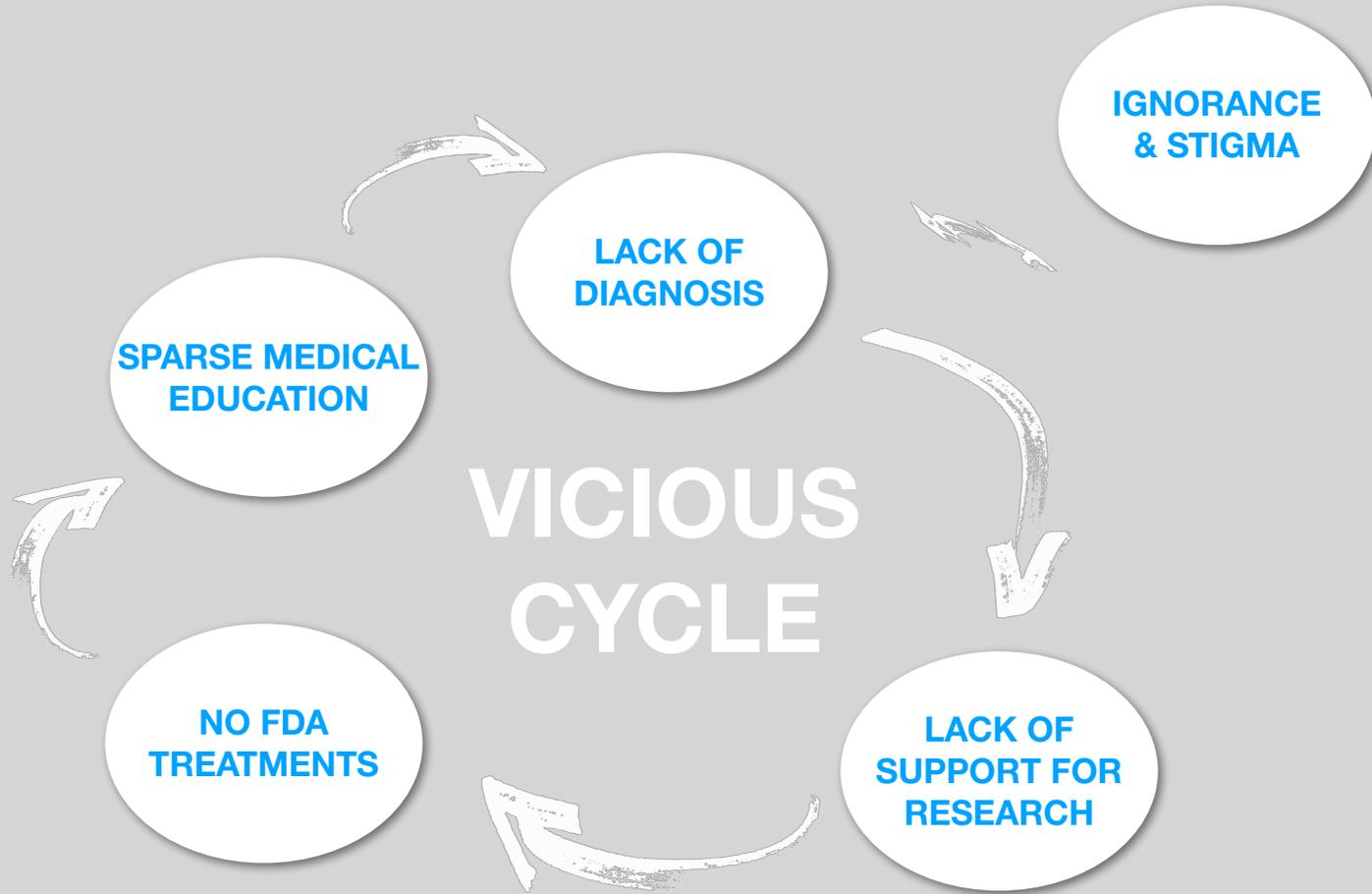


# ME/CFS Background Information: Community Perspective

Prepared for HHS, OASH

November 17, 2021

People with ME/CFS remain trapped in a vicious cycle that leaves them without diagnosis, care and treatment



# Very Limited Access to ME/CFS Specialist Clinics for 1-2.5M Americans



## ME/CFS Clinics

- < 15 active clinics
- < 20 active ME/CFS clinicians
- Many are nearing retirement*

## Patients seen at 7 of these clinics (1)

- 74% female
- 95% white, adult
- 95% have insurance
- 75% not working

Note: The most severely ill rarely travel to these clinics and are not seen by local doctors

1) As reported in the CDC multisite study of 7 of these clinics

## **Federal agency response is still failing to address critical needs**

- Consensus on patient selection methods and criteria for research
- Set-aside funding to accelerate research, draw researchers into the field, and identify and validate biomarkers
- Clinical treatment trials for repurposed drugs currently used in ME/CFS treatment
- Comprehensive, geographically-diverse Centers of Excellence
- Accurate surveillance and epidemiological data that is also racially representative
- Proactive outreach to medical associations
- Innovative programs to address entrenched stigma and ignorance
- Fix catastrophic lack of ICD-10-CM coding morbidity and mortality tracking for ME/CFS
- Increased health equity through robust access to social service providers and programs
- **Full integration of ME/CFS into Long COVID research agenda, strategy and structure**

ME/CFS advocates have offered a vision for a strategic federal response to break this vicious cycle

# Advocate's repeated vision to address the vicious cycle

2016  
advocate  
presentation  
to HHS

2021  
advocate  
presentation  
to IAWG

## Create a Community/Agency structure charged to:

- Create a **cross-agency plan** with defined **milestones** and **resource commitments**
- Designate **one person** (e.g. czar) with **accountability** to coordinate HHS's response and proactively engage the community and other key stakeholders (e.g. medical societies)
- Create clear **funding recommendations** to accomplish cross-agency plan which are **commensurate with disease burden** and **scientific opportunity**
- Create the research and drug development **public-private partnerships** needed to expedite progress
- **Build capacity** and improve **access to clinical services** for all ME/CFS patients regardless of geography or income

## Key elements: inter-agency response to ME/CFS needs to...

- Address known structural challenges with urgency
- Include a comprehensive, 5-year strategic plan
- Achieve specific, targeted goals with patient-focused outcomes
- Incorporate clear, meaningful monitoring and accountability measures
- Lead, plan, and execute; not just fill an advisory role
- Invest in solutions commensurate with the seriousness of the problem
- Incorporate meaningful involvement of patient advocates, ensuring transparency and participation at all levels of policy making

# WHAT ABOUT LONG COVID?

ME/CFS research, expertise, stakeholders are a critical part of a successful federal response to Long COVID.

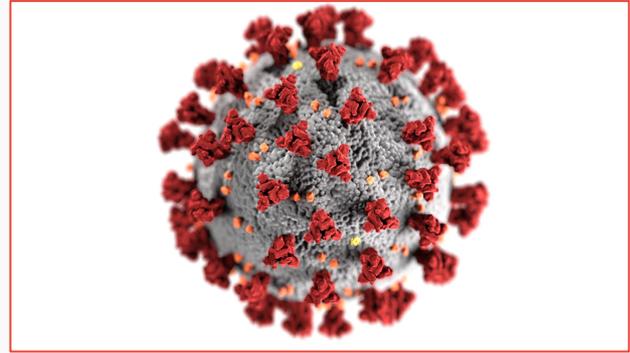
*Post viral illnesses are not new. It wastes time and resources to treat Long COVID as “something we’ve never seen before.”*

# How does ME/CFS relate to Long COVID?: A Refresher

Subset of people with Long COVID have **symptoms indistinguishable** from ME/CFS.

Some of these people still meet the **diagnostic criteria** for ME/CFS even at 1 year.

People with ME/CFS and a subset of Long COVID **share similar needs** and face essentially the same **barriers to care** regardless of proposed case definitions.



**COVID-19 could quickly double the prevalence of ME/CFS cases**

[Komaroff & Bateman \(2021\). Will COVID-19 Lead to Myalgic Encephalomyelitis/Chronic Fatigue Syndrome?](#)

# Insights from ME/CFS may help unravel the pathogenesis of Long COVID

- [Twenty-first century medical technology](#) has uncovered numerous biological abnormalities in people with ME/CFS, including central and autonomic nervous system dysfunction, gastrointestinal dysbiosis, immune dysregulation, disordered energy metabolism, and redox imbalance.
- These scientific advancements [provide promising insights](#) into the pathophysiology of post-infectious lingering illnesses, including post-COVID-19 syndrome (“Long COVID”).
- To fuel progress for Long COVID and all people with post-infectious chronic illness, a robust research agenda will build on cutting-edge ME/CFS research knowledge. This will be the most effective, expedient pathway to uncovering disease etiology, mechanisms, biomarkers and treatments for Long COVID, as well as for ME/CFS.

[SOURCE: Komaroff AL, Lipkin WI. Insights from myalgic encephalomyelitis/chronic fatigue syndrome may help unravel the pathogenesis of postacute COVID-19 syndrome. Trends Mol Med. 2021 Sep;27\(9\):895-906.](#)

# Joint recommendations to NIH for ME/CFS inclusion in the Long COVID research agenda

1. Sufficient **data collection** to determine if post-COVID patients meet **specific ME/CFS criteria**
2. **Control groups of people with ME/CFS** without evidence of past SARS-CoV-2 infection (and other post-infectious fatigue syndromes and chronic illnesses)
3. Create **ME/CFS advisory group** to give input on how ME/CFS research can inform study of Long COVID
4. Inclusion of **areas proving fruitful** in the study of ME/CFS in the PASC **research agenda**:
  - a. metabolomics (energy metabolism), redox imbalance, systemic immune dysfunction, autoimmunity, neuroinflammation, autonomic dysfunction, ion channelopathies, and abnormalities of the gut microbiota
5. **Treatment trials** that are based on the pathophysiological pathways identified in ME/CFS
6. **Expanded support for ME/CFS** studies; can inform Long COVID research and vice versa

August 2021 [joint letter](#) by #MEAction, Solve M.E., Open Medicine Foundation and ME/CFS researchers to NIH on ME/CFS inclusion in RECOVER initiative.

# Questions and Discussion

1. How do we get to a federal response that actually confronts the structural barriers?
2. The challenge is broad and complex; how do we ensure a centralized approach?
3. People with ME/CFS and Long-COVID experience the same needs and barriers, and will benefit from similar solutions. How do we ensure an integrated approach that doesn't leave ME/CFS patients behind again?
4. How do we avoid wasting valuable time and resources by treating Long COVID as if it was “something we've never seen before”?

Additional reference materials

# Many government reports on ME/CFS; no real action

- **2000** - GAO [report](#) ([press release](#))
- **2011** - NIH State of Knowledge [report](#)
- **2013** - FDA Voice of the Patient [report](#)
- **2015** - NIH Pathways to Prevention [report](#)
- **2015** - National Academy of Medicine [report](#)
- **2019** - NIH (NANDS Council) [report](#)
- **2021** - IAWG: Unmet Needs and Barriers to Care Community [presentation](#)  
ME/CFS Clinician Coalition [survey](#)

*From the perspective of people living with ME, little has fundamentally changed*

## #MEAAction response to latest report (NANDS, 2019)

“NIH’s lack of urgency in its response is reinforced by how **little in this report is new. While more detailed, the report reiterates the same problems that have been highlighted over decades...**

**We have spent years outlining the same issues** and yet we find ourselves in much the same position as before: **we see our problems restated again in a formal report with no concrete, comprehensive plans to tackle them.** In fact, almost all of the strategies in this report explicitly defer to another process without a budget or timeline...

**We do not see in this report the tangible, time-bound, outcomes-driven plans for action...**” (#MEAAction [letter](#) to NINDS Director, page 3)

Highlights from  
ME/CFS Clinician Coalition Survey

# Barriers to increasing # of willing/able healthcare providers

## Knowledge and attitudes

- **Clinician stigma and misinformation**
- **Lack of clinician knowledge**
- **Complexity of disease, lack of interest in managing chronic illness**
- Perceived lack of treatment options

## Reimbursement

- **Reimbursement insufficient to cover time, tests, treatments**
- ICD coding, insurance policies, etc.

## Lack of research

- Lack of research and research funding, slow progress
- **Lack of clinical treatment trials and evidence for treatment options**

## Lack of institutional, med society support

- Lack of support from institutions, peers, medical associations, etc.
- Lack of access to support services—e.g., case managers/social services
- Level/type of support needed for severely ill

***Impacting both # of PCPs and specialists as well as ME/CFS experts***

# What is Needed to Mainstream ME/CFS

## **Proactive leadership, comprehensive awareness and education program**

- Proactive leadership from federal agencies and medical societies
- Fully funded, comprehensive program to refute stigma/disinformation, and provide basic education and advanced learning opportunities
  - Including stipends to support the educators, hands-on learners

## **Fix reimbursement issues**

- Especially for internists, family practice doctors, for complex diseases
- Reality based for time and complexity, not just "code" based

## **Healthcare incentives for complex, chronic cases**

- Medical institutions, managed care groups, etc. must incentivize
- For the full spectrum of illness, including the severely ill

## **Diagnostics and treatments**

- More clinical tools to treat and care for patients
- Requires research! Must make ME/CFS research funding a priority

## **Clinical care centers with team-based approach**

- PCPs, clinical subspecialties, PTs, OTs, case mgrs., support services, etc.
- Centers with clinical care plus research and education

#MEAction advocacy to NIH

# NIH: #MEAction engagement (pre-COVID)

- **May & Sep '16** - #MillionsMissing [HHS Protest Demands](#) (includes NIH)
- **May '18** - #MillionsMissing [NIH Protest & Petition](#) ([demand letter only](#))
- **Dec '18** - [Presentation](#) to NIH Director
- **May '19** - [Response](#) to NIH RFI on advancing ME/CFS research
- **Sep '19** - NIH (NANDS Council) working group [report](#) (#MEAction WG member)
- **Oct '19** - [Critical response](#) to NANDS report (#NotEnough4ME campaign)
  - [rebuttal](#) of NINDS director claims
  - Campaign [petition](#), [community videos](#), [holiday cards](#), [direct action](#)

# NIH: #MEAction engagement in 2020

- **Jun '20** - [Statement](#): Post-COVID research & clinical care must include ME/CFS
- **Jul '20** - [Birddogging](#): Dr. Fauci states Long COVID “is highly suggestive of” ME/CFS
- **Jul '20** - [Report](#): what NIH is and isn't doing for ME/CFS & Long COVID research
- **Aug '20** - 1st Interagency working group [meeting](#) (invited to panel discussion)
- **Nov '20** - [List of questions](#) for Trans-NIH ME/CFS working group ([NIH reply](#))

# NIH: #MEAction engagement in 2021

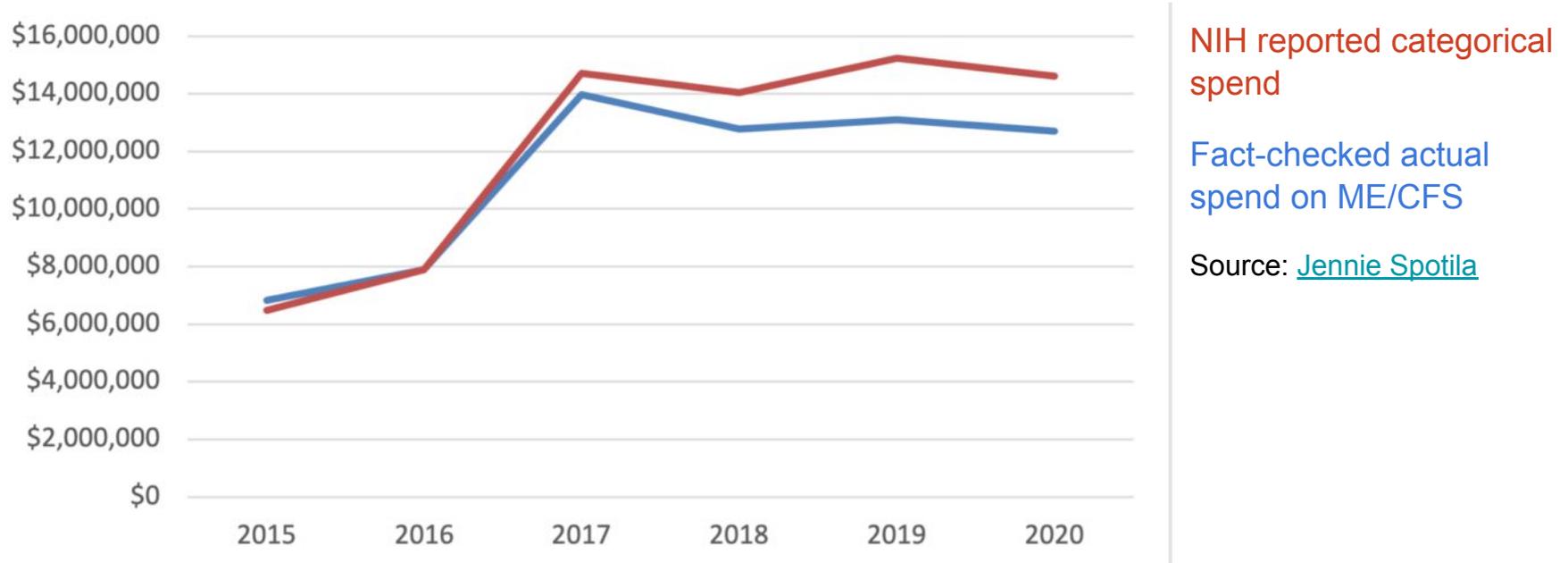
- **Feb '21** - 2nd Interagency working group [meeting](#): Joint advocacy orgs [presentation](#), clinician [survey](#)
- **Mar '21** - [Letter](#): our lack of confidence in NIH & CDC-led interagency approach (NIH [reply](#); CDC [reply](#))
- **Apr '21** - 5 ME/CFS orgs meet with NIH & CDC to express inadequacy of IAWG's current approach
- **May '21** - [Letter](#) to Congress to hold NIH accountable; [Letter](#) to NIH to expedite clinical treatment trials (NIH [reply](#))
- **Aug '21** - [Joint letter](#) by advocacy orgs and researchers to NIH on ME/CFS inclusion in RECOVER initiative
- **Oct '21** - [List of questions](#) for for Trans-NIH ME/CFS working group

# Coalition Letters to NIH about Long COVID & ME/CFS Research

- **Feb '21** - *Long COVID Alliance* [recommendations](#) to NIH (#MEAAction signed)
- **April '21** - *Body Politic* open [letter](#) to NIH;
- **April '21** - *Community Advisory Committee for the NIH ME/CFS Collaborative Research Centers* [letter](#) to NIH
- **May '21** - #MEAAction [letter](#) to expedite clinical treatment trials of repurposed drugs used in ME/CFS for Long COVID patients
- **Aug '21** - [Joint letter](#) by #MEAAction, *Solve M.E.*, *Open Medicine Foundation* and ME/CFS researchers to NIH on ME/CFS inclusion in RECOVER initiative

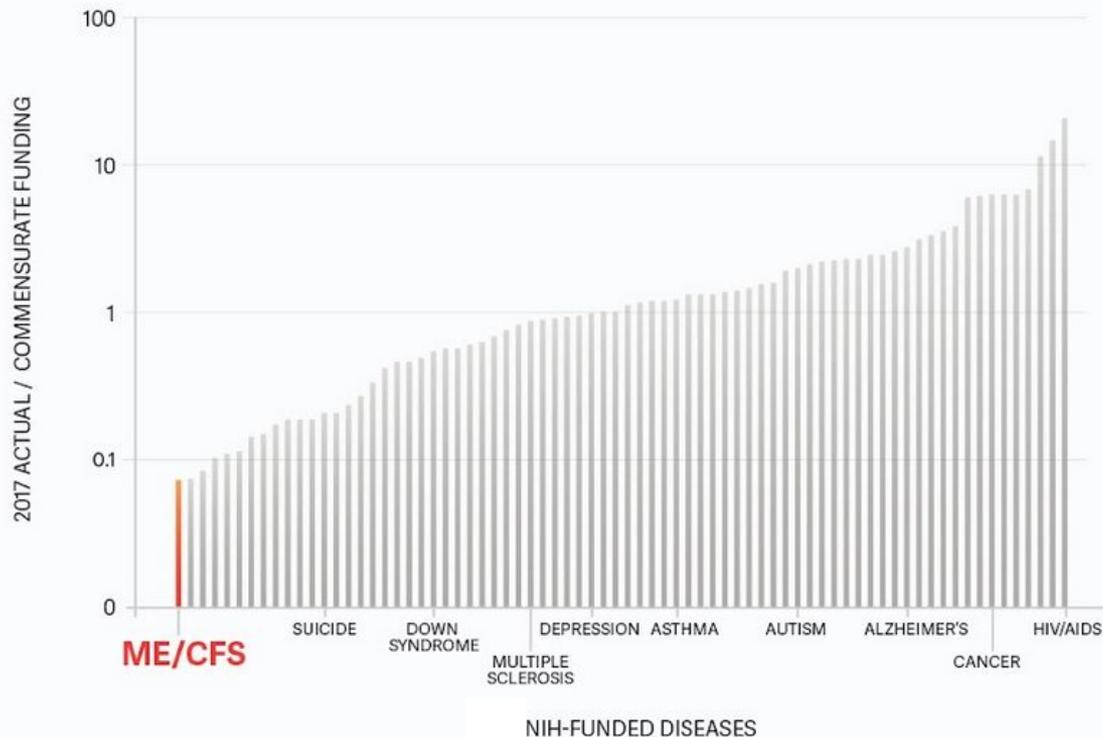
*Repeated recommendations for integrating ME/CFS—and leveraging existing expertise—into Long COVID research agenda have gone unheeded, wasting time and resources.*

# NIH ME/CFS funding: very low and flat-lined



**Actual NIH spending on ME/CFS is still less than \$9 per patient**  
(based on pre-pandemic 1.5M prevalence)

## Ratio of actual funding to burden-commensurate funding of diseases funded by NIH (2017)



ME/CFS is funded lower than all diseases in NIH's funding vs burden analysis.

Commensurate funding would be over **\$200M** annually.

#MEAction advocacy to CDC

# CDC: #MEAction engagement

- **Sep '16** - 1st CDC [Stakeholder Roundtable](#)
- **Aug '18** - [Petition](#) to CDC not to hire prior AHRQ evidence review contractor
- **Aug '18** - 2nd CDC [Stakeholder Roundtable](#)
- **Sep '18** - [Recommended changes](#) to CDC website pages on ME/CFS
- **Aug '19** - [Letter](#) to CDC requesting transparency and progress (CDC [reply](#))
- **Sep '20** - [List of questions](#) for CDC on ME/CFS programs and strategy

# CDC: #MEAAction engagement in 2021

- **Feb '21** - 2nd Interagency working group [meeting](#): Joint advocacy orgs [presentation](#), clinician [survey](#)
- **Mar '21** - [Letter](#): our lack of confidence in NIH & CDC-led interagency approach (NIH [reply](#); CDC [reply](#))
- **Jun '21** - [Recommendations](#) on CDC Long COVID patient materials
- **Aug '21** - [Public comment response & petition](#) to stop CDC evidence review draft ([executive summary](#) only) ([timeline](#) of controversy)
- **Sep '21** - [Joint proposal](#) to NCHS to modify ICD-10-CM code to track ME/CFS
- **Oct '21** - 3rd CDC [Stakeholder Roundtable](#)

August 20, 2021 Presentation to ASH Dr. Rachel Levine

<https://www.meaction.net/wp-content/uploads/2021/11/082021-MEAction-presentation-to-ASH-Dr.-Levine.pdf>

# Questions?

Contact [terri@meaction.net](mailto:terri@meaction.net) or [ben@meaction.net](mailto:ben@meaction.net)