Solve ME/CFS Initiative

Chronic Fatigue Syndrome Advisory Committee

Thursday, January 12, 2017

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Solve ME/CFS Initiative

www.SolveCFS.org

The ME/CFS Public Health Crisis

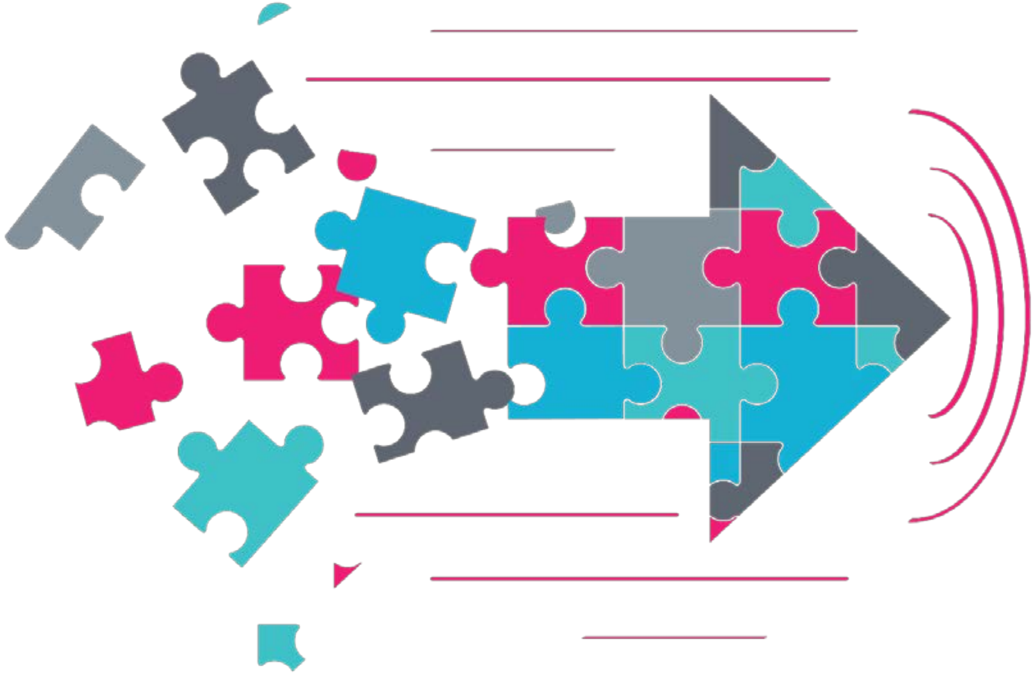
- 30 + years of neglect and misunderstanding
- Up to 2.5 million American patients suffering, documented increased risk of suicide
- Fewer than 12 clinical specialists practicing nationwide
- $17 - $24 billion per year cost to US economy
- Lowest quality of life scores for any disease measured

Why does ME/CFS continue as a public health crisis?

- No central federal leadership and no central coordinating plan
- Minimal resources
- ME/CFS stakeholders not included in programming or planning decisions
- Limited cross-agency collaboration
- No public/private partnerships
- Limited communication and engagement with stakeholders
- No support for clinical care
- Unsuccessful efforts to combat stigma in the medical and clinical fields

Solve ME/CFS Initiative

And, here we are.



CFSAC contains the pieces of the puzzle to make a significant difference for ME/CFS

The Federal ME/CFS Puzzle Pieces

Federal Agencies on CFSAC

- Department of Health and Human Services (HHS)
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Health Resources & Services Administration (HRSA)
- Food and Drug Administration (FDA)
- Social Security Administration (SSA)

Welcome:

- Department of Veterans Affairs (VA)
- Department of Defense (DoD)

Federal Agencies not on CFSAC

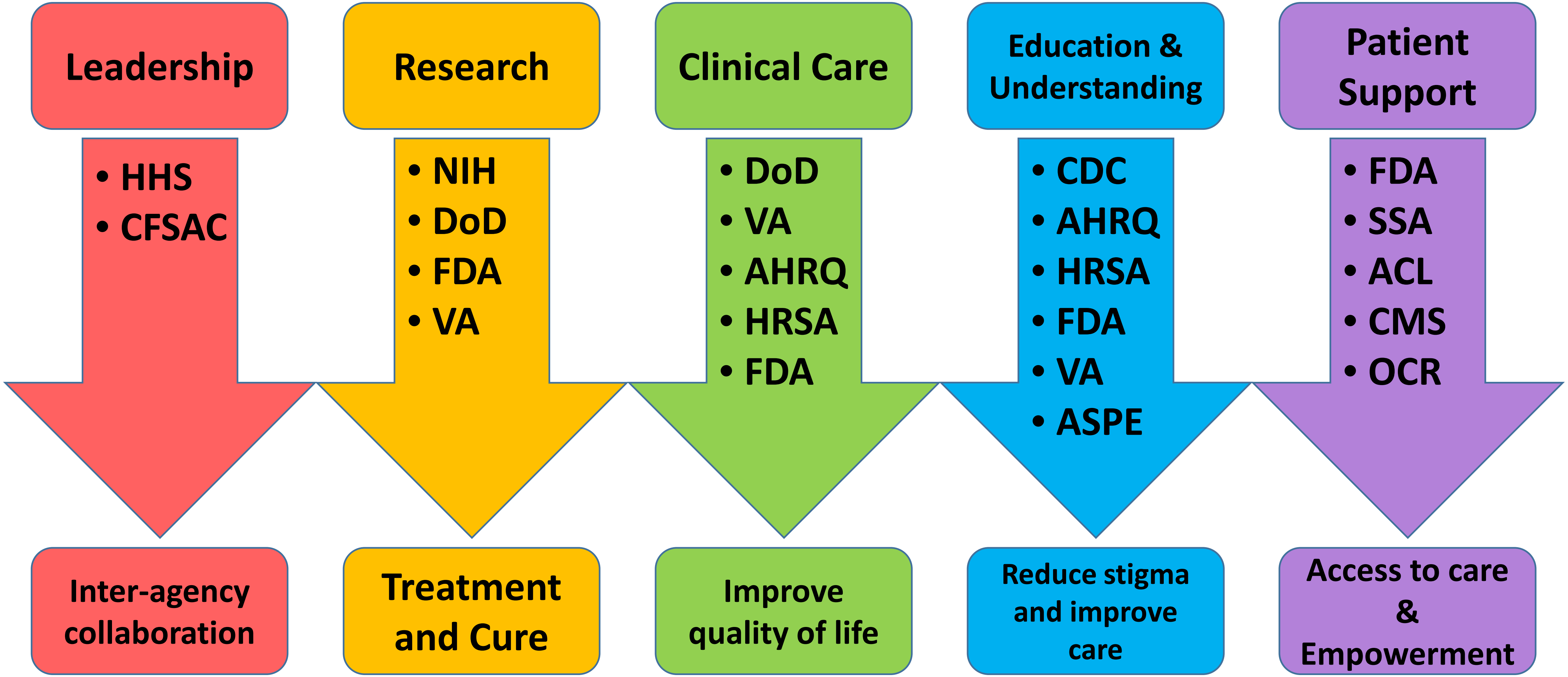
- Administration for Community Living (ACL)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Centers for Medicare and Medicaid Services (CMS)
- Office of Civil Rights (OCR)

The Non-Federal ME/CFS Puzzle Pieces

Non-Federal Stakeholders

- Patients and advocates
- Caregivers
- Research and Non-profit Organizations
- Pharmaceutical companies and biotech industry
- University and Academic Research Institutions
- Clinical care and medical practitioners
- Medical and Nursing schools
- Medical Associations

Fitting the pieces together



Leadership

- HHS
- CFSAC

Inter-agency collaboration

Research

- NIH
- DoD
- FDA
- VA

Treatment and Cure

Clinical Care

- DoD
- VA
- AHRQ
- HRSA
- FDA

Improve quality of life

Education & Understanding

- CDC
- AHRQ
- HRSA
- FDA
- VA
- ASPE

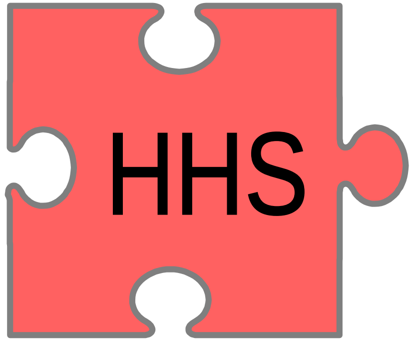
Reduce stigma and improve care

Patient Support

- FDA
- SSA
- ACL
- CMS
- OCR

Access to care & Empowerment

Leadership



Fact: Since 2014, approximately 7% of CFSAC recommendations to the Secretary of HHS are adopted and implemented

HHS must ensure ME/CFS patients and research are a priority

Assistant Secretary of Health

- Work with a newly designated CFSAC member to incorporate the needs of ME/CFS patients into **HHS' 4-year strategic plan**
- Provide inter-agency leadership to **integrate ME/CFS patients** into existing agency program structures
- Add participation in CFSAC from Administration for Community Living (ACL), Assistant Secretary for Planning and Evaluation (ASPE), Centers for Medicare and Medicaid Services (CMS), and Office for Civil Rights (OCR)

Leadership

HHS
cont.

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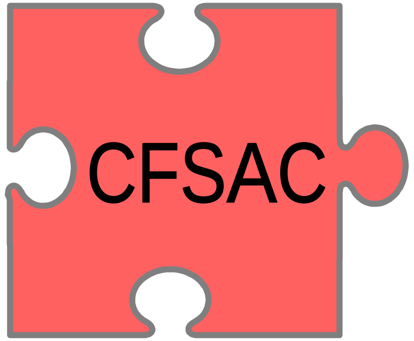
HHS must ensure ME/CFS patients and research are a priority

Assistant Secretary for Planning and Evaluation

- Collaborate with the ME/CFS community to identify agencies and programs that are failing to serve ME/CFS patients
- Conduct a review on these agencies and programs in regards to access and inclusion of patients with ME/CFS and report the findings
- Draft a report with the findings of this review and submit to the Secretary of HHS, Congress, and the ME/CFS community
- Draft and publish strategic plans to address problem areas identified in the report and ensure that ME/CFS patients are able to access and benefit equally from relevant health and human services programs

Leadership



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CFSAC must work with each agency to ensure ME/CFS related actions and activities are being carried out

Administration Transition

- Ensure continuation of CFSAC with continued reporting to HHS
- Educate incoming administration leadership about ME/CFS
- Form an interagency task force on ME/CFS to develop a comprehensive federal plan to make progress on ME/CFS
  - Task force should report quarterly to HHS, CFSAC, and Congress

New Agencies

- Administration for Community Living (ACL)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Centers for Medicare and Medicaid Services (CMS)
- Office of Civil Rights (OCR)

Leadership

CFSAC
cont.

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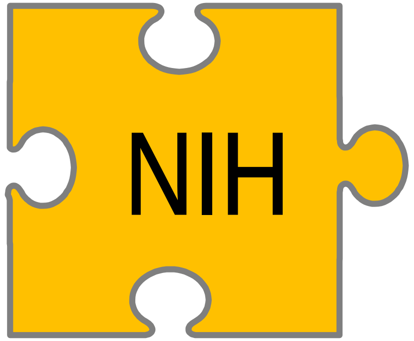
Procedural Recommendations

- Ex-officios submit CFSAC reports two weeks in advance of meetings
- CFSAC submit questions in writing to ex-officios one week in advance of meetings
- Organize public comment by subject
- Schedule time on the agenda for discussion of agency responses to previous recommendations
- In-person meetings twice a year for a full two days

Substantive Recommendations

- Ex-officios answer questions submitted prior during meetings, enable substantive discussion
- Open listening sessions (by call or webinar) in advance of meetings

Research



Fact: If ME/CFS were funded like other diseases of similar prevalence and severity, it would receive $250 million annually from the NIH

NIH must invest in the ME/CFS research ecosystem

Office of the Director

- Accelerate ME/CFS research with urgency and dollars
- Publically acknowledge the public health crisis of ME/CFS
- Create a plan in collaboration with other agencies to improve the ME/CFS research ecosystem, eg…
  - Eureka-style grants for ME/CFS researchers
  - More “New and Early Stage Investigator” and “Training-Related and Mentored Career” awards for promising ME/CFS researchers beginning their careers
  - Loan forgiveness programs for entering the ME/CFS field
  - Convene a US-based ME/CFS research conference

Research

NIH
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Trans-NIH ME/CFS Working Group

- Improve communications with patients and stakeholders
  - Quarterly public conference calls or webinars to update the community
  - Yearly “listening sessions” to receive feedback from the community
- Identify and fund key replication studies to validate previous findings
- Improve transparency and community involvement in the Common Data Elements (CDE) project
  - Work with the CDC to generate an ME/CFS research case definition
- Complete and publish the comprehensive research strategy for ME/CFS (Status?)
- Triple the number of ME/CFS RFAs in FY 18 (6 RFAs)

Research

NIH
cont.

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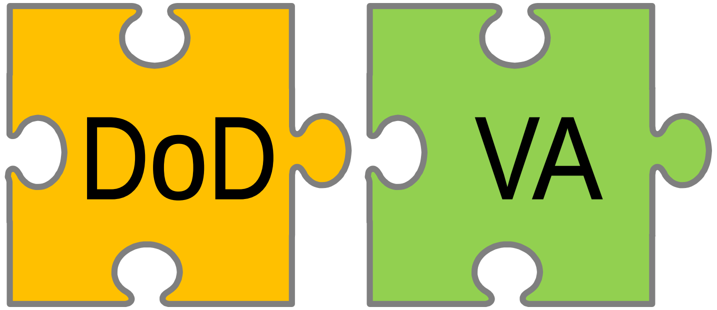
Clinical Trials

- There are no clinical drug trials in progress; we need them
- Improve communications with patients and stakeholders
  - Report on progress at Trans-NIH ME/CFS Working group quarterly calls
- Publically release protocols, schedule, and patient participation protections

Research and Clinical Care



Fact: Gulf War Illness and ME/CFS have significant overlap in symptoms and research findings; Gulf War veterans show a 16x increased risk of ME/CFS

DoD and VA must prioritize ME/CFS in existing education and patient care programs

Gulf War Illness

- Study veterans with ME/CFS in addition to Gulf War Illness

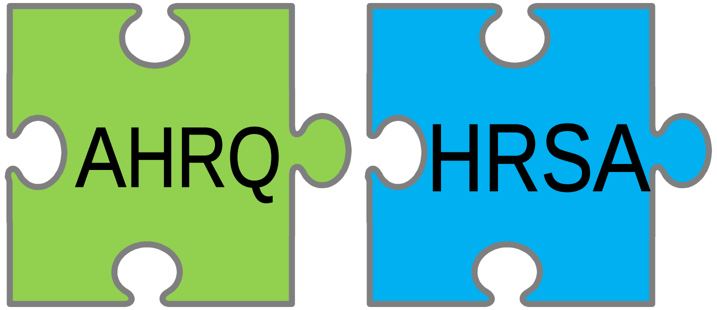
Medical Education

- Inform active duty medical personnel and VA staff about ME/CFS
- Loan forgiveness for students and personnel entering into ME/CFS field

Patient Support

- Ensure ME/CFS and GWI are included as protected disability
- Offer participation at VA facilities with clinical trials in collaboration with NIH and CDC

Clinical Care and Education



Fact: Less than 1/3 of medical schools include ME/CFS specific information in the curriculum and only 40% of medical textbooks include ME/CFS

AHRQ and HRSA must develop and distribute recommendations to improve ME/CFS understanding and care

SMCI applauds AHRQ for re-evaluating the Oxford case definition and issuing the July 2016 addendum and encourages the inclusion of the addendum into the Annals article

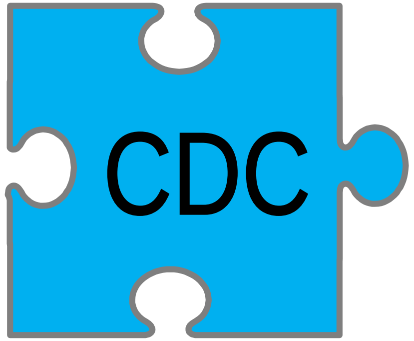
Understanding

- Research into the experience of ME/CFS patients in health care settings and provide recommendations to improve their experience

Medical Education

- Research into medical knowledge of ME/CFS in practicing providers and provide recommendations to improve their knowledge and understanding
- Help distribute ME/CFS findings into medical education curriculums, major medical associations, conferences, and disease clinics (with CDC)

Education



Fact: Recommendations for Graded Exercise Therapy (GET) remain on the CDC website, despite being shown in studies to cause harm to patients

CDC must use expert-reviewed and evidence based materials to ensure medical professionals are informed about ME/CFS

Website

- Immediately remove GET recommendations, which were downgraded by the AHRQ, and have been shown to cause harm to patients
- Diagnosis criteria – Using the IOM? IOM does not appear in MedEdPortal video

Medical Education

- ME/CFS experts and stakeholders MUST review materials – Why was CFSAC not informed or included on ME/CFS education materials distributed earlier this month?
- Develop curriculum with updated medical information for medical students and health practitioners
- Develop a plan for Fukuda patients who do not meet IOM criteria

Education

CDC
cont.

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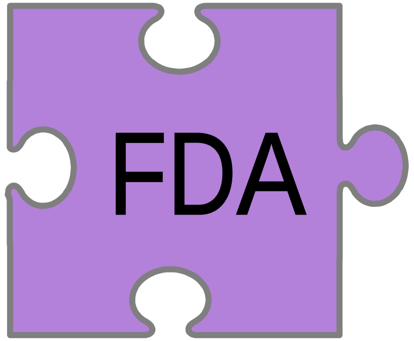
Inter-agency Collaboration

- Track ME/CFS prevalence and disease burden, last report was in 2002
- Address the faulty ICD-10 CM codes, currently doctors use the ICD code for ME/CFS which is the same as the one for chronic fatigue
- Common Data Elements Project – identify research case definition

Multi-site study

- Improve communications with patients and stakeholders – utilize community skills and knowledge
- Publically release the study protocol

Patient Support



Fact: There are no FDA approved treatments for ME/CFS. This year, Ampligen was approved by Brazil as the first ME/CFS treatment

FDA must identify the key barriers to treatment approval and communicate to other agencies those needs

Rituximab & Ampligen

- Provide guidance for research protocols to fast track for approval
- Coordinate with public and private partners to bring about clinical trials

21st Century Cures

- How can FDA provisions for “rare and misunderstood” diseases assist ME/CFS?

Stakeholder Engagement

- FDA has led the way in ME/CFS stakeholder listening sessions. FDA can work with other agencies to develop their own successful stakeholder engagement

Patient Support

SSA

Fact: Between 35% to 69% of ME/CFS patients are unemployed

SSA must create guidelines for ME/CFS

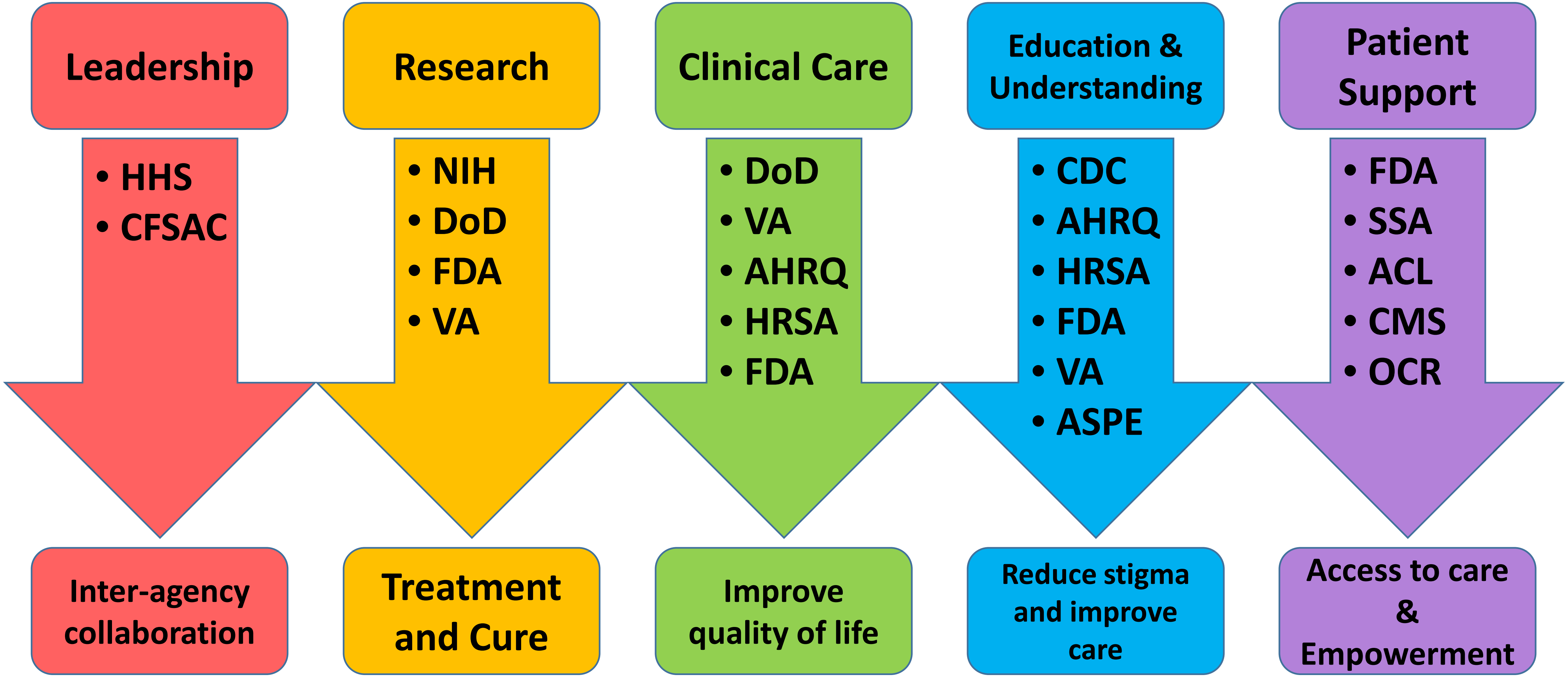
Patient Support

- Educate SSA staff about ME/CFS
- Continue to update disability guidelines for ME/CFS cases for staff and patients
- Create an outreach and education strategy for ME/CFS patients

Create Understanding

- Update 2012 report on ME/CFS cases and claims
  - How do ME/CFS cases and claim success rates compare to other diseases?
  - Is the average length of an ME/CFS claim process longer or shorter compared to other diseases?
  - How do client satisfaction reports for ME/CFS cases compare to other diseases?

Fitting the pieces together



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Access to care & Empowerment

We need the pieces to work together

1. An ME/CFS Inter-agency Task-Force
    - To LEAD, PLAN, and EXECUTE – not an advisory role
    - Create a comprehensive 5-year strategic plan
        - specific targeted goals
        - Inter-agency collaboration
2. Invest in a Solution
    - $250 million per year
3. Make ME/CFS patients part of your agency and program success
    - Are your programs and services serving this community equitably and fairly?
    - Are you considering ME/CFS patients in program design and execution?
    - Are ME/CFS patients part of the conversation regarding their own future?

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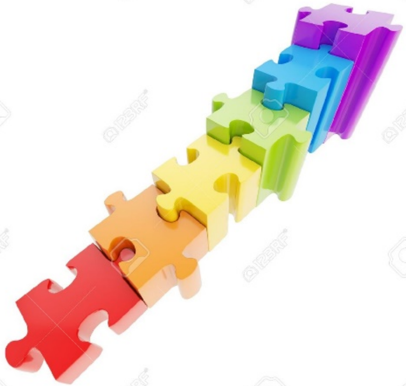
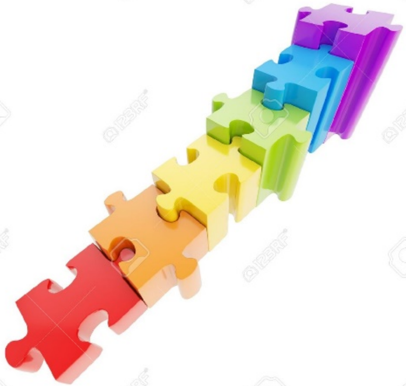


We can do this.
We MUST do this.



Our mission

To make ME/CFS understood, diagnosable, and treatable

www.SolveCFS.org