

NINDS CDE Project
Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)
Quality of Life/Functional Status (CPET)/Activity Subgroup

In making their recommendations, the subgroup considered the experiences of patients living with ME/CFS and also the experiences of medical professionals who treat ME/CFS patients in their practices. One member of the subgroup is a person living with ME/CFS.

The subgroup considered the following factors related to the burden and/or acceptability of instruments to people with ME/CFS: the length of time required to administer each instrument was considered to reduce the burden on patients, and instruments were carefully considered to assess their limitations so that the recommendations highlight the situations where each instrument would/wouldn't be useful.

The subgroup also considered the appropriate population to recommend for each of the instruments and CRFs as shown in the table below. CPET testing yields numerous variables that are compared against well-established age and sex normative values for adults. CPET results from testing, particularly, pre-adolescent children are influenced by a combination of factors that include current fitness level, physical and physiological maturation, and illness status. Maturation status varies considerably by age and sex in prepubertal children making comparisons of CPET results against age and sex normative values less valid than in the adult population. For this reason, the value of CPET testing a pediatric patient may not outweigh both the risk and low validity of comparison with normative data.

Due to the limits of the currently available instruments, the subgroup did not feel that the recommendations capture the diversity and complexity of ME/CFS presentations. For example, severely affected patients are likely not represented in most of the currently-available instruments. The recommendations made here represent the best options of those that are currently available, but the subgroup feels that there is room for improvement in this area so that all the different presentations of ME/CFS can be captured. There is a need for an instrument that accomplishes all of these criteria:

- differentiates between physical and cognitive function
- separates mental health from physical health
- is easy to administer
- validated in ME/CFS to differentiate between patients
- captures patients who are severely affected
- validated across diseases to differentiate between patients with ME/CFS and patients with other conditions
- captures the cyclical nature of ME/CFS symptoms, not just a single point in time

Recommendations Summary Table

Instrument/CRF Name	Population	Classification
Cardiopulmonary Exercise Testing (CPET)	Adult	Supplemental
Short Form 36 (SF-36)	Adult	Supplemental
Functional Disability Inventory (Child and Adolescent Form)	Pediatric	Supplemental
Functional Disability Inventory (Parent Form)	Pediatric	Supplemental
Activities of Daily Living	Adult	Exploratory
Bell Scale	Adult	Exploratory
Euro-QoL	Adult and Pediatric (Age Range: EQ-5D adult version – 16+ EQ-5D-Y 8-16)	Exploratory
Health Related Quality of Life (HRQoL)	Adult (Age Range: HRQOL-4 – 12+)	Exploratory
Karnofsky Performance Scale	Adult (Age Range: 16+)	Exploratory
World Health Organization Disability Assessment Schedule (WHODAS)	Adult (Age Range: 18+)	Exploratory
Child Health Questionnaire	Pediatric	Supplemental- Highly Recommended