An estimated 836,000 to 2.5 million Americans have ME/CFS.

ME/CFS affects four times more women than men.

25% of ME/CFS patients will become bedbound or housebound in their lifetime.

ME/CFS can strike anyone at any time; Onset is reported from ages 10 to 80.

Up to 91% of patients are undiagnosed; Nearly all are initially misdiagnosed.

The cause of ME/CFS is unknown.

There are NO FDA-approved treatments available.

We have POOR grasp of the natural history of ME/CFS; No large-scale studies.

Many Challenges for ME/CFS:
- Misinformation and antagonism
- Lack of critical mass of researchers
- Insignificant funding for research
- Several diagnostic criteria
- Elusive etiology
- Lack of FDA approved drugs
- Absent Pharma investment
- Insurance and ICD coding databases
- Hard career path for researchers
- No feasible biomarkers
- Poor grasp of Natural history
- Minimal patient support

The Cardinal Problem: Severe knowledge Gap

Number of Peer-Reviewed Research Publications by Disease, 1940 to Present

- ME/CFS
- Chronic Fatigue Syndrome
- Myalgic Encephalomyelitis
- Influenza
- HIV/AIDS
- Diabetes
- Asthma
- Depression
- Autism

The Invisible Health Crisis: ME/CFS

(MYALGIC ENCEPHALOMYELITIS (ME), commonly referred to as CHRONIC FATIGUE SYNDROME (CFS), is a chronic, complex, systemic disease that profoundly limits the health and productivity of afflicted patients.)

Source: Institute of Medicine (IOM) – February 2015

The visible needs of ME/CFS - May 18, 2017

Insignificant funding for research
Lack of critical mass of researchers
Misinformation and antagonism
Lack of FDA approved drugs
Elusive etiology
Several diagnostic criteria
Hard career path for researchers
No feasible biomarkers
Poor grasp of Natural history
Minimal patient support
Descriptive (Hypothesis-generating)
- Observations
- Natural history
- Omics data

Mechanistic (Hypothesis-driven)
- Etiologies (mol basis)
- Causality
- Cell Signaling

Therapeutic
- Safe
- Effective
- Feasible

All three research domains must cross-talk towards a better understanding of ME/CFS

Shortage in Descriptive, Mechanistic and Therapeutic Studies in ME/CFS

"was unable to define subgroups of patients or even to clearly define the natural history of the disease"
IOM report, 2015

Myth #1: Blood test came back normal!

"The results of standard laboratory blood tests all came back normal!"

In fact, some standard laboratory tests do distinguish cases from matched healthy control subjects.

More important, newer technologies (metabolomic, immunologic) reveal other clear differences between cases and controls, as shown next.

Fact: Blood testing using personalized, modern analysis reveal serious abnormalities

With the Metabolon team and collaborators
Fact: Quality of Life for Patients with ME/CFS ranks the lowest when compared to other devastating diseases.
The Controversy Surrounding ME/CFS

The central question: Given that CFS/ME is defined exclusively by symptoms, are there underlying objective biological abnormalities?

The Science And Policy Paradigm: Towards More Ladders And less Chutes!

Ladders
4 – Advanced technologies
5 – Visionary policies
7 – New discoveries and breakthroughs
18 – Science-based entrepreneurship
22 – Access to information, transparency
27 – Active patient participation
41 – Rigorous study design
42 – Up to date medical education
49 – Committed, talented investigators

Chutes
11 – Poor quality research
16 – Maladaptive policies
36 – Poor investment in science and technologies
46 – Inability to retain talent
56 – (Mostly) Profit-driven private sector investment
59 – Politicizing innovation, science and discoveries

A Little About SMCI

• Improve the overall ME/CFS ecosystem through many key functions:
  - Promote cross-pollination of ideas through think tanks
  - Feature current scientific & medical developments
  - Advocate for effective policies and federal action
  - Facilitate patient participation in research
  - Debunk fallacies & misinformation about ME

• Initiate and support high-quality research across every phase of the Discovery Process:
Many Challenges for ME/CFS

- Misinformation and antagonism
- Lack of critical mass of researchers
- Insignificant funding for research
- Several diagnostic criteria
- Elusive etiology
- Lack of FDA-approved drugs
- Absent Pharma investment
- Insurance and ICD coding debacles
- Hard career path for researchers
- No feasible biomarkers
- Poor grasp of Natural history
- Minimal patient support

Some Policy Solutions to These Challenges

- Creating the critical mass (e.g., grants and investments (NIH, Others))
- Driving the equitable funding for research (e.g., NIH, consortia)
- Promoting standardization (e.g., Common Data Elements (CDC/NIH))
- Investing in Mechanistic Studies (e.g., Ramsay awards)
- Supporting promising drugs (e.g., new own initiatives, others)
- Working to attract start-ups (e.g., guiding/helping entrepreneurs)
- Streamlining and advocating for clear ICD coding (e.g., CDC, WHO)
- Promoting policies for the retention of talents (e.g., Fellowships, R01)
- Investing in Biomarkers discovery (e.g., SMCI targeted initiatives)
- Creating technological platforms (e.g., SMCI PEER Registry)
- Assisting patients (e.g., referrals, consultations and participation)

A Perspective on the Federal Response to the ME/CFS Crisis

- Since ME/CFS first recognized 30 years ago, federal response piecemeal
- Some improvement in the past 3 years
- Yet lacking unity, consistency, collaboration, and investment.
  - CDC – inconsistent prevalence studies, research, and education
  - NIH – low funding and harmful review process stunted research
  - HRSA – lack of integration of ME/CFS patients into existing programming structures
  - AHRQ – strong evidence review, but lacks consensus in the field
As a result, ME/CFS funding is extremely low

ME/CFS is treated like a rare disease, but it is not – estimated 2.5 million

Select Chronic Disease Prevalence Statistics in the USA*

- Diabetes 25.6 million
- Alzheimer's 5.2 million
- Glaucoma 2.8 million
- Parkinson's 1.0 million
- HIV/AIDS 0.6 million
- Crohn's 0.5 million
- Hemophilia 0.02 million

* https://goo.gl/MqBw2Z

And the suffering can be extraordinary
25% of patients — “severe” ME/CFS

Costs U.S. economy $24 billion / year

Where is US policy and prioritization of ME/CFS now?

Perspective of landscape and understanding:

• ME/CFS is where MS was 30 years ago and where Autism was 20 years ago
  • Patients were not believed
  • Scientific research investment was low
  • Government structures failed to address a desperate growing need

We know better now

• For MS and Autism, it took tenacious work of advocates to create that change that we know is just.
• This is a social justice issue now for ME/CFS patients.
• Desperate ME/CFS patients cannot wait another 30 years
What do we want to accomplish in Washington DC this week?

• Raise awareness of the disease among influential and passionate people, like all of you, who can make a difference for those who suffer.
• You can be the vanguard in changing our culture and understanding
• Find LEADERS to create a unified, consistent, and comprehensive policy on ME/CFS

What can Members of Congress do to fight for ME/CFS patients in their districts?

• Support funding for biomedical research and clinical programs at the NIH, CDC, AHRQ
• Call or write the NIH and ask them to prioritize ME/CFS research funding as part of their recent $2 billion increase.
• Preserve the Prevention and Public Health fund. A cut to this fund will threaten CDC funding for ME/CFS (roughly $5.4 million)

Millions of patients are counting us

Thank you

We welcome your questions

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