ME/CFS Research Year-End Summary

Carol E. Head
Solve ME/CFS Initiative
President & CEO

Suzanne D. Vernon, PhD
Solve ME/CFS Initiative
Scientific Director
Introduction – Thank you for joining us.
Our Goals for This Webinar

• Distill some of the recent and promising areas of research

• Update federal agency activity

• “What does all of this mean to you?”
Burden of Illness

• FDA considers ME/CFS a serious condition with unmet medical need
  – “A serious disease or condition is associated with morbidity that has substantial impact on day-to-day functioning”
  – “An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet medical need includes an immediate need for a defined population (i.e., to treat a serious condition with no or limited treatment)”

• Serious disease with unmet medical need
  • Too few clinicians
  • No FDA-approved diagnostic tests or treatments
Top 10 Research Advances

1. *Delineating heterogeneity
2. *Oxidative stress
3. Inflamed brain
4. *Central sensitivity
5. *Autoimmunity
6. *Patient-centered research
7. Risk factors
8. Brain white matter
9. *Autonomic nervous system
10. *Pathogens

http://solvecfs.org/research_digest_2014top10/
Heterogeneity, Patient-Reported Outcomes

Evidence that ME/CFS is a heterogeneous illness

The patients voice, personal tracking and monitoring
Meaningful to patients

1. Dizziness
2. Vertigo
3. Night sweats
4. Dyspnea
5. Muscle Hypertonia
6. Ageusia
7. Other insomnia
8. Cramp in lower leg associated with rest
9. Cardiac symptom
10. Slight temperature
Oxidative Stress, Inflamed Brain

Oxidative stress  Neuroinflammation
Autonomic Nervous System, Central Sensitization

Blood flow to the brain

Amplified brain signal

Normal transmission

Central Sensitization
Autoimmunity, Risk Factors

- Evidence for an autoimmune subtype
- Women are at increased risk, allostatic load (inflammation)

Effector T cells

- Eliminate the pathogens
- Repair damage
- Regenerate tissues

Regulatory T cells

- Prevent autoreactivity
- Curb excess inflammation

Inflammation
Pathogen
Clearance
Pathogens, White Matter

Viruses are latent or can cause damage in remote organs.

Signal transmission, arcuate fasiculus - language.

Image credit: Earth’s virology professor, Vincent Racaniello
http://www.virology.ws/

Image credit: arcuatefasciculus.blogspot.com
Where are the bottlenecks?
A Look Ahead into 2015

**PHASE 1**
Recruit patient community and collect core data, lab results, experiential data, medical history.

**ME/CFS RESEARCH READY COMMUNITY**

**PHASE 2**
Molecular deep dive—Genotype, Epigenetics, Micro RNA, Metabolomics, Virome, Antibody profiling.

**ME/CFS MOLECULAR SIGNATURES**

**PHASE 3**
Build Information Commons and Knowledge Network. Iterative analysis to discover subtypes.

**ME/CFS SUBTYPE DISCOVERY**

---

**PROJECT OUTCOMES**

> Define subtypes, benefitting RESEARCHERS, PATIENTS and DOCTORS
> ENDURING Information Commons and Knowledge Network
> Committed partners for DIAGNOSTIC and DRUG DEVELOPMENT
Breaking news!
SMCI Awarded $500,000

• Catalyst Research Program of the Falk Medical Research Trust
  – Support research that leads directly to the development of treatments and cures for diseases for which there are no effective treatments or cures today.
  – Partner with Drs. Lucinda Bateman and Patrick McGowan
    • Expand epigenetic study and “restock” SolveCFS BioBank inventory
• Very competitive grant application. Their confidence validates the work of our organization.
• Gives us a head start on in 2015 research. Yet much more research yet to be done…
Addressing Unmet Need

• ME/CFS is on the federal radar – we help to keep it there!

• CFS Advisory Committee. SMCI has a seat at the table
Federal Activity


• HHS – Contracted with the Institute of Medicine to make recommendations re: ME/CFS. Spring 2015 report.


• CDC-sponsored multi-site study.
Be at the Center of the Solution

• Sign up for our Research1st e-newsletter, blog updates and to receive the SolveCFS Chronicle at solvecfs.org/get-involved/newsletters

• Join the BioBank! Email BioBank@SolveCFS.org http://solvecfs.org/solvecfs-biobank/eligibility/

• Drive research and fuel progress by donating! SolveCFS.org/donate/
Thank You!

**Our Mission:**
Make ME/CFS understood, diagnosable and treatable.

**Our Strategy:**
Stimulate participatory research aimed at the early detection, objective diagnosis and effective treatment of ME/CFS through expanded public, private and commercial investment.