


Solve ME/CFS Initiative


#ME ACTION


THE INVISIBLE HEALTH CRISIS: ME/CFS


(CHRONIC FATIGUE SYNDROME)

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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


- 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

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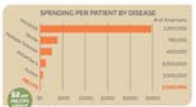
Many Challenges for ME/CFS

- 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

The Cardinal Problem: Severe knowledge Gap



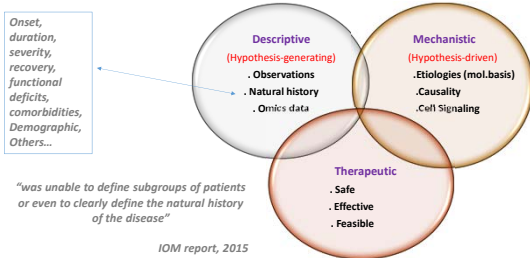
Number of Peer-Reviewed Research Publications by Disease, 1940 to Present



SPENDING PER PATIENT BY DISEASE

Shortage In Descriptive, Mechanistic And Therapeutic Studies In ME/CFS

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



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Myth # 1: blood test came back normal!

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

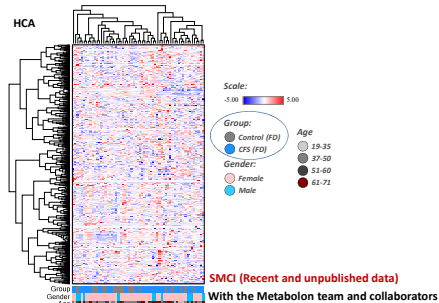
In fact, some standard laboratory tests do distinguish cases from matched healthy control subjects.

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

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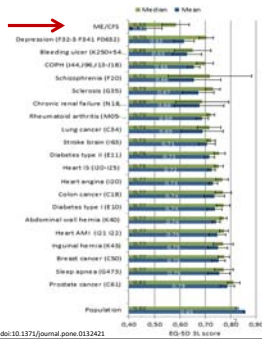
Fact: blood testing using personalized, modern analysis reveal serious abnormalities



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Myth # 2: You look normal!

Fact: Quality of Life for Patients with ME/CFS ranks the **lowest** when compared to other devastating diseases



Falk Heidberg et al. PLoS ONE 10(7): e0132421. doi:10.1371/journal.pone.0132421

Myth # 3: This is caused by Depression/Anxiety

Evidence of quite the opposite

Depression/Anxiety

- 1- HYPER-cortisolism
- 2- Enlarged adrenal glands
- 3- Reduced serotonin
- 4- Anhedonia, guilt, lack of motivation
- 5- Exercise improves states in depression

ME/CFS

- 1- HYPO-cortisolism
- 2- Reduced in size and function
- 2- Abnormal increase in serotonin!
- 3- The opposite: lack of energy not interest
- 4- Exercise (if possible) causes PEM/crash

Fact: Depression/Anxiety are the most common secondary responses to complex chronic diseases

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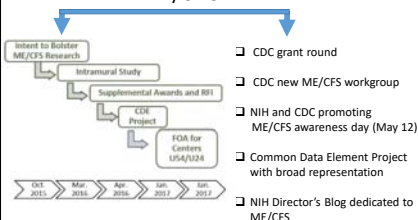
Challenges Persist Yet Recent Positive Developments Are Also Palpable

- 1) Better commitment from government agencies
- 2) Increased scientific and advocacy efforts

"Of the many mysterious human illnesses that science has yet to unravel, ME/CFS has proven to be one of the most challenging."

Francis Collins MD, PhD, Director, National Institutes of Health

NIH/CDC



Determined stakeholders

- Patients and their families
- Organizations like SMC1 and others
- Many interested academic entities and initiatives at major universities
- Upcoming NIH-sponsored ME/CFS Consortiums and Data Management Centers

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The Controversy Surrounding ME/CFS

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

Institute of Medicine Case Definition

Patient has each of the following three symptoms at least half of the time, to at least a moderately severe degree:


1. A substantial reduction in function that persists for more than 6 months, with profound fatigue of new or definite onset (not lifelong), that is not substantially alleviated by rest, AND
2. Post-exertional malaise, AND
3. Unrefreshing sleep.

PLUS at least one of the two following manifestations (chronic, severe):

1. Cognitive impairment. OR
2. Orthostatic intolerance

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



Ladders

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

Chutes

- 34 – Poor quality research
- 38 – Maladaptive policies
- 43 – Poor investment in science and technologies
- 46 – Inability to retain talent
- 56 – (Mostly) Profit-driven private sector investment
- 57 – Misinformation
- 59 – Politicizing innovation, science and discoveries

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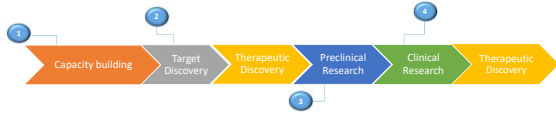
A Little About SMCI

• Improve the overall ME/CFS ecosystem through many key functions:

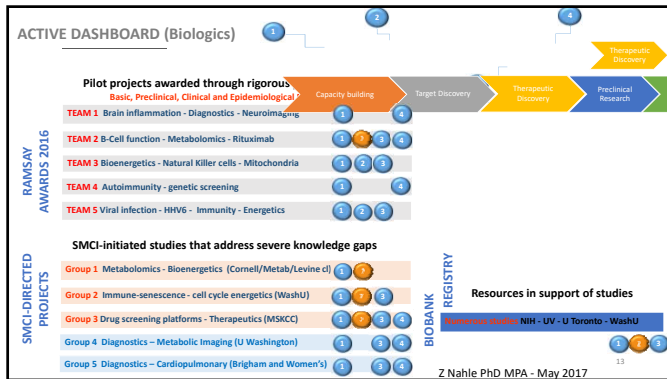
Debunk fallacies & misinformation about ME	Advocate for effective policies and federal actions
Create opportunities for researchers	Feature current scientific & medical developments
Facilitate patients participation in research	Promote cross-pollination of ideas thru think tanks

360°

• Initiate and support high-quality research across every phase of the Discovery Process:



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Many Challenges for ME/CFS	Some Policy Solutions to These Challenges
Misinformation and antagonism	Institutionalizing the accurate narrative through PPP (e.g., CDC, AMA)
Lack of critical mass of researchers	Creating the critical mass (e.g., grants and investments (NIH, Others))
Insignificant funding for research	Driving the equitable funding for research (e.g., NIH, consortiums)
Several diagnostic criteria	Promoting standardization (e.g., Common Data Elements (CDC/NIH))
Elusive etiology	Investing in Mechanistic Studies (e.g., Ramsay awards)
Lack of FDA approved drugs	Supporting promising drugs (e.g., new own initiative, others)
Absent Pharma investment	Working to attract start-ups (e.g., guiding/helping entrepreneurs)
Insurance and ICD coding debates	Streamlining and advocating for clear ICD coding (e.g., CDC, WHO)
Hard career path for researchers	Promoting policies for the retention of talents (e.g., Fellowships, R01)
No feasible biomarkers	Investing in Biomarkers discovery (e.g., SMCI targeted initiatives)
Poor grasp of Natural history	Creating technological platforms (e.g., SMCI PEER Registry)
Minimal patient support	Assisting patients (e.g., referrals, consultations and participation)

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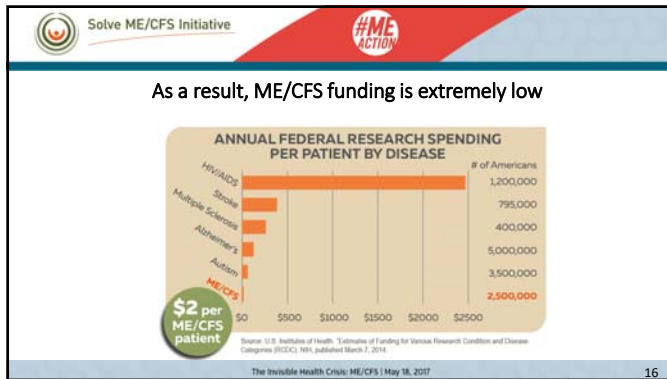
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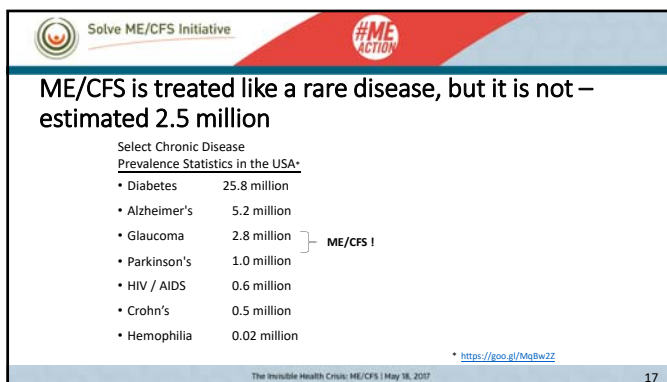
A Perspective on the Federal Response to the ME/CFS Crisis

- 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 stagnated research
 - HRSA – lack of integration of ME/CFS patients into existing programming structures
 - AHRQ – strong evidence review, but lacks consensus in the field


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25% of patients – “severe” ME/CFS



Tom
4 years later




One month before illness 95 days of hospitalization

- Roughly 625,000 Americans
- More than the population of Ft. Worth, TX
- Require full-time care

Costs U.S. economy \$24 billion / year

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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


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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

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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

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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)

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Millions of patients are counting us

Thank you

We welcome your questions

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