Minimum Data Elements for Research Reports on CFS

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Problem we Confront

- Variability in CFS research highlighted at the NIH's 2011 State of the Knowledge of CFS meeting
- Prompting researchers to consider the critical information that should be included in CFS research published reports
  - Deal with difficulties comparing data collected in different laboratories
    - variability in basic information regarding descriptions of:
      - sampling methods
      - patient characteristics
      - clinical assessments

Currently

- Limited clinical and laboratory information is presented in CFS scientific articles
- Available checklists for describing phenotypes have considerable overlap contain
  - arbitrary variations in wording and structuring
  - are applied inconsistently
- Need for improved standardization procedures and increased communication across research groups

Work completed since June

- Our group is working toward developing a consensus on the minimum data elements that should be included in all CFS research reports
- These recommendations are intended to improve the consistency of reported methods and the interpretability of reported results
- Adherence to minimum standards and increased reporting consistency will allow for
  - better comparisons among published CFS articles
  - provide guidance for future research
  - foster the generation of knowledge that can directly benefit the patient

Need for Minimum Reporting

- Biomedical communities now developing minimum reporting guidelines for publication of scientific articles
  - Minimum Information for Biological and Biomedical Investigations (MIBBI) project
    - compilation of "minimum information checklists" that outline the key information needed for reporting results of experimental studies using specific techniques
    - fMRI studies or studies using cellular assays
      - (Taylor et al., 2008)

Framework

- Our work will provide a framework for improving consistency of what is reported in CFS research articles
  - ensure that appropriate scientific standards are met
- We will suggest validated instruments and procedures that could help build consensus with respect to research methods reported in journals

Essential Elements 1

- We recommend that as many of the following tests/criteria as possible be included in order to better define and standardize patient populations between studies
- Domains that should be reported in articles with CFS samples are labeled
  - I Essential Elements

Case Definitions

- Fukuda et al. (1994)
  - Reeves et al. (2005)
- Carruthers et al. (2003)
- Carruthers et al (2011)
- London criteria (Dowsett, Ramsay, McCartney, & Bell, 1990)

Study Design

- Type of study:
  - case-control
  - case-only
  - cross-sectional
  - longitudinal
- Randomization protocol
  - when employed
- Primary and secondary outcomes
- Site and method of recruitment
- Time-frame
  - specific dates and time intervals when data were collected
- Language or languages used to collect data
- Statistical methods for primary and secondary analyses

Exclusionary Medical Conditions

- List medical conditions considered exclusionary
- List medical conditions considered co-morbid
  - not exclusionary
- Method of identifying medical conditions
- Laboratory tests and cut-off values for exclusion

Demographic Characteristics

- Age, race, ethnicity
- Education
- socioeconomic status (SES)
- Body mass index (BMI)
- Marital status and children
- Living arrangements
  - number and relationship of others in home
- Employment status
- Insurance status
- Disability status
- Mode of onset
  - acute
  - gradual
  - definition used to determine mode of onset
- Duration of illness
- Exacerbating factors and triggers

Self-Reported Functional Impairment and Physical Activity

- Medical Outcomes Survey Short Form-36, Short Form-12, Sickness Impact Profile (SIP)
- Validated instruments for the assessment of physical activity behaviors
  - International Physical Activity Questionnaire (IPAQ)
  - The Seven-Day Physical Activity Recall Questionnaire

Symptom Inventories

- Include all case defining symptoms:
  - frequency and severity
- Sleep
  - Epworth, other standardized questionnaires
- Pain Scales

II Additional Elements

- A larger battery of tests and criteria are labeled as II Additional Elements
- CFS researchers can not include all of these in their articles
- May be useful for guiding researchers interested in specific areas of CFS research
  - brain
  - immune
  - autonomic nervous system

Allergies

- Allergies include specific IgE measurements either by skin test or *in* vitro assessment of inhalant allergens:
  - pollens
  - molds
  - dust mites
  - animal dander

Much Work to Still be Done

- CFS researchers need to agree on the use of standardized and valid instruments
- We hope that our work helps
  - bring greater attention to this factor
  - promotes increased collaboration among investigators
  - facilitates agreement upon minimum standards for reporting findings