



Solve M.E. Policy Advocacy Statement

This Solve ME/CFS Initiative (Solve M.E.) policy statement will drive the organization's efforts to create significant change and improvement for patients. Solve's actions are dependent on resources and board approval to execute an appropriate implementation plan.

About Solve

The Solve ME/CFS Initiative (Solve M.E.) is a non-profit organization that serves as a catalyst for critical research into diagnostics, treatments, and cures for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), Long Covid and other infection associated chronic conditions and illnesses (IACCI's). Our work with the scientific, medical, and pharmaceutical communities, advocacy with government agencies, and alliances with patient groups around the world is laying the foundation for breakthroughs that can improve the lives of millions who suffer from various "long haul" conditions and illnesses. Solve M.E. acknowledges and strives to dismantle systemic barriers to appropriate care and quality of life which can include racism, ableism, sexism, and othewithout adequate assistancer forms of discrimination and medical gaslighting experienced by historically marginalized and underserved communities living with IACCI's.

Solve M.E. and other public health advocacy organizations predicted a widespread public health crisis back in 2020, which has since materialized as what we now recognize as the Long Covid crisis. As the science has continued to emerge from this crisis, it has become increasingly clear that ME/CFS, Long COVID, and other infection-associated chronic illness are inextricably linked by similar clusters of symptoms, multi-systemic impact, experiences navigating the medical systems, and political roadblocks.

Our mission is to make infection associated chronic conditions and illnesses medically understood, diagnosable, and treatable, and to improve patient engagement in research.

Facts

Infection-associated chronic conditions and illnesses¹ are complex, chronic, and debilitating illnesses with a serious impact on one's quality of life, work, and family. While most commonly associated with viral infection, other triggers (e.g. toxins, bacteria, fungi, vaccines, etc.)^{2 3 4} have also been identified. While women⁵, latinos/latinas⁶, Gulf-war veterans⁷ and other minority groups⁸ have been shown to be disproportionately impacted, **infection-associated chronic conditions and illnesses can impact anyone, at any time.** Evidence suggests there may be a genetic predisposition not yet identified.⁹

Infection associated chronic conditions and illnesses, especially Myalgic Encephalomyelitis (ME), formerly known as Chronic Fatigue Syndrome (CFS), and Postural Orthostatic Tachycardia Syndrome (POTS), are known to be associated with SARS-CoV-2 infection.^{10 11} Long Covid is the patient preferred term for new or worsening symptoms lingering after the acute infection has passed, also known as Post Acute Sequelae of COVID-19 (PASC).

As of December 2023, [1.3% of U.S. Adults](#) live with ME/CFS. Additionally, [6.4% of U.S Adults](#) reported ever having experienced Long COVID. ME/CFS is estimated to cost the U.S economy [\\$36-51 billion a year](#). Harvard estimates Long COVID costs the United States economy an estimated [\\$3.7 trillion](#). In total, according to CDC data, up to 7.3% (~19 million) of American adults have experienced ME/CFS and/or Long COVID. Further research is ongoing to estimate the prevalence, cost, and impact of infection-associated chronic conditions and illnesses.

¹IACC List and Terminology [here](#)

² Jason LA, Yoo S, Bhatia S. Patient perceptions of infectious illnesses preceding Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. *Chronic Illn.* 2022 Dec;18(4):901-910. doi: 10.1177/17423953211043106. Epub 2021 Sep 20. PMID: 34541918; PMCID: PMC9152619.

³ Underhill RA. Myalgic encephalomyelitis, chronic fatigue syndrome: An infectious disease. *Med Hypotheses.* 2015 Dec;85(6):765-73. doi: 10.1016/j.mehy.2015.10.011. Epub 2016 Oct 19. PMID: 26604026.

⁴ Bretherick AD, McGrath SJ, Devereux-Cooke A, Leary S, Northwood E, Redshaw A, Stacey P, Tripp C, Wilson J, Chowdhury S, Lewis I, Almelid Ø, Baby SV, Baker T, Becher H, Boutin T, Clyde M, Garcia D, Ireland J, Kerr SM, McDowall E, Perry D, Samms GL, Vitart V, Wolfe JC, Ponting CP. Typing myalgic encephalomyelitis by infection at onset: A DecodeME study. *NIHR Open Res.* 2023 Aug 21;3:20. doi: 10.3310/nihropenres.13421.4. PMID: 37881452; PMCID: PMC10593357.

⁵ Bretherick AD, McGrath SJ, Devereux-Cooke A et al. Typing myalgic encephalomyelitis by infection at onset: A DecodeME study [version 4; peer review: 2 approved]. *NIHR Open Res* 2023, 3:20 (<https://doi.org/10.3310/nihropenres.13421.4>)

⁶ Jason LA, Katz BZ, Sunnquist M, Torres C, Cotler J, Bhatia S. The Prevalence of Pediatric Myalgic Encephalomyelitis/Chronic Fatigue Syndrome in a Community-Based Sample. *Child Youth Care Forum.* 2020 Aug;49(4):563-579. doi: 10.1007/s10566-019-09543-3. Epub 2020 Jan 23. PMID: 34113066; PMCID: PMC8186295.

⁷ McCauley LA, Joos SK, Barkhuizen A, Shuell T, Tyree WA, Bourdette DN. Chronic fatigue in a population-based study of Gulf War veterans. *Arch Environ Health.* 2002 Jul-Aug;57(4):340-8. doi: 10.1080/00039890209601419. PMID: 12530602.

⁸ Sokratis Dinos, Bernadette Khoshaba, Deborah Ashby, Peter D White, James Nazroo, Simon Wessely, Kamaldeep S Bhui, A systematic review of chronic fatigue, its syndromes and ethnicity: prevalence, severity, co-morbidity and coping, *International Journal of Epidemiology*, Volume 38, Issue 6, December 2009, Pages 1554–1570, <https://doi.org/10.1093/ije/dyp147>

⁹ Das, S., Taylor, K., Kozubek, J. et al. Genetic risk factors for ME/CFS identified using combinatorial analysis. *J Transl Med* 20, 598 (2022). <https://doi.org/10.1186/s12967-022-03815-8>

¹⁰ Mallick D, Goyal L, Chourasia P, Zapata MR, Yashi K, Surani S. COVID-19 Induced Postural Orthostatic Tachycardia Syndrome (POTS): A Review. *Cureus.* 2023 Mar 31;15(3):e36955. doi: 10.7759/cureus.36955. PMID: 37009342; PMCID: PMC10065129.

¹¹ Wong T, Weitzer D. Long COVID and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)—A systemic review and comparison of clinical presentation and symptomatology. *Medicina (Kaunas).* (2021) 57:418. doi: 10.3390/medicina57050418

Over [200 symptoms have been associated](#) with infection-associated chronic conditions and illnesses. Significant symptoms, such as crippling fatigue, post-exertional malaise, neural inflammation, pain, and cognitive dysfunction, are shared among infection associated chronic conditions and illnesses. The severity of such symptoms can be disastrous to one's quality of life regardless of the severity of the initial illness or trigger. These symptoms can often be difficult to identify and diagnose due to the fluctuating nature of disease severity and symptoms.

[Nearly half of Long COVID patients meet the diagnostic criteria for ME/CFS](#). ME/CFS patients have the [lowest median quality of life scores](#) of any disease tested, including lung cancer, rheumatoid arthritis, and brain stroke.

Background

Infection-associated chronic conditions and illnesses are not new - people have been getting sick and experiencing new or lingering symptoms for many years. However, the current Long COVID public health crisis has highlighted the connections between many infection associated chronic conditions and illnesses, and has made it clear that we are best served by working together as a broader community to reach our collective research and care goals and ensuring that our community no longer suffers due to neglect, inaction, and lack of funding.

The plight of patients with infection-associated chronic conditions and illnesses, such as Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), has been characterized by decades of neglect from federal, private, and medical sectors. According to [Mirin and Dimmock](#), the disease burden of ME/CFS exceeds that of HIV/AIDS and is significantly underfunded relative to its impact, receiving merely 7% of the funding it should receive commensurate with the burden of disease it causes. This chronic underfunding has stymied research, patient care, and support, leaving many without the help they desperately need.

The burden of infection-associated chronic conditions and illnesses disproportionately affects underserved populations, with systemic biases such as racism, sexism, and ableism further compounding the issue. The stigma surrounding conditions and illnesses like ME/CFS exacerbates discrimination and dismissal, harming patients and hindering progress.

These illnesses are often “invisible disabilities,” meaning that they are invisible to the casual observer while severely impacting quality of life and function of the patient. They frequently wax and wane, or follow a relapsing/remitting pattern. The current binary view of disability in support mechanisms fails to accommodate the variable nature of these conditions, leaving many patients without adequate assistance. Additionally, for many patients in rural areas, there are additional barriers to accessing care at all.

In order to make progress in tackling this crucial mission, the IACCI community needs the government to invest in more research and improved research coordination in order to advance the science to the point that pharmaceutical companies are willing to take the risk of running comprehensive treatment trials, leading to FDA approved treatments for patients. One of the

challenges we face in achieving progress towards this goal is the low number and size of requests for applications (RFAs) published and funded by the National Institutes of Health (NIH) regarding ME/CFS are inadequate to attract and retain researchers who have historically avoided the field because of a lack of funding. Solve will continue to advocate with government partners to encourage more RFAs, and will continue to work alongside the scientific community to ensure that when RFAs are published, they receive a volume of applications that reflects the scope of the disease burden faced by the IACC community.

Solve M.E. strives to validate the work of our government partners and will continue to educate members of congress as key allies, partners, and champions in the efforts to improve life for IACCI patients. We acknowledge and appreciate the impact of the \$1 billion+ RECOVER investment into Long COVID research. However, many valid concerns have been raised by the community and stakeholders regarding the direction and approach of RECOVER.

Considering the extremely limited funding for ME and other infection-associated chronic illnesses, we have made remarkable progress in scientific understanding of these conditions and illnesses. We applaud the progress made so far, but it is not enough.

Our Purpose

The purpose of Solve's Advocacy Policy is to return those with infection-associated chronic conditions and illnesses to their pre-disease lives as quickly and completely as possible. Solve's activities include seeking treatments and cures, increasing patient functionality and quality of life, and educating medical providers, service providers, and the general public to ensure the best possible care for patients and their families.

Solve ME/CFS Initiative (Solve) is committed to catalyzing initiatives at federal, state, local, private, and public levels. These initiatives are focused on securing vital funding, support, awareness, and education in the fields of ME/CFS, Long Covid, and other infection associated chronic conditions and illnesses research, diagnosis, treatment, and patient care. Our goals are to:

1. Expand, Coordinate, and Accelerate Research Investment
2. Expedite and Expand Government Response to the Infection Associated Chronic Disease Public Health Crisis
3. Increase the Quality and Accessibility of Clinical Care and Patient Support
4. Raise Awareness and Improve Understanding of ME/CFS in the General Public
5. Elevate and center patient voices and lived experience experts in research and policy

1) Expand, Coordinate, and Accelerate Research Investment

Solve urgently appeals to key stakeholders—government agencies, academia, the pharmaceutical industry, and other private entities—to significantly increase funding and support for research efforts that are commensurate with the substantial burden posed by infection-associated chronic conditions and illnesses. We critically need to better understand the pathobiology and epidemiology of infection-associated chronic conditions and illnesses, to identify biomarkers, to conduct clinical trials, to develop FDA approved treatments, and to establish robust prevention strategies.

Solve will spearhead investments in the ecosystem of academic researchers (especially early career researchers) and educate pharmaceutical companies about infection-associated chronic conditions and illnesses.

Some ways we believe research can be expanded, coordinated, and accelerated include:

- **Establishment of a Dedicated NIH Entity:** The creation of a specific office, center, or institute within the National Institutes of Health (NIH) dedicated to coordinating multisystemic research across different medical specialties. This entity would serve as a central point for guiding research efforts, ensuring a cohesive strategy that bridges gaps between disciplines and fosters comprehensive studies into the mechanisms, treatments, and impacts of infection-associated chronic conditions and illnesses.
- **Increased Funding and RFAs:** There should be an immediate increase in the number and size of Requests for Applications (RFAs) specifically targeted at ME/CFS, Long COVID, and other infection-associated chronic conditions and illnesses. This includes a stronger financial and strategic commitment to support investigator-initiated research, facilitating a broader and more innovative exploration of these conditions.
- **Interagency Collaboration:** Encouraging and fostering collaboration between different government agencies, can lead to a more integrated and less siloed approach to research and treatment development. Such collaboration can leverage the unique resources and perspectives of each agency to tackle the multifaceted challenges these conditions and illnesses present.
- **Unified Research Definition:** Adopting a unified definition for infection-associated chronic conditions and illnesses, such as the National Academies of Sciences, Engineering, and Medicine (NASEM) working definition, can standardize research efforts and ensure consistency across studies. This would facilitate comparability of findings and streamline the aggregation of data for meta-analyses.
- **Investment in Groundbreaking Studies:** Strategic investments should be made into groundbreaking studies, similar to those under the Advanced Research Projects Agency for Health (ARPA-H) program. Such investments can drive innovation in understanding the underlying mechanisms of these conditions and illnesses and lead to transformative treatment approaches.
- **NSF Grant Prioritization:** The National Science Foundation (NSF) should prioritize grants that focus on infection-associated chronic conditions and illnesses. By supporting

research in this area, the NSF can contribute to the foundational scientific knowledge needed to advance treatment and management strategies.

- **FDA Clinical Trials and Drug Repurposing:** The Food and Drug Administration (FDA) should implement initiatives to facilitate clinical trials and the acceptance of existing drugs for "off-label" use in treating infection-associated chronic conditions. This approach can expedite the availability of treatments by utilizing already-approved medications.
- **Inclusive Clinical Trials:** Clinical trials and studies focused on Long COVID should include specific arms for ME/CFS, Postural Orthostatic Tachycardia Syndrome (POTS), other dysautonomias, chronic Lyme disease, and other infection associated chronic conditions. This inclusion ensures that research encompasses a broad spectrum of infection-associated chronic conditions and illnesses, enhancing the relevance and applicability of findings.
- **Congressional Earmarks for Research Funding:** There should be a congressionally earmarked, consistent, and recurrent amount of protected set-aside research funding across the Department of Health and Human Services (HHS) agencies. This funding would create a predictable path for financial support and encourage the growth of a dedicated research workforce. Addressing the significant public health needs associated with ME/CFS and other infection-associated conditions and illnesses requires stable and substantial investment.
- **International Collaboration:** Solve recognizes that breakthroughs in the realm of infection-associated chronic conditions and illnesses can be expedited when we collaborate internationally, and will continue to support and participate in alliances and coalitions that advance the cause around the world.

By implementing these strategies, we can significantly enhance the scope, coordination, and impact of research into infection-associated chronic conditions and illnesses, paving the way for breakthroughs in understanding, treatment, and patient care.

Lessons from previous research efforts (like RECOVER) have taught us several key traits of effective IACCI research. The best and most meaningful research:

- Focuses on multiple IACCIs
- Takes a multidisciplinary and multisystemic approach
- Acknowledges ME/CFS and other IACCIs overlap
- Focusing on symptoms and symptom clusters
- Takes into account current knowledge of the IACCI field
- Wherever possible, includes multi-cohort studies
- Utilizes common data elements
- Focuses on treatment and quality of life
- Integrates patient engagement and lived experience experts at every stage

2) Expedite and Expand Government Response to the Infection Associated Chronic Conditions and Illness Public Health Crisis

Solve urgently calls on the government to both acknowledge and take coordinated action against the public health crisis presented by infection-associated chronic conditions and illnesses, including ME/CFS and Long Covid. These conditions must be recognized as top priorities, and require immediate and effective strategies to address their significant impact on public health.

Solve calls upon all relevant government agencies, including but not limited to the NIH, CDC, AHRQ, NASEM, ARPA-H, NSF, FDA, NHC, and DOD, to acknowledge the public health crisis posed by IACDs and to take immediate action. This includes leveraging their unique resources, expertise, and authority to address the challenges of these illnesses and conditions head-on.

Some of the ways we plan to support an expedited and expanded government response include:

- Advocating for government investments, initiatives, policies, public/private partnerships, and programs that will improve the lives and ease the suffering of millions of ME/CFS, Long Covid, and infection associated chronic illness patients.
- Advocating for infection associated chronic conditions and illnesses to be acknowledged as public health emergencies, necessitating immediate and coordinated action at all levels of government.
- Pushing for increased government investments in research, treatment development, and patient support services for infection-associated chronic conditions and illness.
- Promoting collaborations between government agencies and private entities to pool resources, expertise, and funding, aiming to accelerate the development of effective treatments.
- Calling upon governments to effectively engage the stakeholders of the ME/CFS, Long Covid, and infection associated condition and illness communities in planning and executing policies and programs.
- Advocating for reducing barriers to accessing social safety net and benefits for people with energy limiting disabilities, including calling for updated guidelines for accommodations for people with energy limiting disabilities
- Continuing to support and advocate for the Centers for Disease Control and Prevention (CDC) to enhance its surveillance and tracking of infection-associated chronic conditions and illnesses, providing critical data to inform policy and response strategies.
- Facilitating and advocating for increased collaboration between government agencies to streamline research efforts, share knowledge, and break down silos that hinder progress in understanding and treating infection-associated chronic conditions and illnesses.
- Encouraging the Agency for Healthcare Research and Quality (AHRQ) to issue treatment efficacy guidelines for infection-associated chronic conditions and illnesses, providing a foundation for evidence-based care.

- Advocating for the establishment of an FDA advisory panel focused on infection-associated conditions and illnesses, ensuring that regulatory considerations are informed by the latest scientific understanding and patient needs.
- Working towards the establishment of mechanisms that ensure comprehensive insurance coverage for treatments and interventions related to infection-associated chronic conditions and illnesses, mirroring successful models like those seen in the HIV/AIDS space.
 - The HIV/AIDS approach was notable for its comprehensive approach to providing services to those affected by HIV/AIDS, including funding for treatment, support services, and advocacy for patients' rights. Replicating elements of this response—such as dedicated funding streams, access to care, and patient advocacy can provide a blueprint for addressing the needs of those with infection-associated chronic conditions and illnesses.
- Finding and advocating for the implementation of mechanisms to ensure that treatment for infection-associated chronic conditions and illnesses are fully covered by insurance.
- We will also coordinate internationally and utilize the power of international agencies and organizations to raise the standard of what is expected from governments worldwide in relation to those living with infection-associated chronic conditions and illnesses.

3) Increase the Quality and Accessibility of Clinical Care and Patient Support

Solve seeks to create and expand programs (such as centers of excellence) and policies by the government, the medical community, and other entities that will dramatically increase the availability of knowledgeable infection associated disease experts and care specialists and improve the quality, accessibility, and affordability of clinical care and patient support for patients.

We call for the development and aggressive distribution of medically accurate and expert-reviewed education materials and curriculum by governmental, academic, medical associations, other institutions, and other advocacy groups for the purpose of improving the understanding and outcomes, providing patient and caretaker support, and combating the stigma of ME/CFS, Long Covid, and infection associated chronic conditions and illnesses. Possible models of ways to approach relevant medical education include the [ECHO LC&FIRP telementoring](#) model, and the [Medical School Curriculum Initiative Model](#).

In addition, Solve M.E. supports programs that will improve cross clinician collaboration in clinical care and research, providing an enhanced medical infrastructure to exploit emerging research, drive dramatic improvement in clinical standards of practice, and ensure clinicians across the United States are informed of the latest research findings and diagnostic and treatment protocols.

We will consistently advocate to increase clinical capacity and quantity of expert clinicians by using technology and legislation such as telementoring and cross state license portability efforts to overcome accessibility issues and geographic barriers.

Solve will also advocate for enhanced accessibility to informed healthcare results in earlier intervention, decreased disease chronicity, and improved care management.

4) Raise awareness and Improve Understanding of ME/CFS and Long Covid in the General Public

In order to awareness and improve understanding of ME/CFS and Long Covid among the general public, Solve will fight for dramatically expanded efforts to inform government agencies, employers, schools, and the public that ME/CFS and Long Covid are disabling conditions entitled to all governmental protections and benefits available to disabled persons under federal, state, and local laws, and is specifically covered by the Americans with Disabilities Act (ADA), the Individuals with Disabilities Education Act (IDEA), and all other civil rights laws protecting disabled persons.

Additionally, we will demand accurate information about ME/CFS, Long Covid, and infection associated chronic conditions and illnesses be effectively communicated through multiple methods (e.g. CDC, NIH, SSA, and patient support and advocacy groups) to combat stigma, change the disease narrative, and foster positive interactions with clinicians, employers, potential donors, and government support agencies. Additionally, Solve will seek out notable and highly visible stakeholders and community members that can assist in raising awareness.

Finally, Solve will elevate the stories and lived experiences of people with infection-associated chronic conditions and illnesses in existing education efforts.

5) Elevate and center patient voices and lived experience experts in research and policy

Solve strongly supports the concept of “nothing about us without us”.

In order to elevate and center the voices of those with lived experience of infection-associated chronic conditions and illnesses, Solve will highlight patients in research and policy, especially those who may not have education or professional experiences and those who are often excluded in these areas. Solve recognizes that patients are the experts in their own experiences with these conditions and illnesses. In order to make this feasible, Solve will pay patient experts for their time when they contribute to Solve initiatives in alignment with [NHC compensation calculator](#)

Additionally, Solve commits to training patient leaders in advocacy, supports, empowering, and equipping them with the information and skills to best represent their experiences in the research and policy domains.

We seek to align and achieve the highest levels of patient engagement as described in Patient-Led Research Collaborative's [Patient Engagement Scorecard](#).