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Functional Status Scale: New Pediatric Outcome Measure



WHAT'S KNOWN ON THIS SUBJECT: No pediatric functional status measures are suitable for large outcome studies. Adaptive behavior is the pediatric version of activities of daily living, but methods for measuring this are time-consuming, often are dependent on the observer, and are not well standardized.



WHAT THIS STUDY ADDS: The FSS is suitable for measuring functional status in hospitalized children of all ages. Its performance indicates that it is suitable for use in large outcome studies.

abstract

OBJECTIVE: The goal was to create a functional status outcome measure for large outcome studies that is well defined, quantitative, rapid, reliable, minimally dependent on subjective assessments, and applicable to hospitalized pediatric patients across a wide range of ages and inpatient environments.

METHODS: Functional Status Scale (FSS) domains of functioning included mental status, sensory functioning, communication, motor functioning, feeding, and respiratory status, categorized from normal (score = 1) to very severe dysfunction (score = 5). The Adaptive Behavior Assessment System II (ABAS II) established construct validity and calibration within domains. Seven institutions provided PICU patients within 24 hours before or after PICU discharge, high-risk non-PICU patients within 24 hours after admission, and technology-dependent children. Primary care nurses completed the ABAS II. Statistical analyses were performed.

RESULTS: A total of 836 children, with a mean FSS score of 10.3 (SD: 4.4), were studied. Eighteen percent had the minimal possible FSS score of 6, 44% had FSS scores of ≥ 10 , 14% had FSS scores of ≥ 15 , and 6% had FSS scores of ≥ 20 . Each FSS domain was associated with mean ABAS II scores ($P < .0001$). Cells in each domain were collapsed and reweighted, which improved correlations with ABAS II scores ($P < .001$ for improvements). Discrimination was very good for moderate and severe dysfunction (ABAS II categories) and improved with FSS weighting. Intraclass correlations of original and weighted total FSS scores were 0.95 and 0.94, respectively.

CONCLUSIONS: The FSS met our objectives and is well suited for large outcome studies. *Pediatrics* 2009;124:e18–e28

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KEY WORDS

functional status, outcome assessment, activities of daily living, adaptive behavior, health status indicators, health utilities index, treatment outcome, child

ABBREVIATIONS

FSS—Functional Status Scale
ABAS II—Adaptive Behavior Assessment System II
ROC—receiver operating characteristic

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One major challenge of pediatrics and its subspecialties is to develop a functional outcome measure that is well defined, quantitative, rapid, reliable, minimally dependent on subjective assessments, applicable to as broad an age range as possible, and pertinent to hospitalized patients in as many inpatient environments as possible. Because existing measures available for children are excessively time-consuming to use,^{1,2} are available or validated for a limited age range,³ or simply require too much subjective assessment and future projection by raters,^{4,5} a new functional outcome measure fulfilling these criteria is especially desirable to enable large outcome studies.

We wanted to be able to measure the changing functional status (such as motor or major cognitive deficits) of children during hospitalization. Although results are not necessarily predictive of long-term outcomes, we wanted to enable a large PICU outcome study. The conceptual framework for development of this measure was the activities of daily living scale used in outcome studies with adults. In children, however, the expected performance of activities of daily living changes with developmental stages. A similar conceptual characterization for children is adaptive behavior, but the formal assessment of adaptive behavior is time-consuming and requires specific expertise. The aim of this study was to develop a quantitative, rapid, reliable scale of functional status for children that is conceptually similar to activities of daily living and to compare the performance of the scale against a validated, more-extensive measure of adaptive behavior.

METHODS

Study Sites

This study was conducted at the 7 PICUs participating in the National Institute of Child Health and Human De-

velopment Collaborative Pediatric Critical Care Research Network. The institutional review board at each site approved the protocol.

Functional Status Scale

The Functional Status Scale (FSS) was developed through a formal consensus process by health care professionals from 11 institutions within and outside the research network, including pediatricians, pediatric neurologists, pediatric developmental psychologists, pediatric physiatrists, pediatric nurses, pediatric intensivists, and pediatric respiratory therapists. A previous, single-institution, pilot study demonstrated the utility of using the primary nurse as a suitable observer for functional status, the potential of a simple scale to reflect functional status (as measured through adaptive behavior) accurately, and the potential to categorize patients correctly according to functional status. The pilot study showed very good interrater reliability between 2 data collectors and supported the use of adaptive behavior to establish external validity. Domains of functioning selected during the consensus process included mental status, sensory functioning, communication, motor functioning, feeding, and respiratory status (Table 1). Functional status for each domain was categorized from normal (score of 1) to very severe dysfunction (score of 5). FSS scores ranged from 6 to 30. The definitions of the domain cells are presented in the Appendix.

Adaptive Behavior Assessment System II

The Adaptive Behavior Assessment System II (ABAS II),⁶ a validated questionnaire for assessment of adaptive behavior, was used to establish construct validity and to provide calibration of the FSS scores within each domain. We selected adaptive behavior as a similar but not identical measure

of function, recognizing that the correlation between adaptive behavior scales purporting to measure the same functions, such as the ABAS II and the Vineland Adaptive Behavior Scales,¹ is only moderate. For example, the correlations between the ABAS II skill areas and the Vineland Adaptive Behavior Scales domains ranged from 0.17 to 0.79, and the overall correlation between the scores, both of which represent in-depth assessments of adaptive behavior, was 0.75. Correlation between the ABAS II and the Scales of Independent Behavior-Revised, a screening test, was only 0.18.⁶ Because functional status and adaptive behavior are not identical concepts, we expected only modest correlation between FSS and ABAS II scores.

The ABAS II has 10 skill areas that are scaled to age-normalized performance, with each scaled skill area having a mean \pm SD of 10 ± 3 . Because not all skill areas were relevant to hospitalized children, we assessed only selected skill areas. For children 0 to 6 years of age, we assessed the communication, preacademics, health and safety, leisure, self-care, self-direction, social, and motor skill areas. For children 6 through 18 years of age, we assessed the communication, health and safety, leisure, self-care, self-direction, and social skill areas. The standard selected for establishment of acceptable correlation of FSS scores was the mean partial ABAS II score, calculated as the mean of all skill area scores available for a participating child. In this report, all ABAS II values reported refer to this partial application of the full instrument.

Data Collection

Patients were eligible if they were born at >38 weeks of gestation, were <18 years of age, and met the criteria for 1 of 3 study groups of patients at high risk for functional disabilities (for ex-

TABLE 1 FSS Domains of Functioning

	Normal (Score = 1)	Mild Dysfunction (Score = 2)	Moderate Dysfunction (Score = 3)	Severe Dysfunction (Score = 4)	Very Severe Dysfunction (Score = 5)
Mental status	Normal sleep/wake periods; appropriate responsiveness	Sleepy but arousable to noise/touch/movement and/or periods of social nonresponsiveness	Lethargic and/or irritable	Minimal arousal to stimuli (stupor)	Unresponsive, coma, and/or vegetative state
Sensory functioning	Intact hearing and vision and responsive to touch	Suspected hearing or vision loss	Not reactive to auditory stimuli or to visual stimuli	Not reactive to auditory stimuli and to visual stimuli	Abnormal responses to pain or touch
Communication	Appropriate noncrying vocalizations, interactive facial expressiveness, or gestures	Diminished vocalization, facial expression, and/or social responsiveness	Absence of attention-getting behavior	No demonstration of discomfort	Absence of communication
Motor functioning	Coordinated body movements, normal muscle control, and awareness of action and reason	1 limb functionally impaired	≥2 limbs functionally impaired	Poor head control	Diffuse spasticity, paralysis, or decerebrate/decorticate posturing
Feeding	All food taken by mouth with age-appropriate help	Nothing by mouth or need for age-inappropriate help with feeding	Oral and tube feedings	Parenteral nutrition with oral or tube feedings	All parenteral nutrition
Respiratory status	Room air and no artificial support or aids	Oxygen treatment and/or suctioning	Tracheostomy	Continuous positive airway pressure treatment for all or part of the day and/or mechanical ventilatory support for part of the day	Mechanical ventilatory support for all of the day and night

ample, anatomic abnormalities of the brain, metabolic conditions, or chronic respiratory disease). These groups were PICU patients within 24 hours before discharge, high-risk non-PICU patients within 24 hours after hospital admission, and technology-dependent children. The study sample was selected to achieve a final distribution of 40% PICU discharges, 40% high-risk admissions, and 20% technology-dependent children. High-risk hospitalizations were based on, but were not limited to, a preselected set of diagnoses, including spina bifida, mental retardation, seizure disorders, other neurologic disorders, and chromosomal abnormalities. Technology-dependent patients were studied during their acute hospitalization, at long-term care facilities, or during a clinic visit. If, in a given day during the study period, more eligible patients were available within a study group than could be assessed, study patients

were selected randomly. Patients were enrolled on weekdays from July 28, 2006, through March 1, 2007.

Data included subject age, gender, acute diagnosis, major clinical events resulting in or likely to result in major decrements in functional status, emergency/elective status at admission, operative status at the time of inclusion, and use of sedatives, narcotics, sleeping aids, or other therapies that might interfere with functional status, including restraints, arm boards, bandages, casts, and other devices. FSS data were collected by a research coordinator (nurse or respiratory therapist) or physician investigator at each site. All individuals who collected data were trained by the data coordinating center in the same training session. The ABAS II was completed by the primary care nurse within 4 hours after the collection of the FSS data, on the basis of his or her understanding of

the patient's functioning at the time the FSS was completed. Nurses were oriented to the study before its onset.

We randomly selected 10% of study days for evaluation of interrater reliability. On those days, a study physician and a research coordinator completed the FSS evaluation independently, within 4 hours of each other.

Statistical Methods

The mean ABAS II score for all available skill areas was selected as the standard for comparison with the FSS score (see above). A more-complex skill area-weighting approach was not implemented, because the covariance structures of the ABAS II subscales in the population used to derive and to validate the ABAS II were not available.

We recognized a priori that the cells of dysfunction within each domain were ordered by the experts but were not necessarily assigned appropriate rel-

ative weights. To assess this possibility, we allocated randomly two thirds of the sample for use in the estimation set and one third for use in the validation set for each study site and study arm (PICU, high-risk hospital, or technology-dependent). We retained all FSS domains because they were thought to be important during the expert consensus process. Our approach evaluated the relationship between each of the FSS domains separately and the mean ABAS II score by using univariate linear regression analyses, to establish a new relative weighting system for the cells of each domain. These scores were scaled to a value of 1, representing normal function (weighted FSS scores). Cells in each FSS domain were collapsed (combined) if their coefficients and their SEs indicated significant overlap, there was lack of appropriate ordering of the coefficient values, and the clinical significance of the cells could be meaningfully combined. The stability of the observations and changes in the estimation set was confirmed with the validation set.

Face validity and logical content validity of the FSS were established through the expert consensus process. Construct validity was established by correlating the performance of the FSS with adaptive behavior measured with the ABAS II. Discriminant validity was established through receiver operating characteristic (ROC) curve analysis using dysfunction groups classified with the ABAS II. Associations between FSS scores (original and weighted) and ABAS II scores were assessed by using Pearson correlations. The signif-

icance of the difference between these 2 (dependent) correlation coefficients was assessed with the *t* test, by using an asymptotic approach described by Hotelling.⁷ The significance of the difference between 2 ROC curves was assessed by using the nonparametric approach described by DeLong et al,⁸ implemented in SAS (SAS Institute, Cary, NC) through the %ROC macro.

Interrater reliability was assessed with the weighted κ statistic for the various components of the FSS.⁹ The total FSS score was treated as a continuous variable for the reliability analysis, and the intraclass correlation coefficient was used to assess the reliability of this score. The research coordinator and study physician assessments were treated as separate observations. An intercept-only linear mixed model was fitted with the total FSS score as the outcome, with a random intercept for each subject. The intraclass correlation coefficient was then calculated as the estimated variance attributable to subject divided by the sum of this variance plus the residual variance.

RESULTS

Characteristics of Enrolled Subjects

A total of 836 patients in the 3 groups were enrolled in the 7 hospitals (Table 2). Table 3 presents the descriptive data. A total of 32% of PICU and high-risk hospitalizations were postoperative, with neurosurgery being the predominant surgical type, and 65% were emergency admissions. The primary

systems of dysfunction were neurologic, respiratory, cardiovascular, gastrointestinal, oncologic, and orthopedic. Only 2% of patients had orders for limitations of care at the time of the assessment. Comparison of the estimation and validation samples (Table 3) showed that these samples were very similar. Medications and physical restraints influencing or potentially influencing FSS scores were common (Table 4).

FSS Score Distribution and Association With ABAS II Scores

Figure 1 shows the relative frequencies of the FSS scores in the total sample. There was a wide range of functioning, ranging from normal in all domains (score of 6) to very severe dysfunction (maximal score of 30, with very severe dysfunction in all domains). The average FSS score was 10.3 ± 4.4 . A total of 18% of patients had FSS scores of 6, whereas 6% had scores of ≥ 20 , with the highest score being 29.

For assessment of associations with ABAS II scores and appropriate reweighting, the FSS scores were compared with the mean ABAS II scores for the estimation set. The average ABAS II score for the 570 estimation sample subjects was 6.8 ± 4.3 . Figure 2 shows the relationship between mean ABAS II scores and original FSS scores for the estimation set. The Pearson coefficient for the correlation between the mean ABAS II scores and the FSS scores was -0.58 ($P < .001$). Each FSS domain was highly significantly associated with the mean ABAS II score ($P < .0001$ for each FSS domain).

The relative importance of the cells in each FSS domain is shown as the mean ABAS II score for each cell (Table 5). According to these estimates, cells in each domain for the estimation set were reweighted (Table 6). The analysis resulted in collapsing of 2 cells (se-

TABLE 2 Location of Enrollment for Study Patients

	n (%)		
	All (N = 836)	Estimation Set (N = 570)	Validation Set (N = 266)
PICU	345 (41)	235 (41)	110 (41)
High-risk, non-PICU	340 (41)	230 (40)	110 (41)
Technology-dependent	151 (18)	105 (18)	46 (17)

TABLE 3 Characteristics of Study Patients

	All	Estimation Set	Validation Set
All study arms, <i>N</i>	836	570	266
Age, mean ± SD, y	6.8 ± 5.5	6.7 ± 5.4	6.9 ± 5.5
Female, <i>n</i> (%)	331 (40)	218 (38)	113 (42)
Race, <i>n</i> (%)			
Black	212 (25)	142 (25)	70 (26)
White	561 (67)	387 (68)	174 (65)
Asian	31 (4)	19 (3)	12 (5)
Other/unknown	32 (4)	22 (4)	10 (4)
Hispanic ethnicity, <i>n</i> (%)	140 (17)	91 (16)	49 (18)
Postoperative (<i>N</i> = 685), <i>n</i> (%) ^a	218 (32)	142 (31)	76 (35)
Neurosurgical, <i>n</i>	82	54	28
Orthopedic, <i>n</i>	34	24	10
Cardiac, <i>n</i>	30	20	10
Other, <i>n</i>	72	44	28
Emergency admission (<i>N</i> = 685), <i>n</i> (%) ^a	443 (65)	301 (65)	142 (65)
Primary systems of dysfunction, <i>n</i> (%)			
Cardiovascular	91 (11)	65 (11)	26 (10)
Gastrointestinal	59 (7)	44 (8)	15 (6)
Neurologic	284 (34)	203 (36)	81 (30)
Oncologic	62 (7)	42 (7)	20 (8)
Orthopedic	61 (7)	42 (7)	19 (7)
Respiratory status	155 (19)	91 (16)	64 (24)
Other	124 (15)	83 (15)	41 (15)
Limitation of care orders, <i>n</i> (%)	13 (2)	10 (2)	3 (1)
PICU length of stay, mean ± SD, d	4.5 ± 10.4 (<i>N</i> = 345)	4.6 ± 10.7 (<i>N</i> = 235)	4.3 ± 9.7 (<i>N</i> = 110)

^a This characteristic was not applicable to technology-dependent patients.

TABLE 4 Patient Care Factors Potentially Influencing Functional Status

	<i>n</i> (%)		
	All (<i>N</i> = 836)	Estimation Set (<i>N</i> = 570)	Validation Set (<i>N</i> = 266)
Sedative treatment within 24 h after assessment	77 (9)	55 (10)	22 (8)
Paralytic agent treatment in PICU	94 (11)	63 (11)	31 (12)
Narcotic treatment during hospitalization, before assessment	153 (18)	104 (18)	49 (18)
Movement-restricting arm boards	190 (23)	123 (22)	67 (25)
Restraints	17 (2)	16 (3)	1 (0.4)
Movement-restricting bandages or casts	34 (4)	29 (5)	5 (2)

Three subjects in the estimation set had missing data for the arm board, restraint, and bandage/cast factors.

vere and very severe) in the mental status domain and collapsing of 3 cells (moderate, severe, and very severe) in the sensory functioning, communication, and respiratory status domains. In the feeding domain, we collapsed the very severe and mild cells and also the moderate and severe cells. All cells were kept intact in the motor functioning domain. For each domain, the cells collapsed were consistent with the concept of adaptive behavior, as assessed with the ABAS II. For example, the cells for mental status (stupor and coma) affect adaptive behavior to sim-

ilar extents. The collapsing of mild and very severe in the feeding domain also was consistent with inpatient hospital practice of providing total parenteral nutrition to patients receiving nothing by mouth.

The collapsed and reweighted domains then had weights assigned according to the mean ABAS II value in each cell, referenced to a score of 1 for normal. The weighted FSS scores are shown in Table 6, with values ranging from 6 to 41.9. The maximal score is achieved in the very severe category in

all domains except for feeding, for which the highest score is in the severe category because of the collapsing of the mild and very severe feeding domain scores.

The performance of the original FSS and the weighted FSS is shown in Table 7 for both the estimation and validation data sets. Figure 3 shows the relationship between the mean ABAS II scores and the weighted FSS scores for the estimation set. The correlations between ABAS II and FSS scores improved with weighting, from -0.58 to -0.62 for the estimation sample and from -0.60 to -0.63 for the validation sample. The differences between the correlation coefficients for the original and weighted scores were highly statistically significant ($P < .001$) in both data sets. The ability of the FSS to discriminate between functional and dysfunctional patients also was assessed with ROC analysis by using 2 different classification cutoff points, representing 1 and 2 SDs below the general population ABAS II mean. The area under the ROC curve improved from the original FSS to the weighted FSS for both the estimation and validation samples. The weighted FSS showed significantly ($P < .001$) greater areas under the ROC curve for the estimation sample for both cutoff points and trends for greater areas under the ROC curve (ABAS II scores of ≤ 7 , $P = .11$; ABAS II scores of ≤ 4 , $P = .19$) for the smaller validation sample. In addition, FSS scores showed consistent, moderate/strong associations with ABAS II scores across levels of other patient factors examined, including age, elective/emergency status, operative status, patient type (PICU, high-risk hospital, or technology-dependent), and study site.

Reliability of the FSS

Table 8 shows the weighted κ values for the original FSS and weighted FSS

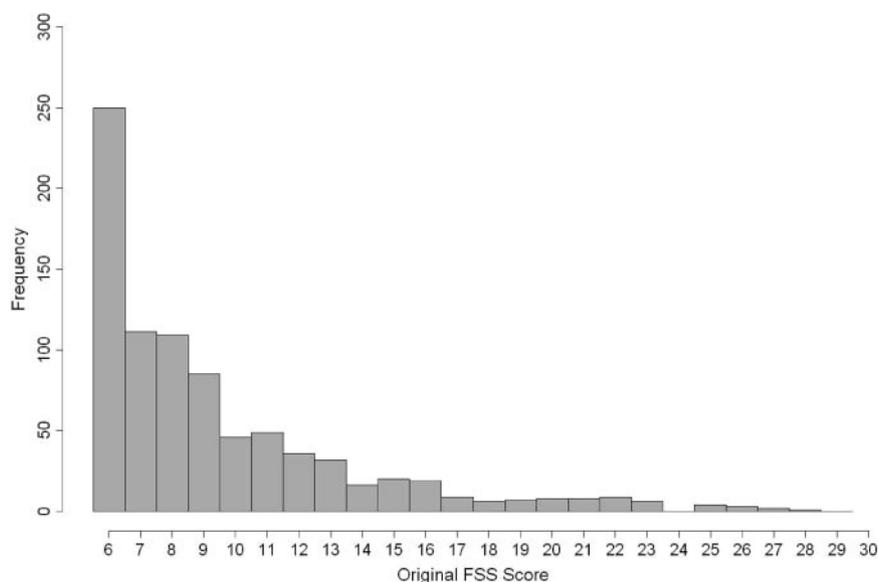


FIGURE 1
Distribution of original FSS scores in the overall studied population of 836 patients.

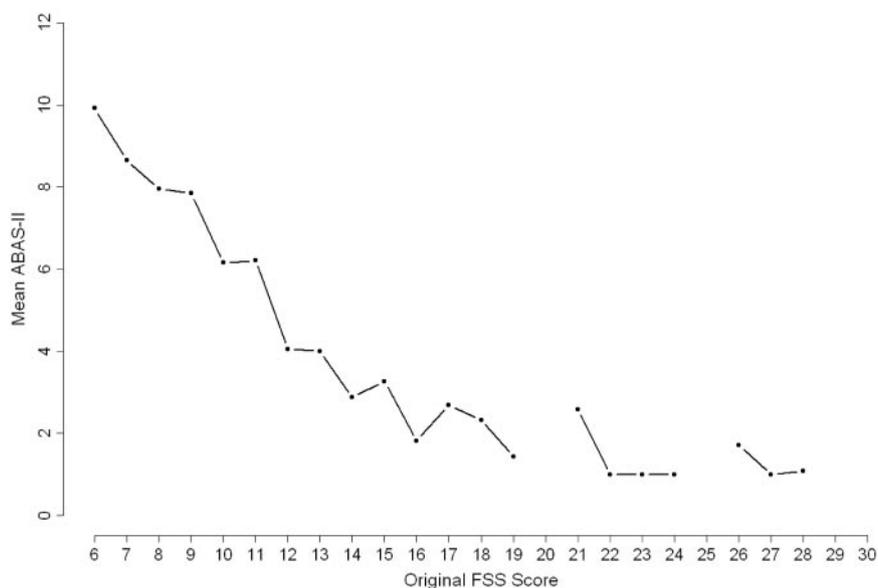


FIGURE 2
Mean ABAS II scores, according to original FSS scores, for the 570 patients in the estimation population.

scores for 97 subjects in the reliability analysis. The intraclass correlation for the original total FSS scores was 0.95, whereas the intraclass correlation for the weighted total FSS scores was 0.94, indicating overall high reproducibility. Domain-specific unweighted κ values ranged from 0.54 to 0.88 for the original FSS and from 0.52 to 0.89 for the weighted FSS components. Some of

the lack of agreement between the observers was undoubtedly attributable to real differences in patient status, because the coordinator and physician observations might have been performed up to 4 hours apart. For example, the worst κ values were noted for mental status, which corresponds in part to actual mental status changes associated with medications,

time of day, and improving patient status.

DISCUSSION

Our goal was to develop a scale that could measure functional status at any time, reflecting the dynamic state of disease and recovery, but was not intended specifically to predict long-term outcomes. The FSS is based conceptually on activities of daily living scales used in adult studies to characterize functioning, disability, and dependency.^{10,11} Because expectations for activities of daily living for children change with developmental stages, we used adaptive behavior. These measures approximate activities of daily living with developmental adjustments, and there is broad overlap in the skill sets identified by the 2 methods. For example, activities of daily living include personal self-care (feeding oneself, bathing, and toileting), mobility (moving from bed to a standing position or to a chair, walking with or without assistance, or using a wheelchair), and continence (with respect to urine and feces).¹² Adaptive skills include a repertoire of skills to meet the daily demands and expectations of the environment, including eating, dressing, expressing needs, communicating, and controlling behavior, as well as more-advanced skills.^{1,6} Because adaptive behavior assessment methods may not be appropriate for large outcome studies, because of the time and expertise required for test administration, we developed and validated the FSS to correlate with but not to duplicate adaptive behavior assessment. Our consensus process used the input from 7 types of health care professionals from 11 institutions to create the FSS domains and their gradations of dysfunction. The 7-institution study of 836 patients included a wide range of patients at high risk of functional disability. The correlation coefficients for

TABLE 5 ABAS II Values for FSS Domains

FSS Domain	ABAS II Score, Mean ± SE				
	None	Mild	Moderate	Severe	Very Severe
Mental status	8.3 ± 0.2	6.0 ± 0.3	4.1 ± 0.5	1.5 ± 0.9 ^a	1.1 ± 1.2
Sensory functioning	7.5 ± 0.2	4.6 ± 0.5	2.1 ± 0.9 ^a	1.4 ± 1.2 ^a	1.0 ± 1.8 ^a
Communication	8.7 ± 0.2	4.9 ± 0.3	1.6 ± 0.5 ^a	1.4 ± 1.1 ^a	1.3 ± 1.0 ^a
Motor functioning	8.5 ± 0.2	7.1 ± 0.3	5.5 ± 0.4	3.0 ± 0.7	1.5 ± 0.6
Feeding	8.7 ± 0.2	6.1 ± 0.3 ^b	3.7 ± 0.3 ^b	4.8 ± 1.0 ^a	6.7 ± 1.0 ^b
Respiratory status	7.5 ± 0.2	6.4 ± 0.5	2.9 ± 0.8 ^a	3.9 ± 1.0 ^a	3.7 ± 0.7

^a Adjacent categories subsequently collapsed in the weighted FSS.

^b Nonadjacent categories subsequently collapsed in the weighted FSS.

TABLE 6 Relative Values for FSS Domain Cells From Univariate Analyses

FSS Domain	Relative Value				
	None	Mild	Moderate	Severe	Very Severe
Mental status	1.0	3.3	5.2	8.0	8.0
Sensory functioning	1.0	3.9	6.8	6.8	6.8
Communication	1.0	4.8	8.2	8.2	8.2
Motor functioning	1.0	2.4	4.1	6.6	8.0
Feeding	1.0	3.5	5.9	5.9	3.5
Respiratory status	1.0	2.1	5.0	5.0	5.0

TABLE 7 Correlations of Original and Weighted FSS Scores With ABAS II Scores and Areas Under the ROC Curves for Predicting ABAS II Cutoff Points

	Correlation Coefficient		
	ABAS II	ROC Curve With ABAS II Cutoff Point of ≤4	ROC Curve With ABAS II Cutoff Point of ≤7
Original FSS, estimation sample	−0.58	0.83	0.79
Original FSS, validation sample	−0.60	0.82	0.86
Weighted FSS, estimation sample	−0.62	0.85	0.81
Weighted FSS, validation sample	−0.63	0.83	0.87

the FSS scores and adaptive behavior measured with the ABAS II were at least −0.58, similar to the correlations between different measures of adaptive behavior.⁶ We considered these correlations to be appropriate, because the FSS was not designed to duplicate adaptive behavior scores. In addition, all of the FSS domains were associated with the mean ABAS II scores ($P < .0001$ for each of the 6 FSS domains). Recognizing that the experts creating the FSS developed functional domains with a series of dysfunctional states that were not scaled appropriately, we created these relative weights statistically, with improved correlation between the weighted FSS and ABAS II scores. Perhaps the most

important aspect of performance was the FSS discrimination for moderate and severe decrements in adaptive behavior (areas under the ROC curve of 0.81 and 0.85, respectively, for the weighted FSS). Performance was stable in the estimation and validation sets, which is an important characteristic for study use. Finally, the reliability of the FSS was very good. The worst κ values were seen in the assessment of mental status, a difference that we think was real, because of the time delay between the 2 raters.

Although the FSS performed well, it is possible that subgroup-specific FSS versions could be constructed that would predict ABAS II scores more ac-

curately and would better summarize functional status within specific subgroups. For example, it is probable that the relationship between the FSS and the ABAS II is not linear across all degrees of dysfunction. A larger sample might have enabled us to better focus on subgroups and to better describe the relationship between the ABAS II and the FSS. Most notably, the study focused only on a specific group of hospitalized patients, and results should not be generalized to other populations without further study. Nevertheless, our study demonstrates that a single FSS instrument is strongly correlated with adaptive behavior across the spectrum of our patient population and this instrument is an appropriate tool to characterize functional status. Future studies may demonstrate that FSS scores at specific points in time correlate with long-term patient mortality and morbidity rates.

The FSS should expand the perspective of pediatric outcome studies. To date, large studies primarily used death as the outcome. Assessments of other outcome measures, including functional status and quality of life, generally have been too time-consuming for large studies, have been available or validated for only a limited age range, or require too much subjective assessment and future projection by raters.^{1–5} In addition, functional status is a very relevant ICU and hospital outcome. Although physiologic status often has been used to predict death,¹⁵ it also may result in functional status changes. For example, cardiovascular compromise may cause neurologic injury and/or may be associated with long-term cardiac compromise as well as death. A functional status assessment would enable studies of quality of care similar to those accomplished with tools such as the Pediatric Risk of Mortality score¹⁴ but using functional status as well as death as an outcome.

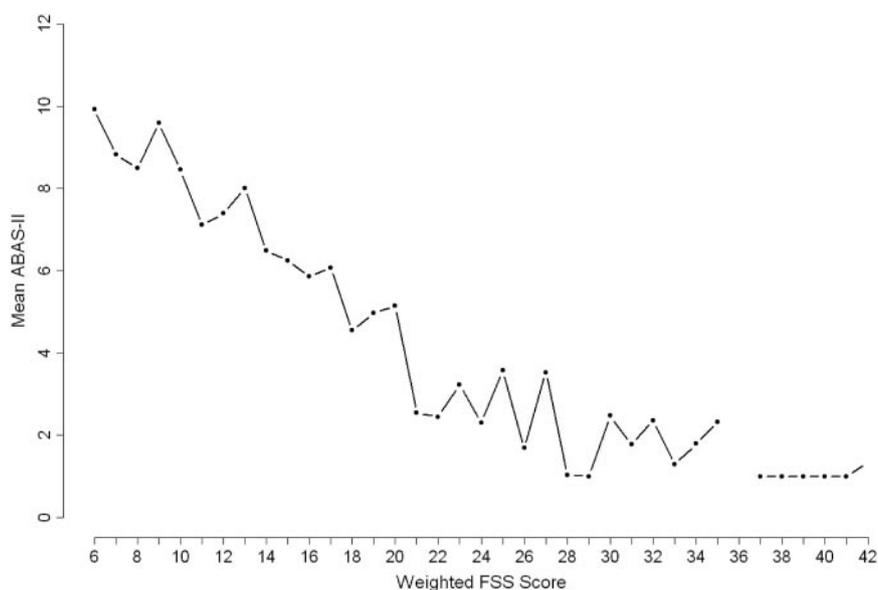


FIGURE 3 Mean ABAS II scores, according to weighted FSS scores rounded to the nearest integer, for the 570 patients in the estimation population.

TABLE 8 Weighted κ Values for Reliability of FSS Components

Domain	Weighted κ	
	Original FSS	Weighted FSS
Mental status	0.54	0.52
Sensory functioning	0.76	0.74
Communication	0.81	0.79
Motor functioning	0.78	0.80
Feeding	0.87	0.88
Respiratory status	0.88	0.89

Appropriate outcome measures often are the limiting factor for important and needed outcome studies.^{15,16} Outcome measures not only must be relevant to the study question but also must be applicable to the age range of the study, must be reliable within that age range, and must measure what they are purported to measure. The FSS is a significant advance for pediatric outcome studies. It is a well-defined, quantitative, rapid, reliable measure of functional status. Importantly, it is not dependent on subjective assessments. It is applicable to the pediatric age range, from term newborns to adolescents, and it is pertinent to hospitalized patients. The FSS is well suited for use in large pediatric outcome studies.

APPENDIX: FSS DEFINITIONS

Mental Status

Normal

Normal indicates normal sleep and wake periods and appropriate social responsiveness. Sleep refers to a restful state without overreaction (crying or 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 the environment.

Mild Dysfunction

Mild dysfunction indicates sleepy but arousable to noise, touch, or movement and/or periods of reduced social responsiveness. Individuals sleep more of the time than is age appropriate, sleep much of the time if left alone but can be aroused with stimulation such as noise, touch, or position changes, show decreased responsiveness to social overtures, and/or do not consistently focus or follow on a person or object crossing the line of vision.

Moderate Dysfunction

Moderate dysfunction indicates lethargic and/or irritable. Lethargic infants and children are drowsy, are 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 increased sensitivity to stimulation. Infants often react to stimuli with a high-pitched cry.

Severe Dysfunction

Severe dysfunction indicates 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 their eyes and focus, but they do not maintain any meaningful reaction to the physical environment. They make little or no eye contact. They respond to noxious stimuli with semipurposeful (ie, poorly organized) movements or withdrawal.

Very Severe Dysfunction

Very severe dysfunction indicates unresponsiveness, and/or coma, and/or vegetative state. These infants and children are unconscious. Coma is a deep or profound state of unconsciousness from which the infants and children cannot be aroused. They do not sense or respond to external stimuli or internal needs. Infants and children in a vegetative state have no evidence of awareness of self or the 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 Functioning

Normal

Normal indicates intact hearing and intact vision. Intact hearing is demon-

strated by individuals localizing/moving their eyes and/or head toward sound stimuli in the room. Intact vision is evidenced by individuals turning their gaze to focus on persons or objects that cross their visual field.

Mild Dysfunction

Mild dysfunction indicates 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

Moderate dysfunction indicates not reactive to auditory stimuli or not reactive to visual stimuli. There is lack of evidence of hearing or vision, as demonstrated by lack of focusing or localization of sound. Responsiveness to touch is not impaired.

Severe Dysfunction

Severe dysfunction indicates not reactive to auditory stimuli and not reactive to visual stimuli. There is lack of evidence of hearing and vision, as demonstrated by lack of tracking and localization of sound. Responsiveness to touch is not impaired.

Very Severe Dysfunction

Very severe dysfunction indicates abnormal responses to touch. Infants and children have abnormal responses to touch or pain, as evidenced by the absence of purposeful or semi-purposeful movements. There may be withdrawal or a spinal response.

Communication

Normal

Normal indicates vocalization appropriate for age and interactive facial expressions or gestures. Infants make sounds to make their presence known. Children use words to convey their needs. Interactive facial expressions and gestures represent a process of

nonverbal communication, often closely associated with emotions.

Mild Dysfunction

Mild dysfunction indicates diminished vocalization or diminished social expression (facial or verbal). There are decreases in socialization and social expression.

Moderate Dysfunction

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

Severe Dysfunction

Severe dysfunction indicates no demonstration of discomfort. Infants and children do not cry or cry very little during painful procedures or if they are uncomfortable.

Very Severe Dysfunction

Very severe dysfunction indicates absence of communication. There is no communication using facial expressions, body posture, or voice. There is no communication regarding physiologic or psychological needs.

Motor Functioning

Normal

Normal indicates coordinated body movements, 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 (eg, infants kick their limbs and vocalize when their parents enter). Infants can hold a rattle and transfer it from one hand to the other. Toddlers carry objects, hold onto stuffed animals, or suck their thumbs. Children write or play with toys.

Mild Dysfunction

Mild dysfunction indicates that 1 limb is functionally impaired. There is partial or complete loss of functionality of the limb. Impairment may be attributable to medical devices such as restraints, intravenous fluid boards, bandages, or casts or to physical issues such as deformities, weakness, stiffness, spasticity, and/or movement disorders. Weakness is demonstrated when infants and children are able to move a 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 ≥ 1 limb has increased resistance to passive motion but is held in normal positions or postures. Stimulation does not result in flexion, extension, or arching.

Moderate Dysfunction

Moderate dysfunction indicates that ≥ 2 limbs are functionally impaired. There is partial or complete loss of functionality of ≥ 2 limbs. Impairment may be attributable to medical devices such as restraints, intravenous fluid boards, bandages, or casts or to physical issues such as deformities, weakness, stiffness, spasticity, and/or movement disorders. Weakness is demonstrated when infants and children are able to move a 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 ≥ 1 limb has increased resistance to passive motion but is held in normal positions or postures. Stimulation does not result in flexion, extension, or arching. Spasticity is abnormally increased muscle tone with involuntary movement. The limb feels tight and rigid, and limb reflexes are exaggerated. There is resistance to bending, and the neck is hyperextended.

Severe Dysfunction

Severe dysfunction indicates poor head control. Head control is poor, with decreased ability to hold the head upright at 90°. The individual cannot hold the head still at <90°. If the trunk is supported, then the head falls back, to the side, or to the front. The individual is unable to bring the head to the upright position if sitting or to the midline if in the supine or prone position.

Very Severe Dysfunction

Very severe dysfunction indicates paralysis or decerebrate/decorticate posturing. Paralysis is the loss of voluntary motor function. There is abnormal muscle tone. Mental status may be preserved or altered. Decerebrate posturing consists of rigid extension of all extremities, with internal rotation. There is downward pointing of the toes. Decorticate posturing consists of rigid flexion of the upper extremities, with clenched fists, and extension of the lower extremities.

Feeding

Normal

Normal indicates the all food is taken by mouth, with age-appropriate help. There is no parenteral or gavage feeding. Feeding methods are age appropriate. The energy content is not part of this category.

Mild Dysfunction

Mild dysfunction indicates nothing by mouth or oral feedings with increased energy density/food. There is no parenteral or tube feeding. Dextrose solutions of $\leq 5\%$ are not included in parenteral feeding. Increased-density oral feedings involve special formulas and/or additions to the diet.

Moderate Dysfunction

Moderate dysfunction indicates a need for age-inappropriate help with feeding. This consists of feeding by a caretaker when independent feeding is ex-

pected or use of a feeding aid (eg, bottle) at an inappropriate age.

Severe Dysfunction

Severe dysfunction indicates use of a feeding tube, with or without parenteral nutrition. Parenteral nutrition includes nutrition administered intravenously through a peripheral or central vein, with a dextrose concentration of $>5\%$; it usually includes fat and protein. Tube feedings involve nasogastric, orogastric, or small-bowel tubes.

Very Severe Dysfunction

Very severe dysfunction indicates all parenteral nutrition. Parenteral nutrition includes nutrition administered intravenously through a peripheral or central vein, with a dextrose concentration of $>5\%$; it usually includes fat and protein.

Respiratory Status

Normal

Normal indicates breathing of room air and no artificial support or aids. Infants and children breath room air without the need for artificial help (eg, suctioning, oxygen administration, or mechanical support).

Mild Dysfunction

Mild dysfunction indicates oxygen administration and/or suctioning. Oxygen is administered through any apparatus (eg, blow-by system, cannula, or face mask). Suctioning includes any oral or tracheal suctioning.

Moderate Dysfunction

Moderate dysfunction indicates tracheostomy.

Severe Dysfunction

Severe dysfunction indicates continuous positive airway pressure treatment for all or part of the day and/or mechanical ventilator support for part of the day. Continuous positive airway pressure treatment may be adminis-

tered through a face mask or tracheostomy. Mechanical support includes positive or negative pressure ventilation devices such as bilevel positive airway pressure and positive pressure mechanical ventilation systems.

Very Severe Dysfunction

Very severe dysfunction indicates mechanical ventilatory support for all day and night. Mechanical support includes positive or negative pressure ventilation devices such as bilevel positive airway pressure and positive pressure mechanical ventilation systems.

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