Collaborative Pediatric Critical Care Research Network

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

Overview of Public Use Datasets

This document provides an overview of the general principles used in creating the public use datasets (PUDs) for the *Eunice Kennedy Shriver* National Institute for Child health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) FSS Study. There are a total of 8 datasets available as both CSV and SAS® (.SAS7BDAT) files (with formats and labels). Accompanying documentation and resources provided include the study protocol, the annotated eCRF, and, for each dataset, a PDF document summarizing variables in the associated dataset (i.e., frequency distributions or descriptive statistics). For SAS software users, an example script to set up the SAS library and apply SAS formats is also provided. The annotated CRF should be referenced frequently during analysis as this is the most complete reference of all variables included in each dataset. Please see the attached Research Data Use Agreement (RDUA) for a description of intended use and disclaimer.

GENERAL NOTES RELATED TO CREATION AND USE OF DATASETS

1. The population for the PUDs is all patients enrolled and included in the primary study analyses (n=836). See the protocol for a detailed list of inclusion/exclusion criteria and for additional details of study conduct including data collection schedule. Patients were excluded from the public use dataset if no ABAS II assessment was performed.

2. The datasets are primarily based on raw data as collected by the clinical sites. All variables are described in the annotated eCRF. Note that many of the available datasets include only one record per patient (unique identifier *subjectID*). Other datasets are relational, that is, may have more than one record per patient. The annotated eCRF provides information as to the structure of each dataset and the unique identifier for each record.

3. Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed. Dates have been recoded to represent time intervals relative to the FSS assessment.

4. Catastrophic events were originally collected on logs that allowed multiple entries per patient. However, for this cohort, no more than one catastrophic event was entered per patient per log. Thus all catastrophic event information is included in the patient-level datasets.

5. Of note when utilizing the mean ABAS II score (*mean_abas*), the original ABAS II instrument has 10 skill areas that are scaled to age-normalized performance, with each scaled skill area having a mean of 10 and a standard deviation of 3. Because not all skill areas were relevant to hospitalized children, we assessed only selected skill areas in the FSS study. 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 mean ABAS II score was calculated as the mean of all skill area scores available for a participating child.

LIST OF DATASETS AVAILABLE

- Demographics (DEMOGRAPHICS)
- PICU Patient (PICU)
- High Risk Non-PICU Patient (NONPICU)
- Technology Dependent Patient (TECHDEPENDENT)
- Functional Status Scale (FSS)
- Functional Status Scale – Medications Altering FSS (FSSMEDS)
- Functional Status Scale – Factors Altering FSS (FSSFACTORS)
- Functional Status Scale – PI Assessment (FSS_PI)