NINDS/NICHD-NCMRR NeuroRehab CDE Project
Infant Pediatrics Subgroup Summary

All pediatric existing NINDS CDEs from disease injury groups were gathered and reviewed.

The subgroup divided measures under consideration into the following categories for further review: behavior, pain, sleep, and quality of life.

Measures validated in and applicable in multiple pediatric populations who may receive rehab and assess key aspects of cognitive, motor, social, and physical development and health were selected.

Some tools apply only to infancy or to older children. Some "gap area" tools are applicable to only certain types of neurorehabilitation.

For infancy period, it is important to adjust for prematurity for some tools.

In younger children and some clinical populations, self-report measures are not appropriate and there is a need to rely on parent report for topics such as quality of life and behavior.

In young children it is possible that their response to rehabilitation may be influenced by family and environmental factors (e.g., home, school). Depending of the nature of the study, investigators should consider measures of family functioning, parental stress, and other environment factors as needed.

There are no other standards that we are aware of.

Neurorehabilitation is quite diverse, depending on the child's age and type of rehabilitation, there are a range of outcomes that could be measured. It may be important to measure functioning outside of the treatment goals (the total child) due to the possibility of moderating or spillover effects (e.g., social emotional functioning). Moderating or spillover effects could be positive or negative.

Given the multiple challenges with assessment of young children (e.g., inability to self-report, variability in a single behavioral assessment session) caregiver report measures should be strongly considered and appropriately weighed in determining efficacy along with other objective outcome measures.

Summary of Recommendations

Instrument/ CRF Name	Population	Classification	Purpose/ Other Information/ Instrument use
Pediatric Quality of Life Inventory (PEDSQL)	Pediatric	NeuroRehab Core	Construct: Quality of Life The PedsQL covers a wide age range (2-18), it has been well used and has reasonable psychometrics. It captures something that the subgroup agrees is important for almost all NeuroRehab scientific studies, especially clinical trials.
Strengths and Difficulties Questionnaire (SDQ),	Pediatric	NeuroRehab Core	Construct: Behavior This measure starts at age 3 and goes up to age 16. It is difficult to capture diagnosis traits in the

Instrument/ CRF Name	Population	Classification	Purpose/ Other Information/ Instrument use
Combined Full and Follow-up versions			first two years of a child's life. This tool looks at positive characteristics and is harmonious with NIH values of showing respect for individual differences.
Infant Pediatrics Demographics	Pediatric	NeuroRehab Core	The subgroup focused on selecting elements that were easy to collect and broadly applicable in the field to maximize the utility of the data that is collected and shared. Gestational age and birth weight questions are recommended for ages 0-2 because this information may not be available as children become older. The General Core CRF collects additional demographic information.

Gap Areas

The subgroup noted several constructs which are important to measure, but did not meet the threshold of NeuroRehab Core, i.e., essential information applicable to all NeuroRehab clinical studies/trials across neurological disorders listed in the NINDS CDE Project. Supplemental – Highly Recommended (S-HR), Supplemental and Exploratory classified elements were not included within the scope of the Infant Pediatrics NeuroRehab v1.0 subgroup, therefore these instruments are listed as gaps.

Sleep: The subgroup did not select any sleep instruments as Core. Except for the PROMIS, the instruments were not validated. PROMIS was moved to the gaps list. Sleep should be monitored as there are often unintended consequences. Sleep is exceptionally important for children and wellbeing. This is an area of concern for children who often need or are included in rehab studies. There are not many measures for sleep that apply to infancy that are applicable to older children as well. Sleep is measured more traditionally in school age children.

Pain: Both the Faces Pain Scale – Revised and PROMIS Pediatric Item Bank v1.0 - Pain Behavior-Short Form 8a were moved to the gaps list. They would be recommended for any condition where pain is a potential issue. Recommendation is based on patient population characteristics or the likelihood that pain is a component of the conditions being studied. It could be a side effect that is either exacerbated or mitigated by rehab. The need to measure pain or sleep would be determined by pre-existing or baseline conditions and the type of interventional study. Including measures of pain and sleep in the gaps list will help bring attention to these constructs for researchers to consider. Pain and sleep may be influenced by comorbid conditions and impact the efficacy of treatment.

Participation: Young Children's Participation and Environment Measure (YC-PEM) has reasonable psychometrics. Many occupational therapists use this measure. Parent council thinks that measures of participation are important to collect because they provide the context for interpreting the social meaning of an improvement on a standardized measure of neuromotor performance or cognition. Measuring this construct can provide information on whether children's opportunities, engagement, and participation make them more or less likely to benefit from an intervention. Participation measures are included in the gaps list to highlight the importance of this construct. YC-PEM and Children's

Assessment of Participation and Enjoyment Scale (CAPE) / Preferences for Activities of Children (PAC) are included in the gaps list. YC-PEM covers the age range 0-5 and the CAPE/PAC cover the age range 6-21.

CRF Module/Instrument	Construct	Comments
Ages & Stages Questionnaires, Third Edition (ASQ-3)	Behavior	Widely used among pediatricians. However, this tool should not be considered a Core tool that is used across all NeuroRehab infant pediatric populations. It is under an important domain but does not measure the entire age range.
Bayley Scales of Infant Development (Bayley III, BSID)	Behavior	Updated version IV
Faces Pain Scale - Revised	Pain	Commonly used tool but no evidence of validation.
PROMIS Pediatric Item Bank v1.0 - Pain Behavior-Short Form 8a	Pain	Only validated pain measure across disorders. However, it is validated for ages 5 and up and is several items long.
Canadian Occupational Performance Measure (COPM)	QoL	Not general enough to be recommended across all NeuroRehab studies.
Health Utilities Index (HUI)	QoL	Too long and it did not focus on QOL.
PROMIS Item Bank v1.0 - Sleep Disturbance	Sleep	Only validated sleep measure within the existing NINDS CDE pediatric CDEs.
Young Children's Participation and Environment Measure (YC-PEM)	Participation	Narrow age range (0-5 years)
Children's Assessment of Participation and Enjoyment Scale (CAPE) / Preferences for Activities of Children (PAC)	Participation	Age range (6-21 years)
Functional Independence Measure and Functional Independence Measure for Children (WeeFIM)		The Functional Independence Measure (FIM) and WeeFIM were designed for use in rehab. FIM has been widely used clinically but is not used across all conditions or study types and is not responsive to change. FIM and WeeFIM are most appropriate for in-patient settings and not out-patient. A trained administrator is required. The FIM has been replaced for clinical use in dual use (adult and pediatric) inpatient units with a similar tool developed by the federal government with only 6 levels to select from. The FIM and WeeFIM are still widely used in pediatric facilities.
Pediatric Evaluation of Disability Inventory (PEDI)		The CAT form is quicker and easier to use, still quite detailed, and some studies suggest that it is sensitive to change over time.

Regarding the existing measures of parent-child stress/family functioning, we have searched the NINDS CDEs and concluded that none met criteria for Core measures for the Infant Pediatrics NeuroRehab subgroup. Measuring parent-child stress/family functioning remains an important gap area.

The PedsQL Infant Scales are also included in the subgroup's identified gap areas because no new CDEs may be recommended as part of NeuroRehab v1.0.