Justifying ME/CFS Centers of Excellence: The Choices

Kenneth J. Friedman, Ph.D.
Presentation Of A Work In Progress
COE Working Group/Justification Sub-Group
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CFS/ME Centers of Excellence are needed because:

ME/CFS is an illness that:

- lacks a precise case definition
- is difficult to diagnose/no biomarker
- Is difficult to manage (treat)
- has no known therapeutic agent
- is misunderstood or not recognized by many healthcare providers
- is not part of medical school curriculum
- lacks current CME courses (physician education)
- under treated or not treated in many parts of the U.S.

CFS/ME Centers of Excellence are needed because:

- With 30 years of:
  - imprecise case definition,
  - difficulty in being diagnosed and treated,
  - no known therapeutic agent,
  - not being recognized or treated by many healthcare professionals,
  - little medical student and/or physician training, and
  - lack of access to treatment in many parts of the U.S.

- ME/CFS patients constitute *a medically underserved population.*

Rectification of the lack of adequate care for ME/CFS patients requires:

- healthcare provider education,
- lay public education,
- improved clinical care, and
- the research to improve
  - diagnosis,
  - illness management,
  - development of therapeutic agents, and
  - an eventual cure.

COE’s will provide the best possible care for ME/CFS patients because:

- ME/CFS Centers of Excellence represent an efficient way to provide the care and perform the necessary research and
- we have identified 11 arguments or justifications demonstrating that COE’s fulfill unmet needs of the underserved ME/CFS community.

Justification #1: Demonstrated Need for NEI Centers

- Incorporation of similar illnesses into ME/CFS COE’s is a more efficient way to study similar illnesses.
- ME/CFS is a chronic illness that involves the nervous, endocrine, immune and cardiovascular systems.
- There is overlap of ME/CFS with Fibromyalgia, Gulf War Illness, Lyme Disease and Multiple Chemical Sensitivity.
- The concept of studying these diseases together and establishing a NeuroEndocrineImmune (NEI) Center was unanimously approved by the NJ House of Assembly and passed the NJ Senate with 1 abstention.

Justification #2: ME/CFS COE's fulfill the goals of the CDC's CFS Awareness Campaign

- Goals of CDC's *CFS Awareness Campaign,* announced on November 3, 2006, are to:
- make "available information and resources for people affected by an illness that affects more than 1 million Americans – 80 percent of whom have not been diagnosed."
- "educate the American public and health care professionals about who is at risk, the symptoms of the illness, treatment and management options, the importance of seeking diagnosis and treatment, and the impact of the illness on both patients and family members."
  - http://www.cdc.gov/news/2006_11/cfs.htm (11/28/14)

Justification #3: ME/CFS COE's support the findings & recommendations of the NIH CFS State of Knowledge Workshop

3. The CFS State of Knowledge Workshop, held April 7-8, 2011, reached the following conclusions:

   1. There is much misunderstanding about the illness; discrimination against patients and the researchers who study the illness.
   2. More interdisciplinary research is needed.
   3. There is a need to attract more researchers to the field of ME/CFS.
   4. There is a need for translational research – from bedside to bench and back again.

Justification #4: 94.4 % of Medical Schools do not have adequate ME/CFS Curriculum Content

- A 2013 Medical School Curriculum Study found that 94.4 % of the medical schools surveyed did <u>not</u> adequately satisfy research, clinical, and curricula criteria for ME/CFS.
- "While the current study is preliminary, it points to significant gaps in the coverage of CFS among medical institutions, which is likely impacting the ability of physicians to fully acknowledge, understand, effectively treat, and find a cure for CFS."

T. Mark Peterson, D.D.S, Thomas W. Peterson, D.D.S., Sarah Emerson, B.S., Eric Regalbuto, Meredyth A. Evans, M.A.,*, Leonard A. Jason, Ph.D. (2013) Universal Journal of Public Health 1(4): 177-179, *Coverage of CFS within U.S. Medical Schools*

Justification #5: Medical Student request for increased ME/CFS coverage for healthcare students

In response to the 2014 NJCFSA Medical Student Scholarship question asking applicants if the name CFS should be changed, a 3rd year medical student wrote:

"*There needs to be a change in the way healthcare students are educated, to prevent the waste of resources and time that precedes the diagnosis of ME/CFS*."

Justification #6: The ME/CFS COE's we propose are similar to currently solicited COE proposals

1. DHHS/NIH/National Center for Complimentary and Alternative Medicine- Third Strategic Plan 2011-2015 solicits applications for COE's that:
   - advance research
   - increase understanding
   - improve capacity for rigorous research
   - develop evidence-based information
   - develop multidisciplinary research teams
   - support synergistic research

Justification #6: The ME/CFS COE's being proposed are similar to currently solicited COE proposals

DHHS/NIH/National Institute of Drug Abuse is soliciting COE proposals until 9/25/15 that:

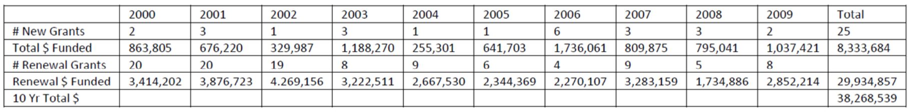
- research on any area within mission
- outstanding, innovative science
- multidisciplinary, thematically integrated, synergistic
- resource for education and outreach
- support education, training, and mentoring of new investigators
- share data and resources to further research

Justification #7: Fulfils the Intent of the PHS Act of 3/13/2013

- The Public Health Service Act of March 13, 2013:
  - mandates the treatment of medically underserved populations. [Declare ME/CFS patients a medically underserved population. (?)]
  - authorizes the Director of the Institute of Allergy and Infectious Diseases[1] to make grants or enter into contracts for the development and operation of CFS centers.
    - [1] Anthony Fauci, Current Director of NIAID

Justification #8: ME/CFS is an under-funded illness.

NIH extramural funding for years 2000 through 2009:

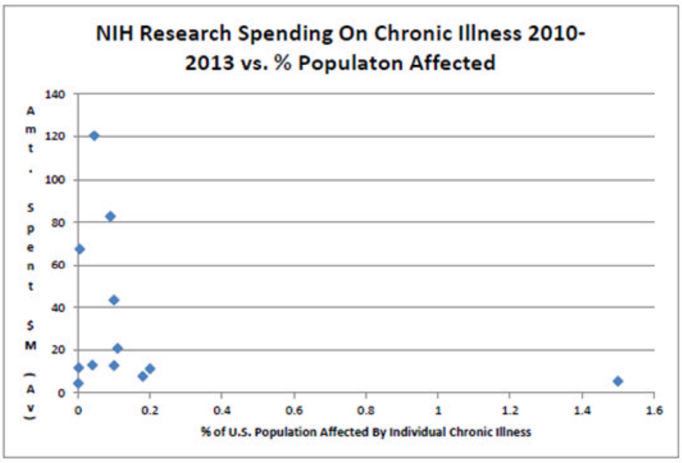


	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
# New Grants	2	3	1	3	1	1	6	3	3	2	25
Total $ Funded	863,805	676,220	329,987	1,188,270	255,301	641,703	1,736,061	809,875	795,041	1,037,421	8,333,684
# Renewal Grants	20	20	19	8	9	6	4	9	5	8	
Renewal $ Funded	3,414,202	3,876,723	4.269,156	3,222,511	2,667,530	2,344,369	2,270,107	3,283,159	1,734,886	2,852,214	29,934,857
10 Yr Total $											38,268,539

For the 10-year period of 2000 – 2009, the total expenditure of NIH for extramural ME/CFS grants (both new and renewals) was $38,268,539 which is an average of $3.8 M/year.

Justification #8: ME/CFS is an under-funded illness.

- Plot % U.S. Population Affected vs Average Amount Spent/Year 2010-2013 for low incidence, chronic illnesses.
- Data point in lower right of plot represents ME/CFS



Justification #9: ME/CFS is an under-researched illness.

10. Justify by the low number of research publications/lack of growth in # of research publications.

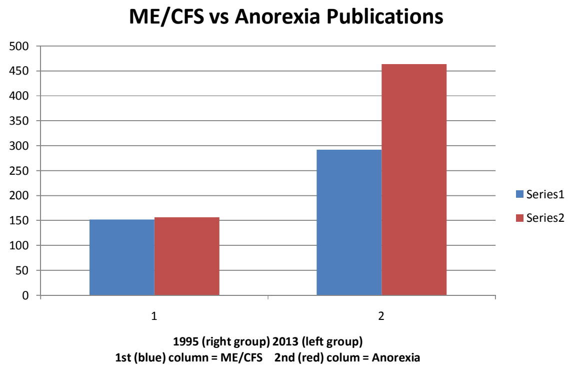
    For an illness that affects 1.5 million people

    - In 1995 < 200 publications
    - In 2013 ~ 325 publications

      (Publications listed in PubMed with “CFS” in the title)

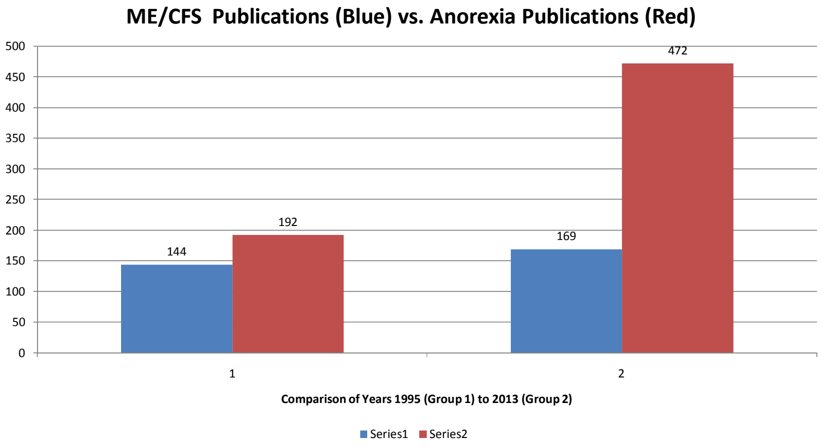
Justification #9: ME/CFS is an under-researched illness

- Compare to Anorexia an illness that affects 63,200 patients (~1/3 that of ME/CFS).



Justification #9: ME/CFS is an under-researched illness

of Studies With ME/CFS or Anorexia Appearing in Title in the Scopus Data Base



Justification #10: P2P Goals for ME/CFS are the goals of a COE

Susan Maier's[1] overview of the goals of the Pathways to Prevention Program for ME/CFS stated:

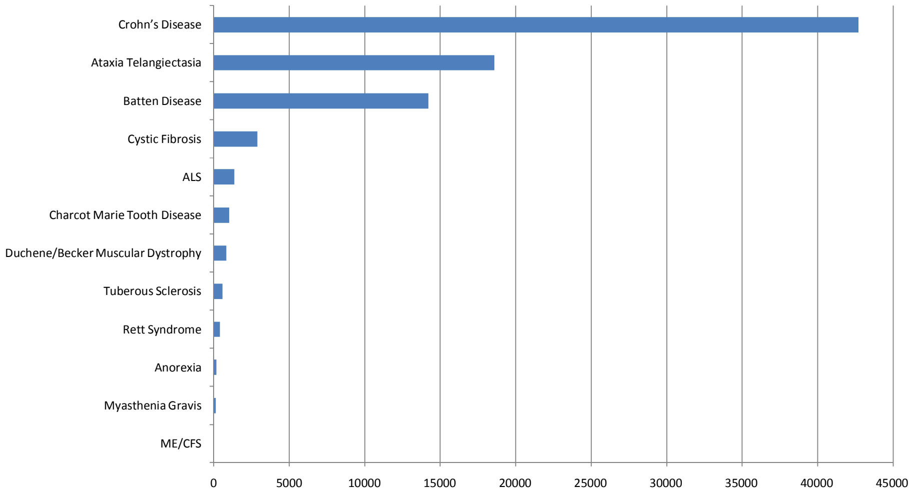
- There is no confirmed ME/CFS etiology.
- There is no FDA approved treatment.
- There is a lack of understanding of the illness in the general population.
- There is lack of agreement on the name of the illness.
- There is disagreement on the type of research to be funded. (The P2P leans toward exercise and behavior modification.)
- Few medical professionals recognize the illness as being real.
- There is little proactive education of PCP's.
- There is limited research funding; private and public.
  - [1] Deputy Director of the NIH Office of Research on Women's Health

Justification #11: Disparity in Funding for ME/CFS in comparison to other chronic illnesses

Justify by the disparity in funding of ME/CFS in comparison to other chronic illnesses.

- For the years 2010 to 2013, an average of $11.16 was spent per ME/CFS patient.
- For the same years, $18,591.77 was spent per Ataxia Telangiectasia patient.
- There are an estimated 474,000 ME/CFS patients in the U.S. while there are an estimated 632 Ataxia patients.
- NIH spent 1,666 times more money on each Ataxia patient that on each ME/CFS patient..
  - *How do you justify the disparity?*

Justify By Proposing Spending An Equal Amt. on Research For All Patients With Chronic Illness: Average Funding/Patient/Year 2010-2013



700.000 Crohn's Disease Patients vs. 1,000,000 ME/CFS Patients

Conclusion

- 11 arguments have been presented which justify the creation of ME/CFS COE's.
- Some arguments may be viewed as being stronger than others.
- The COE Working Group, as a whole, should decide which arguments it wishes to use.
- The arguments presented here may not be an exhaustive list.
- Additional arguments are welcome from CFSAC Members and from the public.
  - Contact kenneth.j.friedman@gmail.com

THANK-YOU!

I appreciate the opportunity to serve.
I appreciate the opportunity of working with you.
I appreciate the opportunity to be heard.