ME/CFS: Classification Issues

Margaret Williams 3rd May 2009

Deborah Waroff expresses concern (Co-Cure: ACT: 3rd May 2009) about the serious danger to the World Health Organisation classification of ME/CFS as a neurological disorder posed by the Wessely School. She bases her concern on a recent paper in Psychological Medicine co-authored by psychiatrist Professor Peter White which states: "*These data also suggest that fatigue syndromes are heterogeneous, and that **CFS/ME and PVFS should be considered as separate conditions**, with CFS/ME having more in common with IBS than PVFS does. **This requires revision of the ICD-10 taxonomy, which classifies PVFS with ME"*** (emphasis added). In apparent support for their desired removal of ME/CFS (which they refer to as "CFS/ME") from the neurological section and its reclassification as a somatisation (behavioural) disorder, the authors assert: *"A strong relationship between CFS and psychiatric, particularly mood, disorders is a constant finding"* (Risk markers for both chronic fatigue and irritable bowel syndromes: a prospective case-control study in primary care. WT Hamilton, AM Gallagher, JM Thomas and PD White.

http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=5446224).

It should be noted that the lead author, Dr William T Hamilton, was a member of the Guideline Development Group (GDG) which drew up the NICE Guideline on "CFS/ME" (CG53) that was published on 22nd August 2007 and which recommended behavioural modification as the primary – indeed the only –management regime for patients with ME/CFS.

In contravention of NICE's own taxonomy, the Guideline erroneously lumped together two completely different disorders (ME/CFS and neurasthenia/chronic fatigue). GDG member Dr Fred Nye wrote in the Journal of Infection: "*We had been advised to adopt an inclusive approach, but this was challenged by the patient representatives who preferred a narrow case definition. A wide definition risks 'medicalising' people who are merely tired"*. This quotation from Dr Nye shows that, under the chairmanship of Professor Richard Baker (see below), the GDG intentionally amalgamated numerous states of chronic "fatigue", leading to a meaningless and worthless Guideline for sufferers of ME/CFS and instead concentrating on people who are merely tired (to use Dr Nye's words) at the expense of the patients who are seriously ill with a chronic neuroimmune disorder.

The Wessely School's view (which underpinned the Guideline's management recommendations) is set out in Wessely's own paper in The Lancet (Functional somatic syndromes: one or many? Lancet 1999:354:936-939), namely that "*CFS has been described as part of a broader condition that includes a range of disorders including fibromyalgia, irritable bowel syndrome etc"*, about which Wessely's Chronic Fatigue

Service at King's College Hospital, London, commented in the Stakeholders' comments on the draft Guideline that such a view "*will be well received by many doctors, since it reflects their views and emphasises ways in which we can increase our knowledge of one 'syndrome' "*.

This is the heart of the matter, because what NICE refers to as "CFS/ME" is <u>not</u> one functional somatic syndrome but a conglomeration of numerous states of chronic fatigue into which the distinct neurological disorder ME has been erroneously subsumed by Wessely School psychiatrists upon whose work (acknowledged to be methodologically flawed) the GDG relied so heavily.

There has long been international concern about the Wessely School's determination to ignore the biomedical science and to categorise ME/CFS as a behavioural disorder, and the increasing influence of the Wessely School on the US Centres for Disease Control (CDC) (ME)CFS research programme seems to have caused international experts to speak out about their concerns.

For example, at the CDC (ME)CFS Stakeholders' meeting held on 27th April 2009 in Atlanta, Dr Staci Stevens advised the CDC that: "*Without defining subsets clearly, it will preclude you from meeting your goals. You won't understand aetiology and you won't understand clinical management"*. Dr Lily Chu also emphasised the need for subgrouping: *"Selecting study subjects by using study criteria that have been diluted, such that (they) no longer resemble the illness, will generate erroneous and confusing results"*.

The need not to combine heterogeneous populations (as the NICE Guideline does) was set out by world-renowned immunologists Professors Nancy Klimas and Mary Ann Fletcher from the University of Miami in their exceptional (fully referenced) testimony dated 13th September 2008 for the Court in support of the Judicial Review. They said (amongst five pages of evidence): "*The overall flavour of the Guideline is to lump together all patients with 'medically unexplained fatigue', from relatively mild to profoundly disabling illness and to treat all patients with a standard approach of gradual reconditioning and cognitive behavioural modification. By lumping such a heterogeneous mix of patients, and setting forth very limited diagnostic and treatment recommendations, patients with CFS or ME are left with very limited options, and little hope"*. Professors Klimas and Fletcher continued: *"In our opinion, combining all states of unexplained fatigue narrowly focuses upon a single, poorly defined symptom (fatigue) and promotes misunderstanding of CFS"*. The Statement continued: *"(The Guideline) proscribes immunological and other biologic testing on patients with CFS in the UK – despite the evidence in the world's medical literature that such testing produces most of the biomedical evidence of serious pathology in these patients. Equally unfortunate is the GDG's recommendation for behavioural modification as the single management approach for all 'medically unexplained fatigue'. This month we participated in the International Conference on Fatigue Science in Okinawa, Japan. Dr Peter White of the UK presented his work using behavioural modification and graded exercise. He reported*

a recovery rate of about 25%, a figure much higher than seen in US studies in CFS, and even if possible, simply not hopeful enough to the 75% who fail to recover. The lumping of a heterogeneous population with no biological testing funded hampered this study". The Statement continued: *"In summary, we support your challenge to the GDG Guideline. We hope any future revision acknowledges the importance of immune, autonomic and neuroendocrine influences in this illness".* The Statement concluded: "*We would also ask that the Court consider the far-reaching impact of a Guideline that fails to look forward or even at the present when describing the literature and the causes of this disabling illness".*

Along with approximately 60% of the Claimants' evidence, this testimony was entirely disregarded at the High Court Hearing.

It is clear from Professor Baker's Witness Statement (see below) and from Dr Nye's letter in the Journal of Infection that the GDG's intention from the outset was that the Guideline should cover a whole range of patients suffering from "medically unexplained fatigue", which is classified in the ICD-10 at F48.0 under Mental and Behavioural Disorders, a section **from which ME is expressly excluded by the WHO**, yet the Guideline specifically claims to include ME. The GDG thus failed in its remit to produce an aid to diagnosis for ME/CFS. As Chairman, Professor Baker must bear responsibility for this failure.

Moreover, under the chairmanship of Professor Baker, the GDG specifically refused to accept the WHO classification of ME/CFS as a neurological disorder.

On 24th March 2003 Andre L'Hours from the WHO confirmed that it is mandatory for all member states (which include the UK) to use the ICD-10 codes, and NICE's own Communications Progress Report 8 of September 2002 also stipulates that it is mandatory for NICE to use the ICD-10 codes. This evidence was provided for the GDG and the High Court but was unheeded.

The alleged reason for the GDG's refusal to accept the ICD-10 classification was proffered in the First Witness Statement (he provided two Witness Statements) of Professor Richard Baker on behalf of NICE, whose First Witness Statement was discussed at length in Court (whereby it entered the public domain and can therefore be quoted publicly):

"The claimants argue that the GDG should have recognised the classification given in ICD-10, which lists ME under Section G 'Diseases of the Nervous System'. The GDG acknowledged this classification but considered it best not to adopt it". Quoting from page 68 of the Full Guideline, Professor Baker's First Witness Statement continued: " *'The World Health Organisation (WHO) classifies CFS/ME as a neurological illness (G93.3), and some members of the GDG felt that, until research further identifies its aetiology and pathogenesis, the guideline should recognise this classification. Others felt that to do so did not reflect the nature of the illness and risked restricting research into*

the causes, mechanisms and future treatments for CFS/ME'. As indicated in the extract above, there were two reasons why the GDG did not accept the ICD-10 classification. ***Firstly, there was not enough agreement that it could be said with sufficient certainty that CFS/ME was a neurological condition. Secondly****, given the uncertainty surrounding how the condition is caused and why it progresses in the way that it does,* ***the GDG did not want the Guideline to have the unintended consequence of steering future research down a particular course. The concern was that had the Guideline adopted the ICD-10 classification, that would have made it harder to obtain funding and approval for research into non-neurological factors causing and perpetuating CFS/ME (and) such a consequence would have been highly undesirable"*** (emphasis added).

Professor Baker's First Witness Statement continued: "*In addition to code G93.3 for ME, ICD-10 includes a code F48 – neurasthenia – which describes symptoms typical of CFS/ME and is referred to elsewhere in ICD-10 as covering 'fatigue syndrome'. Furthermore, the classification G93.3 refers only to ME, and not to CFS".*

Thus Professor Baker confirmed that the management recommendations in the Guideline are based on the **feelings** of **some** members of the GDG, thereby ignoring the WHO taxonomy and the concerns of those GDG members who believed that the ICD-10 classification should have been adopted in the Guideline, as well as ignoring the pressing needs of patients with ME/CFS to receive a correct diagnosis and appropriate support.

Given that the WHO has classified ME as a neurological disorder for 40 years, there is abundant international agreement that it can be said with certainty that ME is a neurological condition. There may not have been sufficient agreement amongst GDG members that ME/CFS is a neurological condition, but there is absolute certainty that ME/CFS is a WHO classified neurological disorder.

The NICE Guideline claims to represent the best available evidence. The best available evidence is that since 1969, ME has been an internationally classified neurological disorder (WHO ICD-10: G93.3). **The best available evidence** is that since 2003, ME has been classified as a neurological disorder in the UK Read Codes used by GPs (F286), and that ME is included in the UK National Service Framework for long-term neurological conditions. **The best available evidence** is that the UK Department of Health accepts that ME is a neurological disorder, and that the UK Chief Medical Officer accepts that ME is a neurological disorder with long-term effects on health alongside other illnesses such as multiple sclerosis and motor neurone disease. **The best available evidence** is that there are now over 5,000 peer-reviewed scientific papers demonstrating that ME/CFS is not a behavioural disorder.

As the UK is a member of the WHO World Health Assembly, the GDG does not have the autonomy to reject the formal WHO classification of ME/CFS as a neurological disorder and, as chairman, Professor Baker could have been expected to direct his GDG appropriately. It seems that, influenced by the Wessely School, he failed to do so.

By the wording of that paragraph in his First Witness Statement (ie. *"non-neurological factors **causing and perpetuating** CFS/ME"*), Professor Baker seems to imply that he knows that **non-neurological factors (ie. behavioural factors) cause and perpetuate "CFS/ME"**, but there is no evidence whatever to substantiate his professed knowledge on this issue. There is however, an extensive Wessely School literature asserting that they do, which is based not on scientific evidence but on Wessely's own somatisation hypothesis (adopted by the GDG and whose previously published papers already supported such a notion) that has been stringently challenged by international ME/CFS researchers in the peer-reviewed literature.

NICE was even admonished by the House of Commons Health Select Committee which, in its First Report of Session 2007-08 (Volume 1: 29), stipulated: *"NICE should not recommend interventions when the evidence is weak"*.

NICE itself conceded that in the case of "CFS/ME", the evidence was weak. By letter dated 26th January 2006, a NICE Communications Executive (Sarita Tamber) confirmed: "*With regard to the CFS/ME guideline, because of the lack of evidence it was decided to use formal consensus methods with the GDG. As you are aware, NICE guidelines are based on research evidence but NICE is aware of the lack of evidence on CFS/ME"*.

The revelation from Professor Baker seems clear enough: had the GDG adopted the ICD-10 classification, it would have made it harder to obtain funding for research into "*non-neurological factors*" (ie. "behavioural factors"). In other words, the Wessely School psychiatric gravy-train would have hit the buffers, a gravy-train that has been funded by the State, including the MRC alone to the tune of £3 million since 2002, which is approximately 91% of the MRC's total grant spent on "CFS/ME". It seems that the dominant Wessely School GDG members clearly wanted to ensure continued funding for their studies on "behavioural modification" in CFS/ME.

Underpinning it all is the publicly stated intention of the Wessely School that the next revision of the Diagnostic and Statistical Manual (DSM-V) should include "CFS/ME" as a somatoform disorder (a category that they wish to re-configure).

If NICE had accepted the disorder as neurological, it would have thwarted the Wessely School's objective of eradicating ME and of capturing "CFS/ME" – with their stated intention of eventually dropping the "ME" -- as a psychiatric disorder (with advantageous implications for their paymasters in the medical and permanent health insurance industry), so it seems that their supporters on the GDG (including Dr Hamilton, who is Chief Medical Officer of two major medical insurance companies, the Exeter Friendly Society and the Liverpool Victoria and who also is employed by Friends Provident, a fact that he now admits he failed to declare to NICE) did not allow it to happen.

Given that it was as long ago as 28th June 2001 that Andre L'Hours confirmed that the WHO has no plans to remove ME/PVFS/CFS from the section on Disorders of the Brain and transfer it to a psychiatric classification (confirmation of which was again supplied --

in writing -- by Dr Robert Jakob of the WHO on 5th February 2009 in relation to the forthcoming ICD-11), it seems sinister that the Wessely School continues unrestrained by any vestige of accountability or professional censure in its determination to disregard and over-rule the WHO to the detriment of many thousands of desperately sick patients. If this were to occur with patients suffering from any other organic disorder, be it cancer, multiple sclerosis, lupus or renal failure, a clinician who resolutely refused to accept the abundant evidence of such a disorder and who simply insisted that the patient change their thought processes might face disciplinary proceedings. It is incomprehensible that no such strictures are brought upon the miscreant Wessely School and upon those clinicians who support them.

The Gibson Report of November 2006 called for an inquiry by the appropriate Standards body into the blatant conflicts of interest of certain members of the Wessely School but, like everything else to do with ME/CFS, this call has gone unheeded.

Quite apart from the issue of correct classification, the evidence continues to mount that ME/CFS is essentially a neurological disorder.

For example, a review of the neurological components of ME/CFS is clear. Although this review was published in 2008 (i.e. after the Guideline was published in August 2007), only four of the 47 references cited were not available to the GDG:

"Additional evidence of an underlying neurological disorder requires appropriate neurological evaluation. Available neuroimaging data not only show differences in morphology between patients and controls, but also indicate the brain's response to mental fatigue. Evidence of abnormal perfusion in the brain has led to research on brain metabolism (which) found a significant hypometabolism in the right mediofrontal cortex and brainstem of patients. In summary, an increasing amount of evidence is becoming available to elucidate the close relationship between (ME/CFS) and the CNS. ***The focal point of (ME)CFS research should be transferred to the CNS and exploration of the neuromechanism of (ME)CFS"***. ("Chronic Fatigue Syndrome and the Central Nervous System": R Chen et al; Journal of International Medical Research 2008:36:867-874).

Given the significant amount of evidence that ME/CFS is a neuroimmune disorder, and given the fact that NICE is funded by -- and responsible to -- the Department of Health, it is irrational for NICE to refuse to accept the WHO international classification ICD-10 G93.3 when the Department of Health accepts it. This refusal may indicate the stranglehold exerted by the Wessely School and the medical and permanent health insurance industry upon both NICE and the MRC, of which there is abundant evidence not included here.

In their testimony for the Judicial Review, Professors Klimas and Fletcher pointed out that: "*The Guideline affects not only the UK but is widely quoted throughout the EU, and has influenced health care policy in Norway, Sweden, and the Netherlands"*.

At the CDC CFS Stakeholders' meeting on 27th April 2009 in Atlanta, Dr William Reeves (who is on record as saying in his Introduction to the meeting that the CDC has had four CFS programme reviews in the last four years, the most recent being in November last year) said: *"Dr Peter White participated. Dr Peter White is a representative of, I think, the only country and Ministry of Health in the world that has developed a comprehensive programme for diagnosing, evaluating, and treating CFS. There may be many comments as to whether it is the best, but it is a national health service, which takes this very seriously. And (they) have tried to implement on a national level something"* (with grateful acknowledgement to http://www.cfidsreport.com).

It is Peter White who is striving to get ME removed from the neurological classification of the ICD and reclassified as a behavioural disorder and who lumps together undefined states of "medically unexplained chronic fatigue" that he believes should be uniformly managed by cognitive restructuring that is intended to convince sufferers that they are not sick, merely that they are just not active enough because of their aberrant illness beliefs.

At the same CDC CFS Stakeholders' meeting on 27th April 2009, Professor Klimas was clear: she urged the CDC to consider "*the role of other chronic persistent re-infection in this disease. You just can't say that you are not going to look at infectious disease. **If there is this much immune activation, there is either a pathogen or an autoimmune disorder***".

The Wessely School (including Peter White), NICE and the UK Courts are not listening.

It seems that, by their consistent denial of the documented pathology and by means of their so-called "cognitive re-structuring techniques", the Wessely School is assisting the State to undermine sick people's rational thoughts, feelings and legitimate beliefs about their illness for political, social and economic reasons.

Deborah Waroff is right to be concerned. She is not alone.