Development of a Quantitative Functional Status Scale (FSS) for Pediatric Patients

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Contents

List of Tables

List of Figures

1 Introduction and Purpose

Severity of illness may be considered a continuous variable with extremes of outcomes (survival, death) occurring at low and high values. This concept of severity of illness has been exceptionally productive in pediatric, neonatal and adult intensive care with scores such as PRISM, SNAP, APACHE, and others. Despite wide variability in PICUs, this current concept of severity of illness measurement has enabled investigators to successfully adjust mortality rates for the severity differences of different populations. These methods have found widespread applicability in general risk adjustment, quantitative quality assessment, and cost and containment studies.

Intermediate outcomes associated with physiologic status (e.g. compromised functional status) may occur between the extremes of survival and death. A major challenge of Pediatric Critical Care, and Pediatrics in general is to develop an ability/disability outcome measure that is well defined, unambiguous, quantitative, sufficiently rapid and reliable to use in large-scale studies, minimally dependent on subjective assessments, and available to the full age spectrum seen in hospitalized patients, especially PICUs. The need for this methodology is especially pertinent for large outcome studies. Current scales available for children are either (a) time consuming to conduct (i.e. Vineland, Bayley), (b) not available for all children in the ICU (i.e. WeeFim), or simply require too much subjective assessment and future projection by raters (Pediatric Cerebral and Overall Performance Scales). *The aim of this research is to develop and validate a rapid and reliable measure of functional status, the Functional Status Scale (FSS), that will be applicable to the full age group of pediatric patients.*

2 Background and Significance

Measuring functional status and outcomes in infants and children requires a firm understanding of the type of functioning that is being assessed. For example, intelligence scales are inadequate for assessing many children with severe, non-cognitive dysfunction.[1] Activities of daily living are an appealing way to characterize functioning, disability, and dependency and have been very successful in adult studies.[2] Unfortunately, adult outcome scales have not been validated in children, have poor validation data, or do not account for the natural dependence of infants and children. Also, adult scales do not reflect developmental changes during infancy, childhood and adolescence. Therefore, instruments such as the Glasgow Outcome Scale[3] (GOS), Func-

tional Independence Measure[4] (FIM), the Level of Cognitive Functioning Scale[5] (Los Ranchos Los Amigos Scale), and Rappaport's Disability Rating Scale[5] are not suitable for routine use in PICUs.

2.1 Adaptive Behavior and Activities of Daily Living

Adaptive behavior is a conceptually appealing way to make the adult concepts of disability and dependency relevant in infants and children. Adaptive behavior approximates activities of daily living with a wide overlap in the skill sets identified by both. For example, activities of daily living generally consist of personal self-care (feeding oneself, bathing, toileting), mobility (movement from bed to a standing position or to a chair, walking with or without assistance, or using a wheelchair) and continence (urine, feces). Adaptive skills are comprised of a range of skills that encompass both personal independence and social responsibility. These skills are needed to meet the daily demands and expectations of the environment including eating, dressing, expressing needs, communicating, behavior control, and more advanced skills including managing money, following a schedule, and practicing safety. Recently, the American Association of Mental Retardation (AAMR) recommended that adaptive skills be documented in the context of community and cultural environments typical of the person's age peers and tied to the person's individual need for support.[6] In the context of this study, the community and cultural environment that we wish to document is limited specifically to a hospital environment. *Specifically, we are interested in documenting the (often rapidly) changing adaptive behavior skill sets during critical illness and recovery.*

This study will compare an adaptive behavior scale and the Functional Status Scale (FSS) to establish criterion validity for the FSS. In initial studies conducted at Children's National Medical Center, the Vineland Adaptive Behavior Scales (VABS) were used (Section 3 on page 8). The VABS are frequently used in research, diagnostic evaluations, treatment planning, and long-term follow-up, and are often considered the gold standard for measuring activities of adaptive skills in children.[7–9] Unfortunately, the VABS are administered as an interview requiring considerable skill and time.

2.2 Pediatric Performance Category Scales

Two instruments that are frequently used for outcome assessment in pediatric critical care are the Pediatric Cerebral Performance Category (PCPC) and Pediatric Outcome Performance Category (POPC) Scales.[10,11] The

PCPC and POPC are pediatric modifications of the Glasgow Outcome Scales. While validation studies have demonstrated statistical difference between the PCPC and POPC categories when correlated with Stanford-Binet, Bayley, and VABS scores,[12] there is overlap between the categories. Classification by raters requires substantial projection. Consideration of NG tubes, gastrostomies, technology dependence, specific motor findings, objective functional aids, medical equipment, etc. are not specifically assessed. In previous efforts to use the PCPC and POPC Scales, very large sample sizes were required; in addition, models have not been developed to adjust the PCPC and POPC scores for improved performance.

2.3 Adaptive Behavior Assessment System II (ABAS II)

In this study, the Adaptive Behavior Assessment System II (ABAS II) will be used to measure adaptive behavior. ABAS II was developed by Patti L. Harrison and Thomas Oakland.[13] The test has the major advantage of being administered as a questionnaire to caregivers. This eliminates the need for an interview conducted by a highly trained interviewer (required for VABS). There are other advantages to using the ABAS II. First, the primary interest group for score use is children with difficulties. Second, the respondents may be primary care providers other than parents. Third, if the person being evaluated has never had the opportunity to complete a task, the respondent is instructed to estimate or guess (e.g. would the person be able to perform that activity or behavior if given the opportunity?). Unlike other adaptive behavior interviews or questionnaires, these guesses are tabulated for each skill area.

The skill areas in the ABAS II are: Communication, Community Use, Functional / Pre–Functional Academics, Home/School Living, Health and Safety, Leisure, Self-Care, Self-Direction, Social, and Motor (less than 6 years) or Work (6 years or older). Many of these areas are not relevant to the hospitalized child and many are not assessed in children under 1 year of age. We will omit skill areas that are not administered to children less than 1 year (Community Use, Pre–Functional Academics, Home Living) and those not relevant to assessing adaptive behavior in the hospitalized child, by reviewing the individual questions within each of the skill areas. The following skill areas of the ABAS II are most relevant to hospitalized children (e.g. most if not all of the questions in the section are relevant to the hospitalized child): Communication, Health and Safety, Leisure, Self-care, Self-Direction, Social and Motor (less than 6 years). Although the ABAS II was developed for use in individuals, our purpose is to correlate it to the

more parsimonious Functional Status Scale (FSS).

3 Preliminary Studies

3.1 Adaptive Behavior Measurement after PICU Illness

Results of pilot studies conducted by Dr. Jane Ball and colleagues at Children's National Medical Center support the utility of using adaptive behavior as a measure of functional status in this population. In 92 children assessed following head trauma, the average composite VABS score was 1 standard deviation below the population mean, and 16.5% of these children had VABS scores more than 2 standard deviations below the population mean (indicating severe disability). These studies demonstrated that assessment of adaptive behavior can detect expected functional status changes associated with ICU illness. Unfortunately, the VABS routinely required up to 60 minutes to complete in this setting, and 30 minutes to score. This limits the ability to use VABS for large-scale followup studies of PICU patients.

3.2 Prototype Version of FSS

The initial version of the FSS was developed in 1995, to provide the following characteristics of a rapid and reliable assessment of functional status:

- Reflective of the patients' adaptive behavior and need for aid and support.
- Easily obtainable from the patient's chart or discussion with caregivers.
- Easy to perform, requiring less than 5 minutes to complete.
- Reproducibility across raters.
- Required simple description and rater training.
- Generalizable beyond the ICU or hospital.

Based on thorough review of the full spectrum of pediatric instruments and descriptive scales, ten domains were defined to describe behavior, function and dependency. Mutually exclusive ordinal categories, ranging from

normal to severe dysfunction, were defined. The number of categories or levels of dysfunction in each domain was intentionally minimized (≤ 6). The initial FSS is shown in Table 1 on the next page.

The initial FSS was correlated with the Vineland Adaptive Behavior Scale (VABS), discussed in Section 2 on page 5. At the time of these preliminary studies, the VABS was the most relevant functional status test available for children. Children who had been PICU patients were studied within a day prior to anticipated hospital discharge. The VABS was assessed by a trained professional, who interviewed the primary care nurse for the child. The primary care nurse was assumed to be the best observer for functional status performance contemporary to the test administration. A research assistant obtained the FSS within the same time period.

In these studies, initial sensitivity analysis showed substantial potential for the FSS to classify severe dysfunctional states. Children with severe dysfunction (as demonstrated by VABS < 55) were correctly classified with an FSS cutoff of 3 (correct classification 0.951), with a sensitivity of 0.944, and specificity of 0.954.

Recognizing that the sample size (n=100) was insufficient for statistical inference, exploratory multiple regression analyses were conducted to estimate VABS values from the ten FSS domain scores and age of the patient. For children > 1 year of age, the resulting model had an R^2 of 0.54, while for younger patients, R^2 was 0.67.

Separate regression models were then constructed to develop weight of importance for each domain cell. Dummy variables were created for each FSS domain, and the regression coefficient then represented the relative severity of each level within the domain. Following these analyses, the point values of each cell were derived; the values range from 0 to 47. These are the numbers shown in bold text in Table 1 on the next page. Using these relative severity scores, the regression models improved to an R^2 of 0.57 in those > 1 year (Figure 1 on page 12) and R^2 of 0.71 for those < 1 year (Figure 2 on page 13). These figures demonstrate the potential for the FSS to be used to assess adaptive behavior.

Domain	0	1	2	3	4	5	6
Mental Status	Awake, aware	Lethargic, irritable **(16)**		Developmental Delay	Stuporous **(33)**		Coma Vegetative **(41)**
Sensory Status	Intact hearing, vision	Question of sensory loss**(17)**	Chronic pain, meds < daily	Hearing or vision impaired **(29)**	Chronic pain, meds < daily	Hearing or vision impaired **(29)**	No response to pain **(44)**
Posture/Tone	Normal tone, posture	Stiffness **(16)**	Floppy, weak **(19)**	Arching, posturing **(23)**	Decorticate **(40)**	Decerebrate **(47)**	Flaccid **(47)**
Gross Motor Movement	Head control and voluntary limb	Jittery, shake tremulous **(7)**	Motor delay **(30)**	Encephalopathy Cerebral Palsy **(30)**	Involuntary predominant **(30)**	Frequent seziures **(46)**	
Physical Impairment	No limb impaired	1 limb impaired **(1)**	2 limbs impaired **(30)**	3 limbs impared **(30)**	4 limbs impared **(30)**	Impaired head control **(38)**	
Functional Feeder	All PO	PO + caloric supplement **(4)**		No PO NG/NJ/GT **(38)**		All IV **(38)**	
Respiratory Status	Room air		Oxygen **(5)**		CPAP **(5)**		Ventilator **(5)**
Social Responsivity	Responds to social solicitation	Maintains eye contact **(2)**		Intermittent eye contact **(10)**		No eye contact **(24)**	No response to touch **(44)**
Communication Vocal	Non-crying vocalizations		Alteration in expressive language **(28)**		Tracheostomy **(9)**	No vocal communication **(39)**	
Communication Non-Vocal	Face expressive: gestures needs	Indications suspect **(30)**		No body language **(30)**		No change in facial expression **(37)**	

Table 1: Initial Version of Functional Status Scale (FSS)

Inter-rater results (20 patients) were done by two raters at the highest standard — exact entry — rather than the often-used standard of measurements differing by one level as being equivalent. Of the 200 possible measurements (20 patients x 10 domains), 171 were identical. Of the 29 differing entries, 17 differed by only one level. In one domain there was perfect agreement. In all others, the agreement was statistically significantly greater than expected by chance, although not perfect. Table 2 on page 14 shows the κ analysis performed on each domain. These results indicate that most of the domains performed very well, while some domains will require better definition and careful training for research personnel performing the FSS evaluation.

4 Methods

4.1 Assessment of Adaptive Behavior

The Adaptive Behavior Assessment System II (ABAS II) will be used to measure adaptive behavior. The test has the major advantage of being administered as a questionnaire to caregivers, not an interview that requires a very skilled interviewer as required by the VABS. The skill areas in the ABAS II are: Communication, Community Use, Functional / Pre–Functional Academics, Home/School Living, Health and Safety, Leisure, Self-Care, Self-Direction, Social, and Motor (less than 6 years) or Work (6 years or older). Many of these areas are not relevant to the hospitalized child and many are not assessed in children less than 1 year of age. We will eliminate those skill areas that are not administered to children less than 1 year (Community Use, Pre–Functional Academics, Home Living) and those not relevant to assessing adaptive behavior in the hospitalized child by reviewing the individual questions within each of the skill areas.

4.2 Functional Status Scale (FSS)

The assignment of relative point values suggested the potential to collapse dysfunction levels and simplify the score. For example, all the respiratory dysfunction classifications were weighted identically, two of the Functional Feeder domain levels were identical, three of the Gross Motor Movement domain levels were identical, 2 of the Posture/Tone domain levels with identical and two of the Communication/Non-vocal domain levels were identical. In a few cases, the magnitude of the value of the single cell was out of sequence (e.g. had a point value lower than the value of a less severe cell).

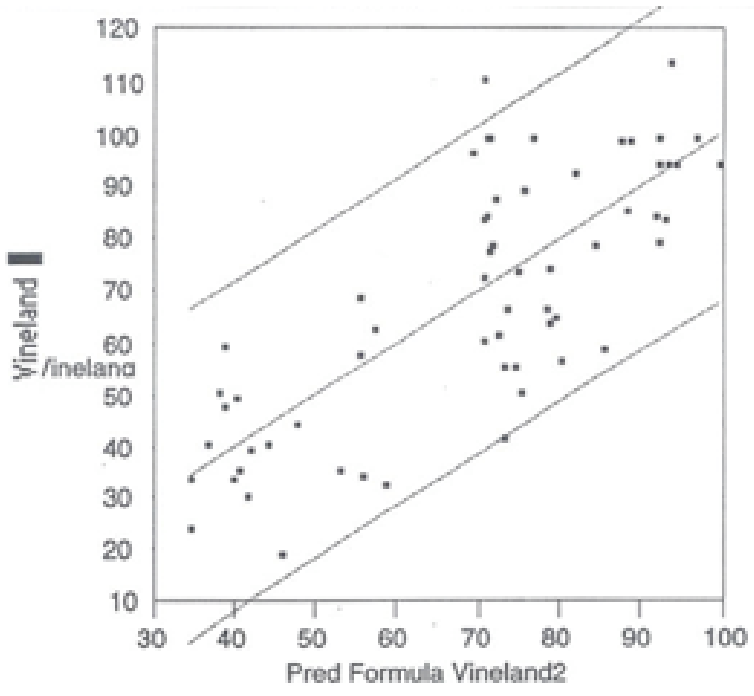

Figure 1: Correlation of initial FSS and Vineland for children > 1 year of age

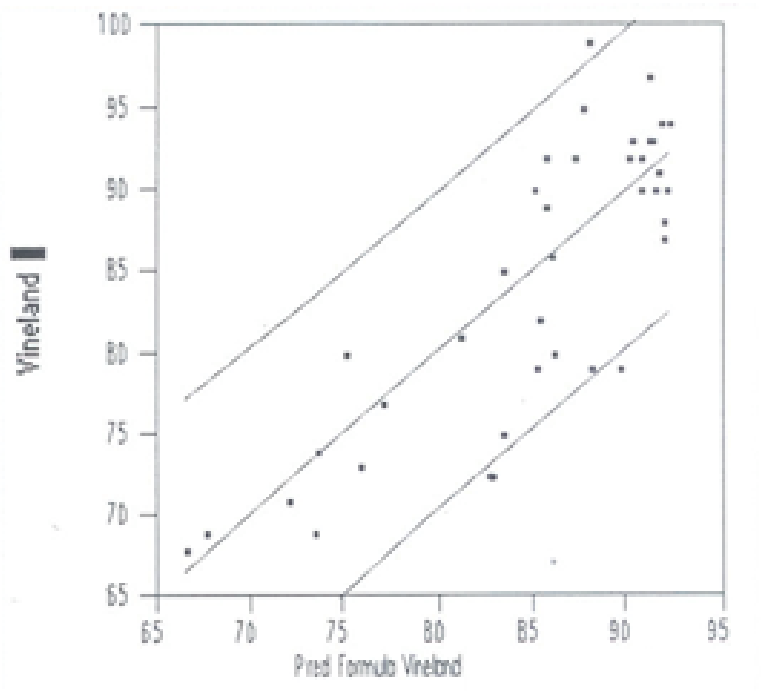

Figure 2: Correlation of initial FSS and Vineland for children < 1 year of age

FSS Domain	κ	p
Mental Status	0.4563	.0003
Sensory Status	0.7015	<.0001
Posture/Tone	0.4256	.0003
Gross Motor Movement	0.3939	.0008
Physical Impairment	0.6129	<.0001
Functional Feeder	0.9057	<.0001
Respiratory Status	1.0000	<.0001
Social Responsivity	0.6800	<.0001
Communication Vocal	0.4770	.0007
Communication Non-Vocal	0.8347	< .0001

Table 2: Inter-rater agreement statistics of initial FSS scoring

Based on these preliminary studies and consensus discussions of the CPCCRN Steering Committee and consultants, the FSS has been modified as follows:

1. The original ten domains have been collapsed into six.
2. The original seven categories of function have been collapsed to five.
3. Better definitions are provided for each domain cell (Appendix A on page 31.

The current FSS is shown in Table 3 on the following page.

The individual who carries out the FSS assessment is permitted to use direct observation, examination of the medical record, or information conveyed by other reliable health care providers. The person conducting the FSS assessment is permitted to ask other health care providers for information in certain situations. For example, if the patient is asleep at the time of the FSS assessment, it is permissible to ask the primary caretaker if the child is able to do certain things, rather than waking the child. In general, however, the FSS assessment should be done independently of other health care personnel.

The Mental Status, Sensory, Communication and Motor functions are scored on the basis of best function level for the last 4 hours prior to assessment. The Feeding functions are based on the last 12 hours prior to assessment, and the Respiratory functions are based on the last 24 hours prior to assessment.

Table 3: Current Version of the Functional Status Scale (FSS)

	NORMAL (1)	MILD DYSFUNCTION (2)	MODERATE DYSFUNCTION (3)	SEVERE DYSFUNCTION (4)	VERY SEVERE DYSFUNCTION (5)
MENTAL STATUS	Normal sleep,wake, appropriate social responsivity	Sleepy but arousable to noise,touch, or movement; or periods of social non-responsivity	Lethargic and/or irritable	Minimal arousal to stimulus (stupor)	Unresponsive, comatose, or vegetative
SENSORY	Intact hearing and vision and responsive to touch	Suspected hearing or suspected vision loss	Non - reactive to auditory OR visual stimuli	Non - reactive to auditory AND visual stimuli	Absence of response to pain
COMMUNICATION	Appropriate non-crying vocalizations, interactive facial expressiveness, or gestures	Diminished vocalization, facial expression or social responsiveness	Absence of attention getting behavior	No demonstration of discomfort	Absence of communication (no cry)
MOTOR FUNCTION	Coordinated body movements with normal muscle control and awareness of the action	1 limb functionally impaired	2 or more limbs functionally impaired	Poor head control	Diffuse spasticity, paralysis, decerebrate or decorticate posturing
FEEDING	All food by mouth with age-appropriate help	NPO or need for age-inappropriate help with feeding	Partial or total tube feedings	Partial parenteral nutrition with enteral feedings	Total parenteral nutrition
RESPIRATORY	Room air, no artificial support or aids	Oxygen or suctioning	Tracheostomy	CPAP for all or part of the day or mechanical ventilation for part of the day	Mechanical ventilation support for all of the day and night

4.3 Patient Sample Selection and Accrual Timeline

All children greater than 38 weeks gestational age and less than 18 years of age are eligible for inclusion in this study, if they are members of one of the sampling groups described below. No child will be excluded based on race, ethnicity, or gender. A child will not be eligible for multiple entries into the study.

This study is designed to establish criterion validity for the FSS. If successful, the CPCCRN will employ the FSS in subsequent efforts to add functional status (assessed by FSS) to PICU outcome predictors. It is also desirable that this methodology be applicable to a wide variety of hospitalized children who may not require PICU admission. For this reason, high-risk patients will be over-sampled, including dysfunctional children who are not in the PICU. This sampling strategy will provide more accurate scale estimation not only for the overall population of pediatric patients, but for the more infrequently encountered PICU patient with impaired functional status across several domains.

There will be 30 patients in an initial pilot phase, recruited entirely at Children's National Medical Center, to assess the process of data collection, feasibility of administration of components of the ABAS II, and FSS evaluation. These pilot patients will not be included in the subsequent samples.

There will be 500 patients in the model-building (estimation) sample. Patients will be recruited (within each CPCCRN center) as follows:

- PICU patients ($\approx 40\%$)
- High-risk non-PICU patients ($\approx 40\%$) including but not limited to children with spina bifida, developmental delay, mental retardation, cerebral palsy, metabolic disorders, chromosomal abnormalities, spinal fusion, seizure disorder, tumors, renal failure, anatomic neurologic abnormalities, or corrections for any of these types of disorders (e.g. shunts).
- Technology dependent patients ($\approx 20\%$) who may be seen in outpatient clinics, rehabilitation facilities, or may be chronically hospitalized.

PICU patients will be studied within 24 hours of discharge from the PICU; high-risk non-PICU patients will be studied within 24 hours of admission to the hospital. Technology dependent patients will be studied on preselected days in the appropriate settings (outpatient ventilator clinics, rehabilitation facilities, during chronic hospitalization).

To avoid selection bias, the Data Coordinating Center will determine a randomization scheme to enroll acutely hospitalized patients (PICU and non-PICU), using a randomly ordered list of the integers 0 to 9 for each day. If all PICU discharges can feasibly be approached, on a specific weekday, then randomization is not required. If there are more PICU discharges than can be studied, however, the research personnel will approach patients in the following randomized order: first approach the patient whose medical record number's last digit is the earliest number on the day's random number list. Ties will be resolved by reviewing the next-to-last (or subsequent) digit(s) in the medical record number. Subsequent patients will be approached, up to the capability of the research staff to enroll patients on a specific weekday, in the same manner.

Children selected from the non-PICU population, based on their diagnoses and the specific day of admission, will be handled in the same manner if the number of subjects exceeds the capacity of the research personnel. Children who are technology dependent will be randomly selected, in a similar manner, at appropriate clinical sites (outpatient clinics, rehabilitation facilities, hospitals).

There will be 250 patients in the validation sample, consisting of PICU (50%) and non-PICU (50%) patients. Thus, a total of 780 patients (30 CNMC pilot, 500 estimation sample, 250 validation sample) will be recruited in this study.

It is desirable to recruit approximately 110 patients from each of the seven sites, but patient enrollment may be increased up to 200 patients at any given site. No site will contribute more than 200 patients to the study, to assure overall generalizability. It is estimated that accrual of the pilot sample will require approximately one month, accrual of the learning sample will require four to eight months, and accrual off the validation sample will require three to four months, for a total estimated accrual period of 12 months.

4.4 Core Data Set

In addition to the FSS and ABAS II components, medical records will be reviewed to obtain the following data:

- Date of birth
- Gender
- Patient type
  - Acute PICU discharge
    - Date of current hospital admission

    - Date of current PICU admission
    - Date of current PICU discharge
    - Admission status
    - Operative status (choice list)
    - Catastrophic event during this hospital admission (Yes or No)
    - If yes to acute catastrophic event, provide description
        - HIE - Hypoxic Ischemic Encephalopathy
        - CA - Cardiac Arrest
        - TBI - Traumatic Brain Injury
        - SCI - Spinal Cord Injury
        - Other - describe with free text
    - If yes to acute catastrophic event, date of event
    - History of previous catastrophic event (Yes or No)
    - If yes to previous catastrophic event, provide description
        - HIE - Hypoxic Ischemic Encephalopathy
        - CA - Cardiac Arrest
        - TBI - Traumatic Brain Injury
        - SCI - Spinal Cord Injury
        - Other - describe with free text
    - If yes to catastrophic event, time interval since event
        - Within last month
        - Within last six months
        - Within last 12 months
        - Greater than 12 months ago
- High-risk non-PICU hospital admission
    - Location in hospital
    - Date of current hospital admission
    - Previous PICU admission (Yes or No)
    - Admission status
    - Operative status
    - History of previous catastrophic event (Yes or No)
    - If yes to catastrophic event, provide description
        - HIE - Hypoxic Ischemic Encephalopathy
        - CA - Cardiac Arrest
        - TBI - Traumatic Brain Injury
        - SCI - Spinal Cord Injury
        - Other - describe with free text
    - If yes to catastrophic event, time interval since event
        - Within last month

            - Within last six months
            - Within last 12 months
            - Greater than 12 months ago
    - Technology dependent, long-term dysfunction
        - Location at time of assessment
        - Previous PICU admission (Yes or No)
        - If previous PICU admission, date of last discharge
            - Within last month
            - Within last six months
            - Within last 12 months
            - Greater than 12 months ago
        - Date of last hospital discharge
            - Within last month
            - Within last six months
            - Within last 12 months
            - Greater than 12 months ago
        - History of previous catastrophic event (Yes or No)
        - If yes to catastrophic event, provide description
            - HIE - Hypoxic Ischemic Encephalopathy
            - CA - Cardiac Arrest
            - TBI - Traumatic Brain Injury
            - SCI - Spinal Cord Injury
            - Other - describe with free text
        - If yes to catastrophic event, time interval since event
            - Within last month
            - Within last six months
            - Within last 12 months
            - Greater than 12 months ago
- Dates and times of FSS and ABAS II testing
- Comments about FSS assessment (free form)
- Medications altering FSS
    - Paralytics within previous week
    - Sedatives within 4 hours
    - Narcotics within 4 hours
    - Other pain medications within 4 hours
    - Sleeping aids within 4 hours
    - Other medication affecting functional status within 4 hours
- Other factors altering FSS
    - Arm boards preventing extremity function
    - Soft or hard restraints preventing extremity function

  - Bandages or casts preventing extremity function
  - Other pain medications within 4 hours
  - Sleeping aids within 4 hours
  - Other medication affecting functional status within 4 hours
- Limitations on care
  - No ventilatory support
  - No chest compressions
  - No ventilatory support or chest compressions
  - Other limitations of therapeutic options
- Diagnoses, unlimited number as free text (not ICD–9)

4.5 Data Collection Training and Reliablility

Training sessions will be conducted by the CPCCRN prior to implementation of this study. The training sessions will be provided for CPCCRN Principal Investigators, additional investigators as deemed feasible by the clinical sites, research coordinators, and additional research assistants as deemed feasible by the clinical sites. The clinical site Principal Investigator is responsible to assure that all personnel at the clinical site are adequately trained to carry out this study.

4.5.1 Functional Status Scale (FSS)

The Functional Status Scale will be administered by research coordinators at each clinical site. These coordinators will have received reading materials and received training provided by the CPCCRN. The FSS will be collected on a paper worksheet, which is the source document for this information. The FSS will be entered into the electronic Case Report Form (eCRF) created in the TrialDB software system maintained by the Data Coordinating Center. This software is accessed via the Internet.

Since the paper form is the source document, it must be retained at the clinical site so that a site monitor can verify values entered into the TrialDB system. These records will need to be retained at the clinical site for several years after the last publication resulting from this research; the precise time for storage will be determined in conjunction with NICHD policies.

The first five patients enrolled at each of the 7 centers will be independently assessed by two observers, and an additional 10% of randomly selected (by the Data Coordinating Center) subsequent patients will also be independently assessed by two observers. This will yield approximately 80 subjects for reliability analysis (all from within the estimation sample).

Inter-observer reliability for the FSS domains and overall FSS will be assessed by the intraclass correlation coefficient for variables considered as continuous measures, and by the κ statistic for data considered as categorical or grouped. If a particular domain of the FSS is found to have poor reliability after maximal training effort, that domain could be considered a poorer candidate for FSS development than an alternate domain with comparable predictive value but substantially higher reliability.

It is permissible to assign any two specific persons to perform this task; it is a requirement that these individuals be physicians or nurses. All κ assessments need to be conducted by these assigned individuals. This will provide more consistency to the FSS evaluations. It is suggested that the Clinical Center PI and alternate PI are ideal individuals to carry out this task.

For the κ statistic, pre-study calculation of precision is difficult, as precision will depend on observed overall cell frequencies as read by each observer.[14] Generally, if the vast majority of subjects have the same value (for example, most are normal for a particular domain), then a given κ statistic will have less precision than in a situation where values are more evenly distributed across subjects. In the simple situation with two domain levels (i.e. normal and abnormal) and assuming that the observed κ is 0.9 (ignoring multiple comparisons), 80 subjects will provide 95% confidence that the actual κ is at least 0.7 if at least 5% of subjects have abnormal values. An inter-rater reliability ≥ 0.7 is often considered a statistical standard[15] for these types of instruments. If the observed κ is 0.85, the confidence interval will still be sufficiently narrow if at least 15% of subjects have abnormal values for a domain.[16]

4.5.2 ABAS II

Research assistants will collect the ABAS II from the primary caretakers, usually the primary nurse for the child, or if the child is an outpatient, the parent or other caretaker. The ABAS II questionnaires will be sent by express mail to the Data Coordinating Center, where they will be entered and scored. The forms will be identified with the TrialDB number that was assigned to the study subject, and will not be identified with patient or parent names.

The ABAS II has age–appropriate instruments. For this study, the 0 – 5 year forms will be used for patients who are < 6 years of age. The 5 – 21 year forms will be used for patients who are ≥ 6 years of age.

4.5.3 Chart Abstraction

The medical record will be abstracted to obtain the data elements described in Section 4.4 on page 18. The data will be entered into the electronic Case Report Form (eCRF) created in the TrialDB software system maintained by the Data Coordinating Center. This software is accessed via the Internet.

Paper worksheets have been created from the TrialDB system to assist research personnel to obtain the information from the medical record prior to computer entry. When site monitoring is conducted, the data in the computer system will be compared with data in the medical record and the worksheets. The worksheets should be retained at the clinical site until all research data have been collected, queries resolved, and the database has been locked.

4.6 Statistics

4.6.1 Descriptive Statistics

Descriptive statistics for continuous scale measurements will include measures of central tendency and variability, mean, standard deviation (SD) and standard error of the mean (SEM), range, minimum and maximum observations, median, and inter-quartile range. Percent of subjects within each domain level will also be reported. Data analysis will emphasize plots of raw data looking for associations between the ABAS II and FSS, trends, cut-offs, etc. Scatter plots of the FSS versus ABAS II will be inspected for outliers that may adversely affect measures of association. Sensitivity analysis will be conducted on the original (unadjusted) ABAS II for age groups. Tests for association between categorical measures will include chi-square or Fisher's exact test, as appropriate, including appropriate measures that take ordering of categories into account. Other tests will include analysis of variance or t-tests and/or Kruskal-Wallis test to assess and understand simple relationships, including defining first order effect modification. A cut-off point analysis will be used for raw FSS scores as well as the models to help define functional status cutoff points, although post hoc selection of cutoffs is data-driven and will require validation with a separate sample of children (validation sample).

For the ABAS II instrument skill areas being administered, raw scores will be converted to Scaled Score equivalents according to each subject's age. The Z-score for each subject will be calculated for each skill area assessed, based on the mean value of 10 and standard deviation of 3 in the normal population used to validate the scale. The mean of these Z-scores (termed

the "Composite ABAS Z-score" will be used as the standard against which the FSS will be validated. The key measurement is the degree of correlation between the overall FSS and the Composite ABAS Z-score.

With a total of 500 subjects in the estimation sample, precision of the estimated Pearson correlation coefficient will be relatively high. For example, if the true correlation between the two measures is 0.85, a two-sided 95% confidence interval for the correlation coefficient has an 83% chance of excluding correlation values of 80% or less. Correlations within age subcategories will have wider confidence intervals, but are anticipated to be useful.

This "mean Z-score" approach is relatively naive because the skill areas of the ABAS II are not completely orthogonal. The Composite ABAS Z-score will be biased because of correlation between skill areas. Furthermore, the FSS is ordinally scaled but might be improved by collapsing the categories or calibrating cells with relative weights. Two complementary approaches will be used to explore a more robust relationship between the FSS and Composite ABAS Z-score: multivariate modeling and structural analyses.

4.6.2 Multivariate Modeling

To determine the importance of each FSS domain for predicting the Composite ABAS Z-score, univariate correlations will be computed. Subsequently, a separate multivariate model will be constructed for each FSS domain, using age and raw FSS score (in that domain) as independent variables, and using the Composite ABAS Z-score as the dependent variable. These models will help determine if there are entire FSS domains that should be collapsed or removed from the FSS, simply because they do not contribute to accurate prediction of the Composite ABAS Z-score.

Stepwise forward regression will then be used to predict Composite ABAS Z-score, using a criterion for variable entry of $p \leq 0.30$. The candidate variables will include raw FSS scores in each domain, and the age of the child. This final model is an uncalibrated model in the sense that each FSS domain cell has an ordinal score from 1 to 5, but the relative importance of values in these cells is assumed to be similar (e.g., a change from 1 to 2 is assumed to have the same magnitude of effect as a change from 4 to 5). This is very unlikely to be true.

The solution to this problem is to re-estimate the values that should be assigned in each FSS domain cell. First, adjacent domain cells will be collapsed if there are fewer than 5 observations. Second, a dummy variable will

be constructed for all surviving domain cells, and these dummy variables will be used as independent variables to predict the Composite ABAS Z-score. Separate models will be constructed for each FSS domain. The parameter estimate for each dummy variable represents the relative importance of each level in the FSS domain. The FSS can be made more parsimonious by collapsing domain cells that have nearly identical importance in predicting the Composite ABAS Z-score. Finally, the result is a model in which each cell in each domain has a specific weight, enabling the use of a continuous FSS total score to estimate the measured Composite ABAS Z-score. Backward stepwise regression methods will then be used to simplify the FSS by eliminating FSS domain cells that do not contribute to overall prediction of the Composite ABAS Z-score. This process is similar to that used in creating the appropriate physiological score ranges in the PRISM III methodology.[17]

The final step in this approach is to select cutoff values of FSS that enable children to be assigned to morbidity classifications. The *a priori* estimate is that 70% of patients will be classified as normal, 15% as moderately dysfunctional, and the remaining 15% as severely dysfunctional.

4.6.3 Structural Analyses

An alternative approach to revising the FSS focuses on structural analyses of the FSS score components, using principal components and factor analysis. Principal components yield combinations of FSS domains and levels that provide the greatest contribution in predicting the Composite ABAS Z-score. These combinations are statistically derived and are often difficult to interpret directly. Examination of the components, however, may provide insight into combinations or contrasts of FSS components that measure differences between children in the estimation sample. More importantly, factor analysis may yield a much simpler final FSS instrument than can be constructed using linear multivariable models, with equivalent predictive value. Considerations including predictive value, interpretability, and parsimony will be used to determine the final composition of the FSS for future studies.

4.6.4 Sample Size Considerations

The estimation sample will have 500 subjects, based on up to 30 separate domain levels; it will be optimal if at least 15 cases are available for each domain level in the final model.[18] Adjacent cells within an FSS domain that contain only 10 subjects each will, nevertheless, have 80% power to detect a

difference in Composite ABAS Z-score of 1.3 standard deviations or greater.

The validation sample will have 250 subjects, which will provide 90% power to establish that the correlation between the FSS-predicted and measured ABAS scores is at least $R^2 \geq 0.65$, assuming that the actual correlation is 0.75 or more.

5 Human Subjects Protection

5.1 Risks and Benefits

This study imposes no additional physical risks to the patient. The ABAS II questionnaire is administered to the primary health care provider and requires no patient contact. The FSS is obtained by brief observation or abstraction from the medical record, and requires no physical contact with the patient. The core data set is obtained by abstraction from the medical record. There is potential risk of breach of confidentiality concerning the patient's medical information. This risk is minimal (see Section 5.3 on the facing page). There are no costs for subjects or their families.

The development of a relatively simple, easy to use, and age-independent numeric measure of functional status will enable future research projects to include functional status as a short and long-term outcome of study. This is particularly important in pediatrics, because mortality is a relatively rare and insensitive outcome for most studies. There are no direct benefits to participating children or their families. There are no reimbursements or payments for inpatient subjects or their families.

The Clinical Center may choose to provide an incentive, such as a small gift certificate, for the primary caretaker who is asked to complete the ABAS II forms. For inpatients, the primary caretaker is the bedside nurse. For outpatients, such as in a ventilator clinic, the primary caretaker may be a parent, guardian, or a home nurse. If such an incentive is used to facilitate completion of the ABAS II forms at a Clinical Center, this must be approved by the IRB.

5.2 Informed Consent

Each Clinical Center Institutional Review Board will determine the need for written informed consent or the applicability of a waiver of written informed consent. Children age 7 to 17 years who are alert and competent, and after an age-appropriate discussion of risks and benefits, will be asked to give assent to the study. Assent will be waived if the child is too young, has a

severely reduced mental age, decreased level of consciousness, psychological problems, or other legitimate reasons as judged by the Institutional Review Board at each site.

5.3 Data Security

The Data Coordinating Center (DCC) at the University of Utah has a dedicated, locked server room within its offices, and the building has 24 hour on-site security guards. The DCC has a state-of-the-art computer infrastructure and coordinates its network infrastructure and security with the Health Sciences Campus (HSC) information systems at the University of Utah. This provides DCC with effective firewall hardware, automatic network intrusion detection, and the expertise of dedicated security experts working at the University. Network equipment includes three high-speed switches and two hubs. User authentication is centralized with two Windows 2003 domain servers. Communication over public networks is encrypted with virtual point-to-point sessions using secure socket layer (SSL) or virtual private network (VPN) technologies, both of which provide at least 128 bit encryption. TrialDB is the clinical trials software used at the DCC, and eRoom^{TM}is used for communications about the study. TrialDB, eRoom^{TM}and other web applications use the SSL protocol to transmit data securely over the Internet.

Direct access to DCC machines is only available while physically located inside the DCC offices, or via a VPN client. All network traffic is monitored for intrusion attempts, security scans are regularly run against our servers, and our IT staff are notified of intrusion alerts. Security is maintained with Windows 2003 user/group domain-level security. Users are required to change their passwords every 90 days, and workstations time out after 10 minutes of inactivity. All files are protected at group and user levels; database security is handled in a similar manner with group level access to databases, tables, and views in Microsoft SQL Server.

The ABAS II forms will be mailed by trackable delivery systems to the DCC for scoring, analysis and entry into TrialDB. Data sheets will have a study number assigned by the TrialDB system, but no identifying information. The FSS and other data will be submitted directly into TrialDB, and are either numeric or coded data that would be meaningless if observed by unauthorized individuals.

The investigators and staff of the Data Coordinating Center are fully committed to the security and confidentiality of all data collected for CPCCRN studies. All personnel at the DCC have signed confidentiality agree-

ments concerning all data encountered in the DCC. Violation of these agreements may result in termination from employment at the University of Utah. In addition, all personnel involved with DCC data systems have received Human Subjects Protection and HIPAA education.

5.4 Record Retention

For federally funded studies subject to the Common Rule, records relating to the research conducted shall be retained for at least 3 years after completion of the research. Completion of the research for this protocol should be anticipated to include subsequent phases of FSS development, and completion of all publications relating to the research. All records shall be accessible for inspection and copying by authorized representatives of the regulatory authorities at reasonable times and in a reasonable manner [45 CFR §46.115(b)].

5.5 Health Insurance Portability and Accountability Act

Registration of research subjects in the TrialDB system requires a date of birth, race, ethnicity, and gender. This demographic data is held in database tables that are separate from coded research data (including clinical data). Additional potential identifier information includes the date of admission. Prior to statistical analyses, dates will be used to calculate lengths of stay and patient age. The final data sets (used for study analyses and archived at the end of the study) will be de–identified, and will exclude these specific dates.

Each Clinical Center will determine the need for written authorization for access to medical information from parents or legal guardians of children who are enrolled in this study. Since the final data sets will be de–identified, and since some Clinical Center IRBs may waive the requirement for written informed consent, some Clinical Centers may choose to waive requirement of written authorization for access to medical information.

For purposes of the DCC handling potential protected health information (PHI) and producing the de–identified research data sets that will be used for analyses, all sites have been offered a Business Associate Agreement with the University of Utah. Copies of executed Business Associate Agreements are maintained at the DCC.

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A FSS Domain Cell Definitions

The Mental Status, Sensory, Communication and Motor functions should be based on the best functioning over the last 4 hours prior to the assessment. The Feeding functions should be based on the last 12 hours prior to the assessment. The Respiratory functions should be based on the last 24 hours prior to the assessment. Appropriate information sources include direct observation or information conveyed by other reliable health care providers.

MENTAL STATUS

Normal

- Normal sleep and wake periods;
- Appropriate social responsivity

Sleep refers to a restful state without over-reaction (crying, agitation) to noises in the environment. Awake refers to awareness with behavior appropriate for age. Infants and children in this state should be appropriately aware, alert and responsive of self and environment.

Mild Dysfunction

- Sleepy but arousable to noise or touch or movement, and/or
- Periods of reduced social responsivity

Sleeps more of the time than is age appropriate; will sleep much of time if left alone but is able to be aroused with stimulation such as noise, if touched or position changes. Alternatively, decreased responsiveness to social overtures and/or does not consistently focus on or follow a person or object crossing the line of vision.

Moderate Dysfunction

- Lethargic and/or
- Irritable

Lethargic infants and children are drowsy, sluggish, or have an unusual lack of energy. They are arousable, but become less responsive or return to a sleep-like state without frequent stimulation. Irritable infants and children are inconsolable often with an increased sensitivity to stimulation. Infants often react to stimuli with a high-pitched cry.

Severe Dysfunction

- Minimal arousal to stimulus (stupor)

Stuporous infants and children have decreased or impaired consciousness marked by diminution in reactions to environmental stimuli. They may open eyes and focus, but do not maintain any meaningful reaction to physical environment. They make little or no eye contact. They will respond to noxious stimuli with semi-purposeful (i.e. poorly organized) movements or withdrawal.

Very Severe Dysfunction

- Unresponsive and/or
- Coma and/or
- Vegetative

These infants and children are unconscious. Coma is a deep or profound state of unconsciousness from which they cannot be aroused. They do not sense or respond to external stimuli or internal needs. Vegetative infants and children have no evidence of awareness of self or environment. They may have intermittent wakefulness manifested by sleep- wake cycles. There is no evidence of sustained, reproducible, purposeful or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli.

SENSORY

Normal

- Intact hearing, and
- Intact vision, and
- Responsive to touch or pain

Intact hearing is demonstrated by individuals localizing/ moving eyes and/or head toward sound stimulus in room. Intact vision is evidenced by individuals turning gaze to focus on person or object that crosses his visual field.

Mild Dysfunction

- Suspected hearing loss, or
- Suspected vision loss

There is suspicion of hearing or vision loss as evidenced by inconsistent focusing or localization of sound. Responsiveness to touch is not impaired.

Moderate Dysfunction

- Not reactive to auditory stimuli, or
- Not reactive to visual stimuli

There is lack of evidence for hearing or vision as demonstrated by lack of focusing, or localization of sound. Responsiveness to touch is not impaired.

Severe Dysfunction

- Not reactive to auditory stimuli, and
- Not reactive to visual stimuli

There is lack of evidence of hearing or vision as evidenced by lack of tracking, and localization of sound. Responsiveness to touch is not impaired.

Very Severe Dysfunction

- Absence of response to pain

Infant/child has no response (withdrawal or better) to pain.

COMMUNICATION

Normal

- Vocalization appropriate for age, and
- Interactive facial expressions or gestures.

Infants make sounds to make presence known. Children use words to convey needs. Interactive facial expressions and gesture are a process of non-verbal communication, often closely associated with emotions.

Mild Dysfunction

- Diminished vocalization
- Diminished social expression - facial or verbal

There is a decrease in socialization and social expression.

Moderate Dysfunction

- Absence of attention-getting behavior

Infants and children who do not demonstrate behavior that "says" "look at me, here I am". Children may initiate attention-getting behavior, but cannot communicate their needs.

Severe Dysfunction

- No demonstration of discomfort

Infants and children do not cry or cry very little with painful procedures or if uncomfortable.

Very Severe Dysfunction

- Absence of communication (no cry).

There is no communication using facial expressions, body posture, or voice. There is no communication regarding physiological or psychological needs. No cry even with touch.

MOTOR FUNCTIONING

Voluntary movements: Normal

- Coordinated body movements, and
- Normal muscle control, and
- Awareness of action

Infants and children have coordinated movements with normal muscle control. They are aware of the action and its purpose (e.g., infant kicks limbs, vocalizes when parent enters.) Infant can hold rattle and transfer it from one hand to another. Toddler carries object, holds onto stuffed animal, sucks thumb. Child writes or plays with toys.

Mild Dysfunction

- 1 limb functionally impaired

There is a partial or complete loss of functionality of the (1) limb. Impairment may be from medical devices such as soft or hard restraints, arm boards for IVs, bandages, casts, or due to physical and medical issues such as deformities, weakness, stiffness, spasticity, and/or movement disorders. Weakness is demonstrated when infants and children are able to move limb off a surface (against gravity) while holding an object or against resistance. They may be able to perform normal age appropriate activities but with increased effort. Stiffness is demonstrated when one or more limbs have increased resistance to passive motion but are still held in normal position or postures. Stimulation does not result in flexion, extension or arching. Spasticity is abnormally increased muscle tone with involuntary movement. Limb(s) feel tight, rigid and limb reflexes are exaggerated. There is resistance to bending and the neck is hyperextended.

Moderate Dysfunction

- 2 or more limbs functionally impaired

There is a partial or complete loss of functionality of 2 or more limbs. Impairment may be from medical devices such as soft or hard restraints, arm boards for IVs, bandages, casts, or due to physical and medical issues such as deformities, weakness, stiffness, spasticity, and/or movement disorders. Weakness is demonstrated when infants and children are able to move limb off a surface (against gravity) while holding an object or against resistance. They may be able to perform normal age appropriate activities but with increased effort. Stiffness is demonstrated when one or more limbs have increased resistance to passive motion but are still held in normal position or postures. Stimulation does not result in flexion, extension or arching. Spasticity is abnormally increased muscle tone with involuntary movement. Limb(s) feel tight, rigid and limb reflexes are exaggerated. There is resistance to bending and the neck is hyperextended.

Severe Dysfunction

- Poor Head Control

Head control is poor with decreased ability to hold head upright at 90°. Unable or cannot hold head still when less than 90°. If trunk is supported

head will fall back, to side or front and he/she is unable to bring head to the upright position if sitting or midline if supine or prone.

Very Severe Dysfunction

- Paralyzed
- Decerebrate/Decorticate Posturing

Paralysis is the loss of voluntary motor function. There is abnormal muscle tone. Mental Status may be preserved or altered. Decerebrate posture consists of rigid extension of all extremities with internal rotation. There is downward pointing of toes. Decorticate posture consists of rigid flexion of upper extremities with clenched fists and extension of lower extremities.

FEEDING

Normal

- All food taken PO with age appropriate help.

There is no parenteral or gavage feeding. Feeding methods are age appropriate. Caloric intake is not a classification criterion for this category.

Mild Dysfunction

- NPO, or
- Need for age–inappropriate help with oral feeding

There is no parenteral nutrition or tube feeding. (Dextrose solutions of 5% or less are not considered parenteral nutrition). Examples of age–inappropriate feeding include feeding by a caretaker when independent feeding is expected or when a feeding aid such as a bottle is used at an inappropriate age.

Moderate Dysfunction

- Tube feedings with or without additional oral intake

Tube feedings include nutrition via a nasogastric, oral-gastric, or small bowel tube. There is no parenteral nutrition. (Dextrose solutions of 5% or less are not considered parenteral nutrition).

Severe Dysfunction

- Parenteral nutrition in addition to oral or tube feeding.

Parenteral nutrition includes intravenous nutrition via a peripheral or central vein with a dextrose concentration greater than 5%. It usually includes fat and protein.

Very Severe Dysfunction

- All nutrition is parenteral

Parenteral nutrition includes intravenous nutrition via a peripheral or central vein with a dextrose concentration greater than 5%. It usually includes fat and protein. Child is unable to tolerate *any* enteral feeds, whether by mouth or tube feedings.

RESPIRATORY STATUS

Normal

- Room air and no artificial support or aids

The infant or child is breathing in room air without the need for artificial help including suctioning, oxygen, or mechanical support.

Mild Dysfunction

- Oxygen, and/or
- Suctioning

Oxygen given via any apparatus including blow-by, cannula, face mask, etc. Suctioning includes any oral or tracheal suctioning.

Moderate Dysfunction

- Tracheostomy

Severe Dysfunction

- CPAP for all or part of the day, and/or
- Mechanical ventilator support for part of the day

CPAP (Continuous positive airway pressure) may be administered through a facemask or tracheostomy. Mechanical support includes positive or negative pressure ventilation devices such as bipap, and positive pressure mechanical ventilation.

Very Severe Dysfunction

- Mechanical ventilatory support for all day and night.

Mechanical support includes positive or negative pressure ventilation devices such as bipap, and positive pressure mechanical ventilation.