February 15-16, 2019.

Dorich, J.M. and Cornwall, R. A Psychometric Comparison of Patient Reported Outcomes on Pediatric Hand Therapy, American Society of Hand Therapy 41st Annual Conference, Dallas, TX, September 19-23, 2018

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Dorich, J.M. and Cornwall, R. "COPM: What Patients Want," 2018 Pediatric Hand Study Group Annual Meeting, Columbus Ohio, April 13-14, 2018

Dorich, J.M. and Cornwall, R. “Results of a Grip Strengthening Protocol for Nonspecific Wrist Pain in Adolescents,” ASHT Annual Conference, Anaheim, CA, October 12-15, 2017.