Unmet Needs and Barriers to Care for Persons with ME/CFS:

The Community Perspective

Interagency Working Group for ME/CFS
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Oved Amitay, Solve ME/CFS Initiative

Together, representing 100 years in the ME/CFS community

Solve M.E.

#ME ACTION

NJCFSA New Jersey Chronic Fatigue Syndrome Association, Inc

Massachusetts ME/CFS & FM ASSOCIATION

EDUCATION, SUPPORT & ADVOCACY SINCE 1985

What is ME/CFS?

- My-al-gic en-ceph-alo-my-e-li-tis/chronic fatigue syndrome (ME/CFS) is a **complex, chronic, debilitating disease with multi-systemic effects.**
- Clinical diagnosis can be made on the basis of a cluster of common symptoms: fatigue, post exertional malaise, sleep problems, cognitive dysfunction, orthostatic intolerance; but most people with ME/CFS experience **many symptoms, which vary in nature and come and go over time**.

- **No biomarker or commonly available lab test for diagnosis**
- **No FDA-approved therapies**
- **No cure!!**

We Stand for:

People living with myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS) who need support and access to compassionate and effective care.

- 1-2.5 million people in the US
- Economic impact between **36 -51 billion dollars** per year

- Jason & Mirin (2021). *Updating the National Academy of Medicine ME/CFS prevalence and economic impact figures to account for population growth and inflation.*

- Up to **75% can't work; 25%**
  - **home/bed-bound**
- Covid-19 would at least **double** the number of Americans suffering from ME/CFS

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

How does ME/CFS relate to Long COVID and other chronic diseases?

- ➔ 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

Takeaway

We know enough to understand the **urgency** with which we must act.

Integrated approach is likely to benefit both communities and even other adjacent diseases

“Voice of the Patient” report

Issued in 2013; developed as part of the FDA’s Patient-Focused Drug Development Initiative

Very comprehensive and readable—and everything in it is still true today

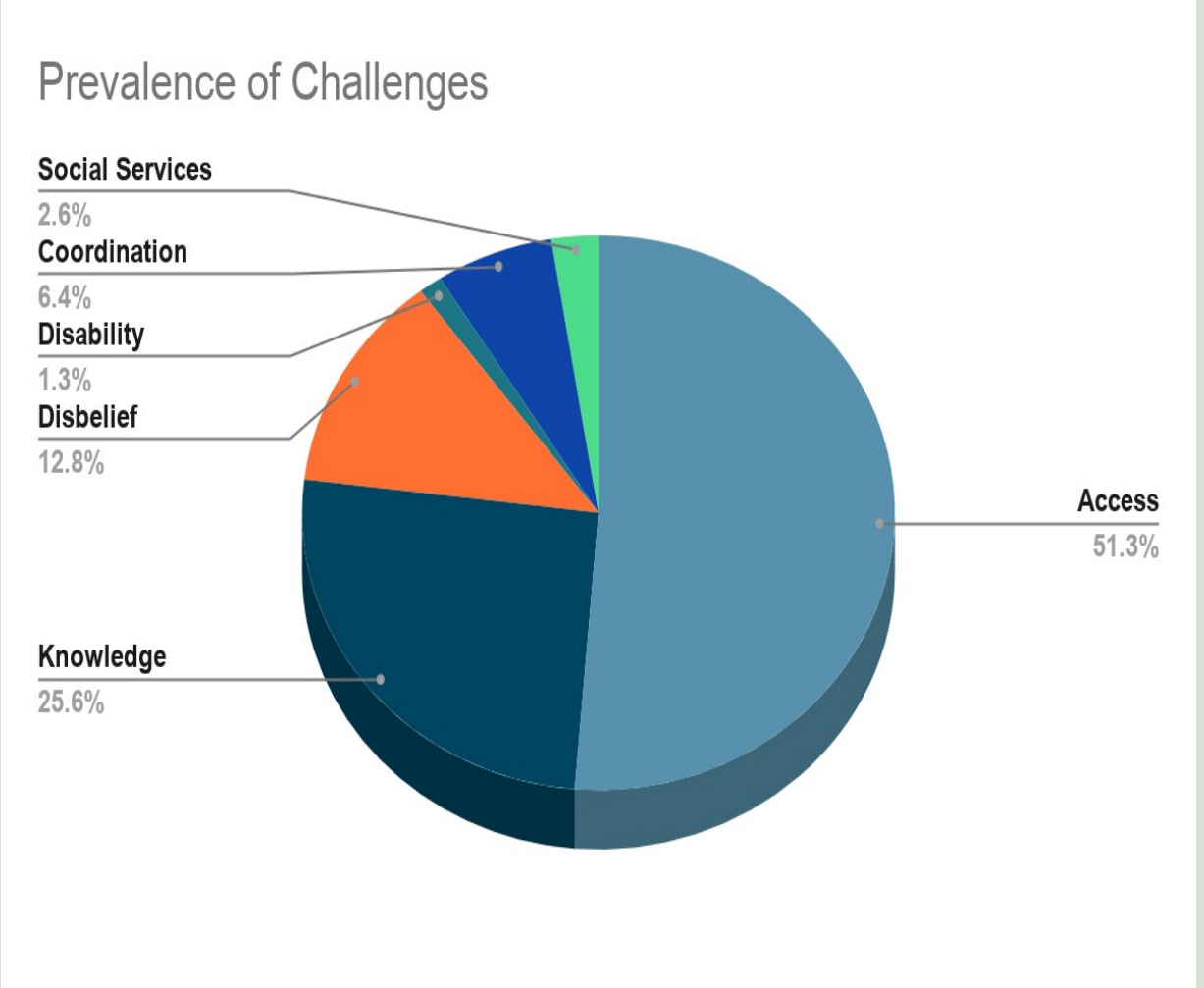
From the perspective of people living with ME/CFS—*nothing has changed*

https://www.fda.gov/media/86879/download

Unmet Needs and Barriers to Care

(MassME/CFS: over 1000 referrals made since 2015)

- Access to ME/CFS Specialists
- HCP's Lack of Knowledge
- Disbelief or Bias
- Coordination of Care
- Documentation of Disability
- Inadequate Social Service Support



MassME/CFS Association Health Care Referral database, 2016-2020. Categories are not mutually exclusive.
Most cases involve multiple challenges. Groupings are based on *first month* of communications.

Crisis in ME/CFS care: Unmet Needs and Barriers to Getting Diagnosis and Appropriate Treatments

Access to knowledgeable providers

- Very limited access to ME/CFS clinical specialists
- HCP's lack of knowledge or confidence
- Harmful misinformation
- Dismissal and disbelief
- Providers unwilling to learn

Any knowledgeable HCP can validate the patient's experience and provide support

Patient Voice: Not Accepting New Patients

“I called Dr. XXX (ME/CFS specialist) and was told that the first available appointment is over a year from now. I tried the other one and their practice is not accepting any new patients. I am in desperate need to find a doctor who understands this illness.”

Patient Voice: Disbelief Makes Everything Worse

- "None of these doctors really recognize CFS as an actual disease, and I need a diagnosis so that I can let others know that I am suffering from a disabling illness. If there is anything worse than going through this, it is not having anyone believe me..."

Crisis in ME/CFS care: Unmet Needs and Barriers to Getting Diagnosis and Appropriate Treatments

Diagnosis

- "Standard" tests show "nothing wrong"
- No insurance coverage for specialized tests
- Medical "silos"—no one to put it all together
- Providers unwilling to make the diagnosis

Treatment

- "No cure" = "no treatment"
- Providers unwilling to try "experimental" treatments or use drugs off-label
- No rigorous clinical research

Patient Voice: Can't Get a Diagnosis

"After years of visiting multiple doctors and having multiple tests and procedures performed, my Hematologist is convinced that I have ME/CFS. Can I please get a provider referral that can give me a definitive dx? I have been so sick for years and as a result lost several jobs, even one being six-figures. I need a dx for proper treatment. Right now everyone is just pushing pain meds and psych drugs on me."

Patient Voice:
Parenting a Child With ME/CFS

- "Please, please help me find a specialist to see my 16-year-old daughter who has been suffering for 3 years (the onset was a virus) with exhaustion, weakness, lightheadedness, stomach pain, joint pain. We have seen rheumatologists, gastroenterologist, sleep neurologist, pulmonologist and psychiatrist, but there is no one who can tie it all together. Everyone treats her like this is psychosomatic and she cannot get accommodations at school."

Crisis in ME/CFS care: Unmet Needs and Barriers to Getting Diagnosis and Appropriate Treatments—Cost

Cost

- High cost of specialty care (may not be covered by insurance)
- No insurance coverage or reimbursement for specialized tests
- Needed drugs unavailable or not covered by insurance
- Out-of-pocket costs for supplements
- With limited income people exhaust their financial resources

Medicaid Not Accepted

- “Ican’t find a PCP who will take Medicaid.” Do they think I want to be on Medicaid? Before I became sick I was working full-time, I was respected for what I did.” I need yourhelp.”

Burden of Disability Documentation

“Social Security Disability is trying to cut me off. My old PCP is retired, and my current PCP is not ME literate, believes I'm a neurotic malingerer. I must find a doctor capable of understanding my illness and willing to help me with documentation. I have been unable to hold a job despite being more functional than some others with the illness. I wish I could work!”

How people with ME/CFS experience the structural barriers to care

Jane's Story

1. Jane is struggling to recover after a case of mono. HCP tells her to exercise, push herself.
2. Jane gets worse & seeks care, bounced from doctor to doctor.
3. Jane is told to seek counseling, although mental health symptoms were secondary.
4. Jane remains sick, counseling does nothing. Employer is threatening to fire her.
5. Jane remains undiagnosed and her provider will not provide documentation for disability.

Structural Barriers

1. Poor medical education =>damaging misinformation. NO biomarker or test.
2. ME/CFS has no "home"—no specialist in her area to whom she can turn.
3. Mental health professionals are not equipped—no psychiatry CME for ME/CFS.
4. No workplace education about managing ME/CFS. No accommodations without a diagnosis and doctors' note.
5. <2% receive disability, although ~90% cannot hold a job. Appeals often rejected.

84–91% of people with ME/CFS are undiagnosed or misdiagnosed

Jane's Story: Part Two

6. Jane finds information online—recognizes her symptoms as ME/CFS.
7. Jane returns to her doctors with online information, told ME/CFS is not a real disease.
8. Jane tries to find an ME/CFS specialist.
9. Jane gets on a waiting list, despite cost barriers. Providers there ask for a telemedicine consult with her current medical team.
10. Jane remains undiagnosed for 6 years and she is now disabled for life.

Structural Barriers

6. Clinical diagnostic criteria are easy to find, easy for patients to recognize.
7. Misinformation and biases.
8. Fewer than 15 specialty clinics for ME/CFS. Most have waiting lists between 2–4 years and do not take insurance.
9. Most insurance will not cover teleconsulting. Cross-state consulting is impossible for most carriers.
10. Interventions in the first two years of illness improve long-term health outcomes.

Estimated <5% recovery rate

Jane's Story: Part Three

11. Jane would do anything to enroll in a clinical trial for an experimental treatment
12. Jane remains sick, disabled, and homebound. She lives with her parents who care for her, but Jane wonders what will happen to her when her parents are no longer around.

Structural Barriers

11. No federally funded clinical trials for treatments. No FDA approved treatments. No ME/CFS specific treatment protocol.
12. Homecare/Respite services are typically denied (ME/CFS is not a recognized condition for most service providers).

Leave no one behind

We must commit to proactively addressing the needs of historically marginalized people with ME/CFS

- People with Severe and Very Severe ME/CFS (25% group)
- Black, Indigenous, and People of Color (BIPOC)
- Low socioeconomic status
- Children
- Rural populations

Community research suggests prevalence is higher in these communities than the demographic seen in ME/CFS specialty clinics.

VISION

1. An ME/CFS + Long COVID Inter-agency structure with resources and accountability
2. Invest in solutions that are commensurate with the seriousness of the problem
3. Make people with ME/CFS and long COVID part of your agency and program success

a) Address structural challenges
b) LEAD, PLAN, and EXECUTE not an advisory role
c) Comprehensive 5-year strategic plan
d) Specific, targeted goals
e) Inter-agency collaboration and coordination

Comprehensively addressing unmet needs: Interagency Autism Coordinating Committee

- Federal advisory committee that coordinates Federal efforts
- Provides advice to the Secretary of Health and Human Services on issues related to autism spectrum disorder (ASD).
- Includes both Federal and public members
- Helps to ensure that a wide range of ideas and perspectives are represented and discussed in a public forum
- The committee reconvened in November 2015 to begin a new session under the Autism CARES Act

https://iacc.hhs.gov/

Comprehensively addressing unmet needs: HIV/AIDS Program

- Medical and support services
- Improving the quality, availability, and organization of health care and support services including drug assistance
- Community-based comprehensive primary health care, specialty care and support services in an outpatient setting
- Eight regional centers and two national centers to advance interprofessional training
- Dental programs that provide additional funding for oral health care

(Ryan White HIV/AIDS Program https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program)

Nothing About Us Without Us

- Together we can face this crisis: people with ME/CFS need to have full and direct participation in the policies that affect their lives
- IAWG meetings an important first-step, but must lead to coordinated, comprehensive efforts, and permanent community seats at the table where policy decisions are being made

Making it Happen

Create a Community/Agency structure charged to:

- Create a cross-agency plan with defined milestones and resource commitments
- Designate one person 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

Questions and Discussion

1. Are we confronting the structural barriers?
2. The challenge is broad and complex; how do we develop a **centralized approach** to these needs?
3. **What agencies need to be here** that aren't?
4. Will the needed focus on Long COVID **leave ME/CFS patients behind again?**
5. What can we do **differently** in a Covid-world?

People with ME/CFS and Long-COVID experience the same needs and barriers, and will benefit from similar solutions

Thank You!