

## Notes for NICE

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Compelling and undeniable evidence of significant biological anomalies continues to mount in patients with ME/CFS (the name now formally adopted by the US Name Change Advisory Board, which includes such luminaries as Professors Anthony Komaroff, Nancy Klimas, Leonard Jason and Charles Lapp, and world-renowned experts Drs Daniel Peterson, David Bell and Lucinda Bateman).

Will the self-styled “independent” and – to date -- much criticised UK Government advisory body known as NICE (The National Institute for Health and Clinical Excellence, whose “independence” needs to be weighed against the fact that it is funded by, and is accountable to, the Department of Health) pay due heed to this evidence before it produces its forthcoming Guideline on the disorder?

That Guideline was originally due in April 2007 but a recent announcement from NICE states: *“Owing to the volume of comments received to the draft consultation document, it has become apparent that the scheduled publication date of April 2007 will no longer be achievable. The publication date will now be 22<sup>nd</sup> August 2007”*.

Sadly, under the iron grip of psychiatrist Professor Peter White, the Department of Work and Pensions (DWP) has paid no heed at all to the ever-increasing biomedical evidence, nor has NHS Plus (whose Policy document is at least 15 years behind the science), so what are the chances that NICE will attempt to restore its credibility by taking on board the scientific evidence that ME/CFS is not a behavioural disorder that can be “managed” by cognitive behavioural therapy and compulsory exercise regimes but a complex multi-system organic disorder whose impact is devastating?

There may be a glimmer of hope. Not only has NICE delayed its Guideline, but a letter dated 23<sup>rd</sup> November 2006 to Dr Ian Gibson MP from the Chairman of NICE, Professor Sir Michael Rawlins, unequivocally confirms that all submissions about ME/CFS -- in whatever format they were submitted -- will be studied: *“We will, of course, look very carefully at all comments – irrespective of the format they are in. I can therefore assure you that all comments will be given full consideration by the guideline development group irrespective of their format”*. This was in reply to a letter of the same date from Dr Gibson which expressed grave concern about the tactics being used by NICE: *“Many very sick people have spent a great deal of time and effort researching and producing these reports. If you refuse these submissions on a technicality at the 11<sup>th</sup> hour we will never be able to move forward. The repercussions will be huge. We should be doing all we can to include patients groups, not alienate them further”*.

The delay in producing the NICE guideline may be fortuitous in another respect. In May 2007 there will be two major conferences on ME/CFS in the UK. One will be at the beginning of the month in London organised by the charity Invest in ME, with an impressive list of speakers including Professor Marty Pall from the School of Molecular Biosciences, Washington State University, USA; Professor Kenny De Meirleir, previously from Belgium and now in the US; Dr Nigel Speight, consultant paediatrician at the University of North Durham who specialises in ME/CFS; Dr Byron Hyde from Canada who has dedicated his entire medical practice to those with ME/CFS; consultant neurologist Dr Abhijit Chaudhuri; vascular biologist Dr Vance Spence from Dundee, and medicinal chemist Professor Malcolm Hooper.

The other conference will be hosted by the charity ME Research UK (formerly known as MERGE) on 25<sup>th</sup> May 2007 at the Edinburgh Conference Centre of Heriott-Watt University, Edinburgh. Although primarily a scientific meeting concentrating on hard data, it will be open to the public. It is an international conference on ME/CFS biomedical research and the keynote speaker will be immunologist Professor Nancy Klimas of the University of Miami. Amongst others, speakers will include physiologist Dr J Nijs from Amsterdam; psychiatrist Dr Ellie Stein from Canada (well-known for not subscribing to the view of some psychiatrists that ME/CFS is a behavioural disorder); Dr Jonathan Kerr from London, whose gene research into ME/CFS has received international acclaim, and Professor Jill Belch, Professor of Medicine and Head of Vascular Diseases Research at the University of Dundee.

Should NICE decide to disregard the highly significant biomedical research findings on ME/CFS, including the evidence that will be presented in Edinburgh four months before it produces its Guideline, it is likely that an application for Judicial Review will be made. If so, the abundant evidence of organic deficit in ME/CFS would be considered by a High Court Judge and NICE would be required to defend -- to the satisfaction of the Judge -- its decision to disregard that evidence.

Given the prevailing propensity of Government bodies and medical insurance companies (to which psychiatrists of the Wessely School are advisers) to focus on management strategies consisting only of behavioural therapy and exercise regimes, it is salutary to note that recent biomedical research has again highlighted a key symptom in people with ME/CFS, namely shortness of breath.

Professor Paul Cheney's view is that in ME/CFS, the cardiac output is insufficient to meet the metabolic demand.

In a post on 27<sup>th</sup> January 2007 (Co-Cure NOT: Progress for Treatment of CFS Slow but Promising), Professor Klimas is on record as stating that the illness is caused by the immune system being super-activated in its response to inflammation, and that the endocrine system is dysfunctional, as is the autonomic nervous system which controls pulse, blood pressure and breathing.

Now a paper by Natelson et al from the Department of Neurosciences at New Jersey Medical School USA has confirmed that some ME/CFS patients experience significantly more shortness of breath than controls

(ref: Hypocapnia is a biological marker for orthostatic intolerance in some patients with chronic fatigue syndrome. Benjamin H Natelson, Julian M Stewart et al. Dynamic Medicine 2007;6:2).

Natelson et al found that the (ME)CFS patients studied had higher rates of abnormal tests than controls and that rates of orthostatic hypocapnia were significantly higher in (ME)CFS patients than in controls.

They further found that this particular (ME)CFS group reported significantly more feelings of illness and shortness of breath than either controls or CFS patients with normal physiological tests.

The authors noted that orthostatic intolerance (OI) is defined by symptoms of lightheadedness, fatigue, neurocognitive deficits, nausea, abdominal pain and shortness of breath when upright and that patients with (ME)CFS commonly complain of symptoms worsening during standing.

Significantly more (ME)CFS patients than controls fulfilled the authors' criteria for abnormal standing tests (53% v 20%) and rates of orthostatic hypocapnia were significantly higher in (ME)CFS than in controls (20.6% v 2.9%). The first occurrence of a hypocapnic value occurred in the first three minutes of standing for eight of thirteen subjects, and the hypocapnia increased over time.

21% of patients in this study had orthostatic hypocapnia, compared with only 3% of controls, and the hypocapnia was sustained and progressive.

The authors point out that there are at least two explanations: hyperventilation, or reduced CO<sub>2</sub> delivery to the lung secondary to reduced venous return to the right heart.

The data indicate that emotional factors related to anxiety or depression are not important.

The authors' working hypothesis is that this phenomenon comes from a complex interaction among the baroreflex, chemoreceptors, and the thoracic blood volume.

The authors state: *"The identification of a subset of (ME)CFS patients with this physiological manifestation of orthostatic intolerance is important in that its existence can be used as a stratification strategy to reduce the patient pool heterogeneity"*

*"Finding such a marker in a subgroup of (ME)CFS patients is the first step in moving this illness from a clinical syndrome to one diagnosable by laboratory testing".*

This research adds to the ever-growing biomedical evidence demonstrating that the UK Government's published policy of imposing exercise regimes on patients with ME/CFS is potentially harmful for at least a subset of those with the disorder.

It also shows how misguided and uninformed are those who continue to regard ME/CFS as a primary mental health disorder.

It also raises once again profound concerns at the Government's proposed changes to the Mental Health Bill. As Denis Campbell wrote in The Observer on 4<sup>th</sup> February 2007: *"Vulnerable people who are not mentally ill or dangerous could be sectioned because government plans to protect the public are flawed. The Bill proposes to change the grounds for a person's detention from a true 'mental disorder' to **any disorder or disability of mind**".*

If the Wessely School psychiatrists have their way, "any disorder or disability of mind" is likely to include those with ME/CFS.

Attention was drawn to this possibility in 2001 (see The 1996 Strasbourg Convention on Biomedicine and the reform of the UK Mental Health Act: have they anything to do with the attempt to re-classify ME/CFS as mental illness in the WHO Guide to Mental Health in Primary Care?" (available online at [www.meactionuk.org.uk/strasbourg.html](http://www.meactionuk.org.uk/strasbourg.html) ).