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New Directions in Medical Understanding about Myalgic Encephalomyelitis

Margaret Williams **26th August 2015**

Please note that two paragraphs in this document have been amended following comments and suggestions. Many thanks to those who pointed out oversights in the original version dated 22nd August 2015.

Background

For almost 30 years the UK psychiatric lobby (in particular, Professor Sir Simon Wessely and Professors Peter White and Michael Sharpe) have taught medical students and clinicians and have advised UK Government Departments, the Medical Royal Colleges, the Medical Research Council, NICE and the permanent health insurance industry that Myalgic Encephalomyelitis (ME) is the same as "chronic fatigue" or "chronic fatigue syndrome" (CFS) and that it is a functional somatic syndrome (ie. a behavioural disorder) that is perpetuated by *"aberrant illness beliefs", "maladaptive coping",* and *"hypervigilance to normal bodily sensations".*

Despite the fact that since 1969, ME has been listed by the WHO as a neurological disorder in the International Classification of Diseases, they assert that neurasthenia would readily suffice for ME (Lancet 1993:342:1247-1248) and that ME is merely a myth (*"I will argue that ME is simply a belief, the belief that one has an illness called ME"*: Simon Wessely: 9th Eliot Slater Memorial Lecture, Institute of Psychiatry, London, 12 May 1994).

They have been insistent that no investigations should be performed to confirm the diagnosis because, according to them, standard tests are normal and doing any additional tests just reinforces patients' erroneous belief that they are physically ill (Joint Royal Colleges' Report on CFS: CR54).

They are certain that "CFS/ME" can be cured by "cognitive restructuring" and graded aerobic exercise to correct the "deconditioning" which they assert results from an irrational fear of exercise, hence Professors White and Sharpe (assisted by Professor Wessely) received over £5 million to carry out their PACE Trial in a determined attempt to prove their own belief that it is a psychogenic disorder. Despite wildly exaggerated media reporting of the alleged success of the trial by the Science Media

Centre, many observers consider the trial unsuccessful due to its methodological shortcomings and failure to deliver objectively measured improvement, facts which the Investigators consistently refuse to acknowledge.

They continue to work assiduously to remove ME from its neurological classification and in the meantime to claim that it has dual listing in ICD-10 – once in the neurological section but again in the mental health section (this in spite of clarification on 23rd January 2004 by the WHO that *"according to the taxonomic principles governing the Tenth Revision of the World Health Organisation's International Statistical Classification of Diseases and Health-Related Problems (ICD-10) it is not permitted for the same condition to be classified to more than one rubric as this would mean that the individual categories were no longer mutually exclusive*" http://www.investinme.org/InfoCentre%20Library.htm; www.meactionuk.org.uk

As "Science Insider" reported on 17th August 2015, there are a lot of *"critically ill patients"* with ME and many people – international clinicians, medical scientists and patients alike – maintain that the harm and distress caused to people with ME by the UK psychiatric lobby is incalculable, but the tide has finally turned and new directions and developments in medical science have vitiated their influence and power, for example:

1. <u>The US Institute of Medicine Report</u>

The Institute of Medicine (IOM) of the National Academies was asked by the Health and Human Services (HHS), the Centres for Disease Control (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ) to convene an expert committee to examine the evidence base for ME/CFS. The committee was charged with developing evidence-based clinical diagnostic criteria for use by clinicians.

Their report "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness" was published on 10th February 2015 and stated that *"ME/CFS is a serious, chronic, complex, multisystem disease that frequently and dramatically limits the activities of affected patients. In its most severe form, this disease can consume the lives of those whom it afflicts. It is 'real' "* https://iom.nationalacademies.org/Reports/2015/ME-CFS.aspx

In his review "Redefining the Chronic Fatigue Syndrome" published on 5th May 2015 in Annals of Internal Medicine, Ganiats commented on the report: *"The literature review found sufficient evidence that ME/CFS is a disease with a physiologic basis. It is not, as many clinicians believe, a psychological problem that should not be taken seriously"* http://annals.org/article.aspx?articleid=2118972

The website of the Department of Health and Human Services includes the following comment about the IOM committee report: *"With their recommendation of a streamlined, yet evidence-based set of diagnostic criteria, the IOM committee has taken a critical step toward assisting medical providers in making a diagnosis for those with this serious and debilitating illness".*

After publication of the IOM committee report, the CDC decided to archive its "CFS Toolkit" which had recommended the cognitive behavioural and exercise interventions so strenuously promoted by the UK psychiatric lobby.

In its "Brief Report" of February 2015 that accompanied the full Report, the IOM pointed out: *"Many health care providers are skeptical about the seriousness of ME/CFS, mistake it for a mental health condition, or consider it a figment of the patient's imagination. Misconceptions or dismissive attitudes on the part of health care providers make the path to diagnosis long and frustrating for many patients. The committee stresses that health care providers should acknowledge ME/CFS as a serious illness that requires timely diagnosis and appropriate care".*

2. <u>The NIH Pathways to Prevention (P2P) Report</u>

The National Institutes of Health (NIH), one of the world's foremost medical research centres, convened a "Pathways to Prevention" (P2P) working group which on 16th July 2015 published its Report "Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome". It is an important document, as it signifies a major change in attitude towards ME/CFS. The Report is clear:

"Strong evidence indicates immunologic and inflammatory pathologies, neurotransmitter signaling disruption, micorobiome perturbation, and metabolic or mitochondrial abnormalities in ME/CFS that are potentially important for defining and treating ME/CFS" (page 3).

"Both society and the medical profession have contributed to ME/CFS patients feeling disrespected and rejected. They are often treated with skepticism, uncertainty, and apprehension and labeled as deconditioned or having a primary psychological disorder. ME/CFS patients often make extraordinary efforts at extreme personal and physical costs to find a physician who will correctly diagnose and treat their symptoms while others are treated inappropriately causing additional harm" (page 4).

"Although psychological repercussions (e.g., depression) may accompany ME/CFS, it is not a primary psychological disease in etiology" (page 5).

"fMRI and imaging technologies should be further studied as diagnostic tools and as methods to better understand the neurologic dysfunction of ME/CFS" (page 10).

"An integrated, systems-level approach should be followed to understand how immunologic, neurologic, and metagenomic factors may contribute to ME/CFS. Immunologic mechanisms of ME/CFS and pathways associated with disease progression must be defined and characterized (e.g., defining cytokine profiles involved in pathogenesis; studying inflammation; and comprehending the basis for natural killer cell dysfunction observed in many ME/CFS patients)" (page 12).

"*Many clinicians do not fully understand ME/CFS. We believe ME/CFS is a distinct disease …..Primary care clinicians will be instrumental in ensuring that patients are treated appropriately and care is optimized. Thus, a properly trained workforce is critical"* (page 14).

"Patients should be active participants in care and decision-making. Lessons can be learned from palliative care, such as communication and symptom management to improve the quality of care" (page 15).

"Clinicians could benefit from enhanced active listening skills and increased education" (page 16).

"Specifically, continuing to use the Oxford definition may impair progress and cause harm. Thus, for needed progress to occur we recommend (1) that the Oxford definition be retired" (page 16).

https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/me-cfs/workshop-resources#finalreport

(The Oxford criteria were formulated by the UK psychiatric lobby and include patients with mental disorders whilst excluding those with cardinal symptoms of ME yet claiming to select those with ME).

3. CFS Advisory Committee Meeting / US Department of Health and Human Services 18th-19th August 2015

The Chronic Fatigue Syndrome Advisory Committee (CFSAC) provides advice and recommendations to the Secretary of Health and Human Services (HHS) on issues related to myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS). Its message is unambiguous: *"CFSAC recommends a co-ordinated cross-agency effort to change the narrative – from "unexplained fatigue" to an understanding of the multi-systemic nature of this disease – through use of the name Myalgic Encephalomyelitis (ME) and consistent with the messaging provided by the IOM and P2P reports".*

Quotations from screenshots of the power point at the CFSAC meeting:

1. *"Myalgic Encephalomyelitis (ME) is an acquired, chronic, multi-systemic disease…resulting in significant relapse after exertion of any sort. The disease*

includes immune, neurological and cognitive impairment, sleep abnormalities and autonomic dysfunction.

2. *There is strong scientific evidence of immunologic and inflammatory pathologies, neurotransmitter signalling disruption, microbiome perturbation and metabolic or mitochrondrial abnormalities in the disease.*

3. *The disease is not psychiatric in nature and should not be equated with neurasthenia, somatic symptom disorder or functional somatic syndrome.*

4. *The disease is not synonymous with "chronic fatigue", "idiopathic fatigue" or "fatigue syndrome".*

5. *<u>Medical Education</u>: Education and awareness is needed regarding…the evidence-based fact that this is not a somatoform or mental health disorder".*

4. <u>Verbatim Quotations from the video of Dr Ronald Davis from The Open Medicine Institute (OMI)</u>

Dr Davis is Professor of Biology and Genetics at Stanford University and Director of Stanford Genome Technology Centre; he is a member of The National Academy of Sciences and was a member of the Institute of Medicine Panel that was re-evaluating ME; he was also involved in a very large trauma study involving 16 universities and 100 investigators. He spoke about his son, who is "*extremely severely*" ill with ME.

"It's been clear from what everybody has said before me that this is a horrible disease….It's clear this disease is a problem medically for people, but one of the horrible things about it is that patients are often told there's nothing wrong with them and I think that hurts an awful lot….We saw how hard that was for them, feeling so sick and yet no-one believed them.

"We will assay everything we can possibly assay … that means blood, saliva, urine, sweat, faeces, and do an extensive analysis.

"This is a horrible problem, and a big one….it's a major disease.

"It's remarkable how insidious this thing is, in the sense that people who have it don't look sick, so nobody believes them.

"The standard medical procedures that the doctor will run – liver function, kidney function etc etc –they're fine, but if you look deeper, (my son) is not fine.

"Some of the things we've measured are 16 standard deviations away from normal. That's a major problem.

"We found several hundred things that are out of whack….Probably that will be the same for other people (with ME).

"Physicians need to take care of the patients….Every person…needs to have some level of support".

https://www.youtube.com/watch?v=lHhJmpHCORw

5. Response by Dr Ronald Davis to Grant Rejection by NINDS

The National Institute of Neurological Diseases and Stroke (NINDS) rejected the pre-application funding proposal from the OMI on the grounds that "*it was not clear that the proposal falls within the mission of NINDS".* Dr Davis' response was unequivocal: *"The mission of NINDS is to study diseases with a neurological component. CFS is clearly such a disease".*

http://www.meaction.net/wpcontent/uploads/2015/08/ResponseToNIHRejectionsRonDavis.pdf

6. Confirmation that high-ranking scientists are willing to carry out research into ME

Following the assertion that there is a paucity of scientists willing to do research into ME, in their letter of 17th August 2015 to Senator Mikulski requesting funding, Dr Ronald Davis et al wrote:

"There are Nobel Laureates, several members of the National Academy of Sciences, biochemists, biophysicists, geneticists, immunologists, neuroscientists, experts in public health and infectious disease, epidemiologists, and physicians eager and ready to study this disease, were adequate funding made available".

http://news.sciencemag.org/biology/2015/08/lobbyists-seek-250-million-new-funds-chronic-fatigue-syndrome-research

The Scientific Advisory Board of the OMI includes the following:

Paul Berg, PhD, Nobel Laureate, Molecular Genetics, Stanford University

Mario Capecchi, PhD, Nobel Laureate, Genetics & Immunology, University of Utah

Mark M. Davis, PhD, Immunology, Stanford University

H. Craig Heller, PhD, Biology & Exercise Physiology, Stanford University

Andreas M. Kogelnik, MD, PhD, Infectious Disease, Open Medicine Institute

Baldomero M. Olivera, PhD, Neurobiology, University of Utah

Ronald G. Tompkins, MD, ScD, Trauma & Metabolism, Harvard Medical School

James D. Watson, PhD, Nobel Laureate, Molecular Genetics, Human Genome Project (with Francis Crick, Nobel Prizewinner for solving the structure of DNA)

Wenzhong Xiao, PhD, Computational Genomics, Harvard University, Stanford University.