Medical Education & Research Case Definition Discussion

Chronic Fatigue Syndrome Advisory Committee
January 13, 2017
Medical Education Discussion
Medical Education: Fundamental Problems

- ME/CFS patients are often unable to access quality clinical care.
- Patients report dismissal by medical professionals and harm from inappropriate recommendations.
- On average, it takes 4 years to get a diagnosis.
- Mainstream online clinical guidance is inaccurate, misleading, and in some cases, harmful.
- Less than 1/3 of medical schools include ME/CFS specific information in the curriculum and only 40% of medical textbooks include ME/CFS.
Medical Education: Basic Needs

Medical professionals and care providers MUST:

- Improve their attitudes towards this disease
- Understand the basics of ME/CFS
- Have easily accessible clinical guidance that reflects the knowledge and best practices of disease experts
- Understand flaws with existing literature
Medical Education: Challenges

Curriculum / material development
- CDC developed and released educational videos earlier this month with no input from 1) the patient community 2) ME/CFS stakeholders 3) CFSAC – when can CFSAC review?

Persistent stigma / misunderstanding
- This is a biological, NOT PSYCHOLOGICAL illness
- Current platforms and validation for views not based in science

No funding to develop and disseminate materials

Bad Science continues to stagnate progress
- Incorrect statements and recommendations drawn from poor case definitions/wrong disease theories (eg. PACE)
Key Issue: Content of materials

- Experts MUST be involved in review and final approval before release of content
- Phasing out Fukuda and/or clear separation of ME/CFS patients from “chronic fatigue” patients
- Diagnosis
- Treatment recommendations
- Stop including inappropriate disease and treatment information
Key Issue: Dissemination of material

A plan to address stigma
- CDC needs to take a public, and proactive position on PACE-style CBT/GET, Oxford, psychogenic disease theories

Plan for active dissemination and outreach to major medical associations
- Needs to include presentation by disease experts at conferences. 2017 conferences are already set – Plan funding and schedule now for 2018

Partner with medical education providers and premier clinics to correct disease misinformation
- Correcting CDC website is not enough, particularly since CDC is only updating its diagnostic information.
Discussion: What else need to happen for success?

- Increase number and accessibility of experts especially critical as disease experts are nearing retirement.
- Fix the ICD code
- Plan for Fukuda patient transition
- Evolve disability guidelines
- Assess and address insurance issues
Medical Education: Discussion

- AHRQ – big first step with addendum
  - what happens next?
- HRSA – “Objective 2.1: Advance the competencies of the healthcare and public health workforce”
  - Can ME/CFS medical education fit into this objective?
- CDC – Information Source & Dissemination
  - What successful education efforts (HIV/AIDS?) can we model a new ME/CFS education plan after?
  - Must include proactive outreach plan to debunk stigma and correct misinformation
Research Case Definition
Discussion
Research Case Definition:
Fundamental Problems

20 different case definitions
- Fundamental differences in inclusion/exclusion criteria
- Specificity problem – e.g. Fukunda – 163 combinations of its “4 of 8” symptoms but only 35 include PEM

Results in muddled evidence base
- Limited comparability across studies and inappropriate clinical guidance (e.g. PACE)

2015 P2P report stated “‘Variability in inclusion and exclusion criteria such as the case definition... has significantly hampered progress.”
Research Case Definition: Current

HHS Plans to Address

- Federal Partners’ Report stated “more research is needed before a case definition can be established.”
- Plan is to instead establish common data elements (CDE) to increase comparability
  - Will standardize what data is collected and how.
  - Does not establish core inclusion and exclusion criteria
- Proposal is if CDEs used, it won’t matter what definition is used
- Rationale is that analytics can slice and dice
Research Case Definition: Concerns with HHS approach

- Perpetuates current problems with evidence base

- CDE alone are not sufficient - ME/CFS cohorts will include patients who do not have the disease
  - Requiring data to be collected on presence/absence of PEM not same as requiring PEM be present for a diagnosis
  - Particular concern as new researchers enter field

- Limits of analytics to sort through ill-defined cohorts

- Many studies globally will only be accessed through published literature
Research Case Definition: Proposal

CFSAC recommend HHS’s CDE initiative first convene and consult researchers to reach consensus on research case definition(s) to select ME/CFS patients

- Could include e.g. choice of CCC or ME-ICC – numerous publications, intramural already doing so
- At minimum, agree to core inclusion/exclusion criteria
- Also agree to what research case definitions will no longer be used because they lack specificity
- Agree to how IOM criteria would be used in research (IOM currently has no exclusion criteria)
Research Case Definition: Discussion

- Concerns with approach
- Recommendation to address
- Move the field of ME/CFS research forward