

A MEDICAL MORASS?

Margaret Williams

17th November 2006

Whilst not written in relation to the current confusion about ME/CFS, an NHS consultant physician recently responded to an article in the BMJ on the issue of “policy versus evidence”: **“Over the past few decades the practice of Medicine has moved from a basis of experience and understanding of the disease process and its treatment towards the application of authorised protocols and guidelines. (This) raises concerns about the situation in which an inadequate evidence base has become canonised into established guidelines (and) Government policy. It takes a bold man indeed to challenge this set of Emperor’s clothes”** (Nick Hardwick: eBMJ re BMJ 2006:333:912-915).

Can anyone doubt that it is the transformation of “protocols and guidelines” into “canonised policy” that has resulted in the morass that is ME/CFS?

For what disorder is NICE preparing its Guideline on “CFS/ME”? Is it ME or is it “CFS”? Are they the same disorder? NICE is relying on two definitions of “CFS” (the 1991 Oxford criteria and the 1994 Centres for Disease Control criteria), neither of which defines authentic ME. A quick look at the evidence makes interesting if disturbing reading.

1988

It is commonly accepted that in 1988, the disease that had previously been called ME was renamed “CFS” by Holmes et al from the US Centres for Disease Control, but is this true, or has there been one of the most devious subterfuges perpetrated in the history of medicine?

It has long been believed that the introduction of the name “CFS” in 1988 emerged from a collaboration involving Dr Stephen Straus from the US Centres for Disease Control (CDC) with the medical insurance industry, the intention being to curtail benefit payments for the rapidly increasing incidence and prevalence of an existing (and chronically incapacitating) disorder that was known as ME. It was apparently anticipated that such curtailment could be achieved by focusing on the single symptom of chronic “fatigue” (a ubiquitous symptom for which benefit payments could expediently be denied).

That people were seriously sick with what international ME experts regarded as ME is not in doubt (see Osler’s Webb: Inside the Labyrinth of the Chronic Fatigue Syndrome Epidemic. Hillary Johnson. Crown Publishers Inc, New York: 1996). Quite certainly the

advisory committee that was to produce the 1988 case definition of “CFS” included two of the leading experts in ME, Dr Alexis Shelokov from the US and Dr Gordon Parish from the UK.

However, both these experts withdrew from the deliberations as they were unable to endorse the new definition of “CFS” because it was so far removed from what, as experts, they knew ME to be, since it excluded the cardinal and well-documented neurological and vascular features of ME and focused instead on “fatigue”. The experts were dismayed that the essential characteristics of ME were no longer to feature in the “new” definition that was claimed to be preferable, ostensibly because it made no assumptions about aetiology.

It is recorded that Holmes himself wanted to keep the term ME but was over-ruled.

If in 1988 “CFS” was indeed meant to be a new name for ME, in 2005 it was acknowledged to have been a major error by one of the physicians on the committee, Professor Anthony Komaroff: *“None of the participants in creating the 1988 CFS case definition, and the illness name, ever expressed any concern that it might trivialise the illness. We simply were insensitive to that possibility, and we were wrong”* (http://www.cfidsreport.com/Articles/NIH/NIH_CFS_4.htm).

In that definition (Chronic Fatigue Syndrome: A Working Case Definition. Gary P Holmes et al. Ann Intern Med 1988;108:387-389), no mention was made of ME or of its cardinal features (either in the text or in the references), only of the chronic Epstein-Barr Virus Syndrome: *“We propose a new name for the chronic Epstein-Barr virus syndrome – the chronic fatigue syndrome”* (EBV being one of the herpes family of viruses seen in mononucleosis, not one of the enteroviruses more commonly seen in ME).

Holmes et al also stated that their case definition described *“a possibly unique clinical entity”*, but how could such a description apply to ME, given that ME had been documented in the medical literature since at least the 1930s and had been formally classified as a neurological disorder in the International Classification of Diseases since 1969 and had been recognised as a nosological entity in 1978 by the UK Royal Society of Medicine?

Further, the listed symptoms of the newly-defined “CFS” included fever; sore throat; painful lymph nodes; generalised muscle weakness; myalgia; sleep disturbance; headaches; depression; decreased memory and prolonged generalised fatigue after exercise, all of which might result from EBV infection. In other words, the symptoms were those seen in a typical (and commonly transient) post-viral state that were usually of little consequence.

Was the over-riding intention to deflect medical and scientific attention away from the world-wide explosion of the devastating and chronic disorder ME and to create a “new” disorder called “CFS” that was of considerably lesser significance and impact, and therefore of less financial consequence for the CDC and the insurance industry?

In the 1988 “CFS” definition, no mention was made of the fact that in ME, there is a sub-normal temperature (not fever), nor of the additional signs and symptoms that define ME (for example, difficulty in standing and walking; neuro-muscular incoordination; vertigo and balance problems with observable nystagmus; abnormal reflexes; blurred vision; frequency of micturition and other evidence of autonomic instability; fasciculation; marked tremor; difficulty swallowing; hair loss; respiratory, cardiac and vascular problems; pancreatic problems; liver involvement; bowel problems including explosive diarrhoea; increased allergies and hypersensitivities; marked variability of symptoms; sensory storms, and the cardinal symptom of *angor animi* – a feeling of imminent death).

A further notable difference is that patients who develop CFS following EBV may succumb to every opportunistic infection and sore throat doing the rounds, whereas those with ME rarely, if ever, get a sore throat or common cold (as noted in the literature on ME, as well as in patients’ own accounts).

Of interest is that in November 2006, the CDC “CFS Toolkit” launch noted that there are two distinct types of “CFS”, one with rapid post-viral onset and the other with a gradual onset and – significantly -- that the two types appear to differ genetically.

The question therefore arises as to what disorder the 1988 “new” case definition was defining if, according to the ME experts, it was not ME?

The alternative question is whether the key features of ME were deliberately omitted in order to portray “CFS” as a less serious (and therefore less expensive) disorder?

It seems that in 1988, ME was considered to be a physical disease that was henceforth to be renamed “CFS”, but whether this in fact occurred (or whether a different entity from ME was created) is open to conjecture.

1991

In 1991, the much-criticised “Oxford” case definition appeared, having been compiled by psychiatrists Michael Sharpe, Peter White and Simon Wessely, amongst others (A report – chronic fatigue syndrome: guidelines for research. MC Sharpe et al. JRSM 1991;84:118-121). This report makes it clear that Holmes et al were indeed referring to ME in their 1988 case definition of “CFS”. However, the 1991 criteria state that the authors were looking at patients “*with a principal complaint of disabling fatigue*” and that “*the aim of the meeting was to seek agreement amongst research workers for future studies of patients with chronic fatigue*”. As in the 1988 case definition of “CFS”, the key symptomatology of ME was missing, yet Sharpe et al claimed to be including “ME” in their definition. How could they be looking at ME when the cardinal features were specifically excluded from their definition? (It is this 1991 “Oxford” definition that NICE relies upon in its Draft Guideline for “CFS/ME”).

It is important to remember that Wessely School psychiatrists' on-the-record goal is to consider all cases of "chronic fatigue" -- from whatever source -- under one umbrella, because they want to determine the role of "fatigue" in psychiatric disorders.

In this respect, why are patients with ME so relentlessly targeted for psychotherapy as the management regime of choice, when patients with leukaemia or multiple sclerosis (both of which cause fatigue) are not so targeted and admonished that they must "exercise back to fitness"?

It is also important to recall that Wessely's cherished aim has long been to "eradicate" ME as a distinct entity: if a disorder does not officially exist, then no-one can suffer from it and there would be no need for expensive provision for it and benefits need not be paid for it. This also seems to have been his *modus operandi* in the case of Gulf War Syndrome.

1992

In July 1992 the WHO published the tenth revision of the International Classification of Diseases (ICD-10), in which an alternative term for ME was listed as "CFS", which subsequently gave rise to the term "ME/CFS".

Also in 1992, the US Physicians' Handbook published by the National Institutes of Health (NIH) stated: "*CFS does not appear to be a new disorder. Epidemics (most often called myalgic encephalomyelitis or ME) have been described in the medical literature for at least 60 years*".

1994

During one of the meetings at which the 1994 CDC revised definition of "CFS" was formulated, in response to a direct question from a physician who was present, Dr Keiji Fukuda (not an ME expert, but lead author of the CDC 1994 definition) stated that the numerous ME epidemics, including the one at the Royal Free Hospital in London in 1955, were definitely **not** CFS. As in the CDC 1988 case definition, the CDC 1994 revised case definition makes no mention of ME or of its key signs and symptomatology. Instead it emphasises that the exclusion of persons with psychiatric disorders including depression and anxiety "*would substantially hinder efforts to clarify the role that psychiatric disorders have in fatiguing illnesses*", adding for good measure that "*chronic fatigue cases preceded by some, but not all, psychiatric syndromes **can be classified as the chronic fatigue syndrome***". Of significance is the fact that the 1994 CDC revised criteria for "CFS" state unequivocally: "***We dropped all physical signs from our inclusion criteria. Whether to retain any symptom other than chronic fatigue generated the most disagreement among the authors***". Thus it seems beyond doubt that ME was not included within the compass of the 1994 CDC revised case definition of

“CFS”, no matter what Sharpe (one of the 1994 authors), Wessely, White et al claimed in 1991 (and subsequently). It is, however, this definition that has been used in research that has revealed the major pathology that underlies (ME)CFS.

Why therefore does the ME community use the composite term “ME/CFS”? For two reasons: firstly because the WHO ICD states that they are the same disorder and secondly because the international research literature makes little mention of “ME”, thus to refuse to use the term “CFS” would exclude the major research literature spanning the last two decades.

So – in 1988, ME was not the same disorder as CFS (because the ME experts said so), but in 1991 and 1992 (according to Wessely School psychiatrists, the WHO and the NIH), ME was the same disorder as CFS, yet in 1994, according to Fukuda, ME was not the same disorder as CFS (even though Wessely School psychiatrists continue to claim that it is).

In other words, CFS was not ME when ME was deemed to be a physical disorder, but as soon as ME came to be considered a psychiatric disorder (by Wessely School psychiatrists), suddenly CFS was ME after all.

Given this conundrum, for what disorder is NICE producing its Guideline?

On what rational grounds does NICE refuse to accept the advancement of medical science and take as its starting point the Canadian case definition (Carruthers, Klimas et al 2003) that incorporates the cardinal features of authentic ME with the international biomedical research on “CFS” into a composite entity?

Confusion over case definition has resulted in confusion over the safety of management regimes

The NICE Draft Guideline for “CFS/ME” is clear that the only recommended interventions are cognitive behavioural therapy, graded (aerobic) exercise and “activity management”.

Is it safe for people with authentic ME to engage in graded exercise?

In a submission to NICE on behalf of the UK 25%ME Group for the Severely Affected, mention was made of the 5th edition (2002, reprinted 2004) of a medical textbook that is likely to be on the desk of every GP in the country (having won the “Highly Commended” BMA Award) and to the fact that it contained statements about ME by psychiatrists Peter White and Anthony Clare that are insupportable. The 6th edition (2005) of the same medical textbook is equally inaccurate. Within the section on CFS (in Functional or Psychosomatic Disorders starting on page 1281), White and Clare talk about “*dysfunctional beliefs and behaviours*” and refer to the “*management of functional disorders*” as being “*rehabilitative therapy*” which includes CBT (to “*challenge*

unhelpful beliefs and coping strategies”) and they recommend three months’ GET “*to reduce inactivity and improve fitness*”.

This is in line with the NICE draft recommendations about aerobic exercise and also with the NHS Plus Policy Document of October 2006 concerning the occupational aspects of CFS that reflect the Wessely School psychiatrists’ strongly-held beliefs.

However, Dr Derek Enlander MD (a former virologist who specialises in ME/CFS, previously Assistant Professor at Columbia University and then Associate Director of Nuclear Medicine at New York University; currently Physician-in-Waiting to the Royal Family and to members of HM Government when they visit New York) is on record about aerobic exercise for patients with ME/CFS: “*I do not want my patients in an aerobic class. I feel this causes considerable damage to (ME)CFS patients*”. (Derek Enlander: Update on the Treatment of Chronic Fatigue Syndrome and Fibromyalgia, 8th November 2006).

Equally, Dr Paul Cheney, who has been studying the disorder since the Lake Tahoe outbreak in 1984, is adamant that such patients should not engage in aerobic exercise: indeed they are unable do so, because the lack of energy generation results in low cardiac output that is not equal to the metabolic demand created by aerobic exercise. (For further information on Cheney’s evidence, see

http://www.meactionuk.org.uk/Klimas_Wessely_and_NICE_-_Redefining_CBT.htm).

The Canadian Guidelines are unequivocal: graded exercise showed the highest negative rating of all management interventions: “*The question arises whether a formal CBT or GET programme adds anything to what is available in the ordinary medical setting. A well-informed physician helps (the patient) achieve optimal exercise and activity levels within their limits in a common-sense, non-ideological manner which is not tied to deadlines or other hidden agenda*” (ME/CFS: Clinical Working Case Definition, Diagnosis and Treatment Protocols. Bruce M Carruthers, Kenny L De Meirleir, Nancy G Klimas et al. JCFS 2003;11:1:7-115).

Moreover, the CDC “CFS Toolkit” released at the beginning of November 2006 is equally clear: “*This kind of exercise (aerobic) can precipitate a full-scale relapse that lasts for weeks or months*”.

It is already known that ME/CFS experts agree that aerobic exercise can cause serious relapse and that it can be dangerous to the extent that it could be life-threatening for some such patients.

CBT/GET is already known not to be effective.

CBT/GET has already been shown to have no lasting benefit.

CBT/GET is already known to be very expensive.

It is already known that, logistically, CBT/GET cannot be delivered without recruiting, training and supervising many more therapists at vast expense.

It is therefore a misuse of funds that could – and should – be better spent on biomedical research.

Why, therefore, is NICE continuing to pay no heed to the evidence and to recommend CBT/GET as the only management regime for those with “CFS/ME”?

Is it because NICE is taking advice from only one source ie. from the Wessely School, whose members are, on their own admission, heavily engaged in social engineering and to which they are so committed? (see “Biopsychosocial Medicine: An integrated approach to understanding illness” edited by Peter White; OUP 2005; chapter 12).

It is such social engineering that turns an inadequate evidence-base into canonised Government policy.

Is this social engineering taking place because the truth is not to be tolerated under any circumstances (the truth being contained in a memo sent on 17th November 2006 from the Director of the US CDC, Dr Julie Gerberding, to CDC staff: **“When we launched the national CFS awareness campaign this month, we demonstrated credible evidence of a genomic and an environmental basis for this condition”**).

In other words, ME/CFS is environmentally acquired. Why is no research permitted in the UK into the “environmental basis” of the condition, but only denial of its very existence?

Already there is evidence that patients are suffering as a direct result of the NICE Draft Guideline: Professor Leslie Findley from the Essex Neurosciences Unit at Romford has confirmed that in this last week, two Primary Care Trusts have altered, or turned down, treatment for patients with ME/CFS on the basis of the content of the Draft Guideline and asks that people should be made aware that the Draft Guideline is currently being misused.

At the All Party Parliamentary Group on ME held at Westminster on 16th November 2006, a representative from NICE was instructed by the APPG Chairman (Dr Des Turner MP) to report back to NICE that NICE would be very unwise to publish its Draft Guideline on “CFS/ME” as it stands, and that Turner was at a loss to know why NICE was doing this and also about what NICE hoped to achieve by it. Sir Michael Rawlins, Chairman of NICE, was to be invited to attend the next APPGME.

For a brief comparison of the difference in the UK and the US about the validity and reality of ME/CFS, the following quotations are taken from the Press Conference held on 3rd November 2006 at the launch of the CDC “CFS Toolkit”:

Dr Julie Gerberding, Director of the US CDC:

“One of the things that CDC hopes to do is to help patients know that they have an illness that requires medical attention, but also to help clinicians be able to understand, diagnose and help people with the illness. **But more importantly, to be able to validate and understand the incredible suffering that many patients and their families experience in this context**”.

“I have heard from hundreds and hundreds of people who are telling their stories – their courage, their commitment to try to live the best possible life they can (and) the tremendous impact that this is having on their ability to function”.

“We are committed to improving the awareness that this is a real illness and that people need real medical care and they deserve the best possible help that we can provide”.

“The science has progressed (which has) helped us define the magnitude and understand better the clinical manifestations (and this has) led to a sorely needed foundation for the recognition of the underlying biological aspects of the illness. We need to respect and make that science more visible”.

Dr William Reeves, Chief of Chronic Viral Diseases Branch at CDC:

“We’ve documented the prevalence of (ME)CFS – the illness affects at least a million Americans”.

“(ME)CFS is responsible for an impact of about \$9.1 billion annually in lost earnings”.

“We’ve documented, as have others, that the level of impairment in people who suffer from (ME)CFS is comparable to multiple sclerosis, AIDS, end-stage renal failure, chronic obstructive pulmonary disease. The disability is equivalent to that of some well-known, very severe medical conditions”.

“We found that (ME)CFS follows a pattern of remitting and relapsing symptoms, the symptoms can change over time, and that spontaneous recovery is rare”.

“We found that the best predictor for (ME)CFS was intensity of the initial infectious disease. The sicker the patient when s/he first got infected, the more likely they were to have persisting chronic symptoms. There were no other factors, psychological or biological, that held up under thorough analysis”.

Professor Anthony Komaroff of the Harvard Medical School:

“There are now over 4,000 published studies that show underlying biological abnormalities in patients with this illness. It’s not an illness that people can simply imagine that they have and it’s not a psychological illness. In my view, that debate, which was waged for 20 years, should now be over”.

“A whole bunch of studies show that the hormone system is different in patients with (ME)CFS than in healthy people, people with depression and other diseases”.

“Brain imaging studies have shown inflammation, reduced blood flow and impaired cellular function in different locations of the brain”.

“Many studies have found that the immune system appears to be in a state of chronic activation (and) genes that control the activation of the immune system are abnormally expressed in patients with this illness”.

“A number of studies have shown that there probably are abnormalities of energy metabolism in patients with this illness”.

During the Question and Answer session, the question was asked: “You’ve cited quite a bit of research that validates that (ME)CFS is actually a real disease. Why is there still such a level of scepticism in the medical community? Is it simply a lack of awareness among health professionals?”

Komaroff replied: **“There are an awful lot of sceptics I’ve met who really just haven’t read the research literature (and) don’t even know there are 4,000 peer-reviewed published papers out there. I think that’s probably the biggest factor, combined with the fact that those people took a stand early on as to what they believe and have been reluctant to back off in the face of the evidence that they’ve not made themselves aware of”.**

Professor Nancy Klimas, Professor of Medicine, University of Miami:

“I’ve treated over 2,000 (ME)CFS patients. I’ve seen patients (who) were angry, frustrated, trying to convince their physicians, their families, their friends that this is a real illness. I’ve seen other patients (who) hid their diagnosis because of the stigma attached and suffered in silence. **It’s been the lack of credibility in this illness that has been one of the major stumbling blocks to making progress”.**

“Today, there is evidence of the biological underpinnings. And there’s evidence that the patients with this illness experience a level of disability that’s equal to that of patients with late-stage AIDS, patients undergoing chemotherapy, patients with multiple sclerosis. And that has certainly given it a level of credibility that should be easily understood”.

“I’m less enthusiastic about the advances in the clinical care of patients”.

“We need disability insurance carriers to believe this is an illness – a disabling illness and do what they should do, and pay our patients when they are disabled”.

“There are diagnostic criteria that enable clinicians to diagnose (ME)CFS in the primary care setting”.

“Key to the effective management of illness is the effective partnership with the patient and the physician. It’s also important for patients to take a proactive role and become informed and seek appropriate care to manage the illness and its impact on their lives”.

“I call on my colleagues in the medical profession to treat (ME)CFS patients with the kind of respect and compassion necessary to make this first step”.

The full Press Conference transcript is available at
<http://www.cdc.gov/od/oc/media/transcripts/t061103.htm?id=36410>

Whatever the motives or mistakes in the past, it is apparent that whatever it is called, ME/CFS can no longer be regarded as a behavioural disorder as the Wessely School has insisted for the last two decades.

It might be wondered what will be the reaction of Wessely, White, Sharpe et al to know that it has been publicly recognised that from their irrefutable published record (although not named personally), they must be included amongst those responsible for the debate that was waged for twenty years against severely physically – and not mentally – sick people, a debate that has both caused and prolonged incalculable suffering and which, despite all the contrary evidence, Wessely et al are still endeavouring to promote under the auspices of NICE, Government Policy Documents and textbooks of medicine.