

## A NICE Conundrum?

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A NICE conundrum seems to have presented itself, which the Judge in the Judicial Review of the NICE Clinical Guideline on “CFS/ME” may require NICE to explain for the benefit of straight-thinking folk who cannot readily understand such brain-teasers.

Straight-thinking folk know that NICE is funded by the UK Department of Health.

These straight-thinking folk also know that the NICE Guideline on “CFS/ME” (CG53) recommended as the primary intervention only behaviour modification, together with incremental aerobic exercise (cognitive behavioural therapy / CBT and graded exercise therapy / GET) for a disorder that NICE’s own paymaster accepts is a neurological disease, this having been confirmed once again in Hansard by the Parliamentary Under-Secretary of State, Department of Health, Lord Darzi, on 2<sup>nd</sup> June 2008.

It seems remarkable indeed that people unfortunate enough to be stricken with a neurological disease should not be permitted by NICE to be adequately investigated, but straight-thinking folk also know that NICE claims that its recommendations for CBT and GET in its Guideline are based on the very best evidence-base, which must surely reassure these straight-thinking folk that they will be receiving the best possible management of their life-destroying disease.

But here’s the conundrum: NICE’s own paymaster (i.e. the Department of Health) is on record as stating – in writing – that it holds no evidence that the interventions recommended by NICE in CG53 actually work in restoring the return to work (this being the underlying purpose of the recommended management interventions).

This was revealed when the Department of Health was asked about the recommendations set out in the NHS Plus National Guideline – which the Department itself notably funded -- that was published in October 2006, (“Occupational Aspects of the Management of Chronic Fatigue Syndrome: A National Guideline” in which Wessely School members Professors Trudie Chalder, Peter White and Michael Sharpe were instrumental), the recommendations in that Guideline being the same recommendations that were adopted by NICE in its Guideline of August 2007.

Crucially, both Guidelines were based on the same “evidence-base”: of six Wessely School studies, three were co-authored by Trudie Chalder and one was co-authored by Peter White. In the NHS Plus Guideline, the Wessely School authors made inflated claims for the efficacy of CBT/GET in returning people with “CFS/ME” to gainful employment (“*CBT and GET have been shown to be effective in restoring the ability to work*”), but a US systematic review of the “evidence-base” had reported that “*No specific*

*interventions have been proved to be effective in restoring the ability to work” (SD Ross et al: Arch Intern Med 2004;164:1098-1107).*

The key fact here is that the NHS Plus Guideline cited the Ross systematic review as its own evidence-base.

An inquiry was therefore made of the DoH how such divergent conclusions could be drawn from the same systematic review of the same publications --- one conclusion by Ross et al and the exactly opposite conclusion by the Wessely School. In the light of such an obvious dichotomy, the DoH was asked a simple and direct question: *“Does the Department agree with the statement that cognitive behavioural therapy and graded exercise therapy have been shown to be effective in restoring the ability to work in those (with ME/CFS) who are currently absent from work?”*

On 6<sup>th</sup> June 2008 the written response from the DoH was unequivocal: *“The Department does not hold any data that support this claim”*.

So here we have a situation in which the Department of Health (which funds NICE and which funded the NHS Plus Guideline) is on record as stating that it has no data to support the claims made by both the NICE Guideline and the NHS Plus Guideline.

If the Department itself holds no data showing that CBT/GET are in fact effective, where is this data? Does it actually exist, or is it merely a contrived “evidence-base” created by the Wessely School, whose vested interests in claiming its efficacy cannot be denied?

Regarding the obvious and serious conflicts of interest of the Wessely School in relation to the NHS Plus Guideline, on 23<sup>rd</sup> December 2008 a remarkable revelation was made – in writing – by Dr Ira Madan, Director of Clinical Standards, NHS Plus (who, with Wessely and Chalder, is based at Kings College): *“The Department of Health have (sic) asked me to investigate your concern that one of the guideline development group members, Professor Trudie Chalder, and the two external assessors, Professor Michael Sharpe and Professor Peter White, had conflicts of interest whilst involved in the production of the guideline. I can confirm that I was aware of the potential for competing interests that you have stated. The roles that Professor White, Professor Sharpe and Professor Chalder have undertaken for the agencies and companies that you stipulate (i.e. the medical insurance industry) were in the public domain prior to the publication of the NHS Plus guideline. I am content, as the Director of that guideline, these potential competing interests did not in any way influence the synthesis of the evidence or the guideline recommendations”*.

As straight-thinking folk will recall, the NHS Plus Guideline states *“No conflicts of interest declared”*, yet Dr Ira Madan is here acknowledging the existence of these Wessely School conflicts of interests, but stating that she is “content” about the situation, as people already knew about them.

In the Wessely School world of NHS Plus, two researchers were allowed to sit in judgment on their own publications, with the permission of Dr Ira Madan. They were not

required to make conflict-of-interest declarations. This is not peer-review as the rest of the scientific world understands it.

Notably, the same people (Chalder, Sharpe and White) who were involved with the production of the NHS Plus Guideline (where they declared no conflict of interests) did declare and list very serious conflicts of interest in the MRC PACE trial documentation: *"PDW has done voluntary and paid consultancy work for the Departments of Health and Work and Pensions and legal companies and a re-insurance company. MCS has done voluntary and paid consultancy work for government and for legal and insurance companies. TC has done consultancy work for insurance companies, is the author of Coping with Chronic Fatigue published by Sheldon Press and co-authors Overcoming Chronic Fatigue with Mary Burgess published by Constable and Robinson."* (<http://www.biomedcentral.com/1471-2377/7/6>).

This is remarkably different from what the Department of Health confirmed in relation to the NHS Plus Guideline – in writing – on 20<sup>th</sup> November 2008: *"I can confirm that the guideline contributors gave written confirmation that they had no conflicts of interest"*.

What can explain such a marked discrepancy, and why should a statement have been published saying that no conflicts of interest exist when serious conflicts of interests are undoubtedly involved?

Not only do we now have written evidence that (i) the Department of Health holds no data that the recommendations in both the NHS Plus Guideline and in the NICE Guideline are in any way effective in restoring the ability of people with ME/CFS to return to work, and (ii) that two members of the DoH (William Scott and Dr Ira Madan) have made statements on the same issue that diametrically oppose each other, but we also have written evidence -- straight from Dr Madan at the Department of Health -- illustrating how the normal rules of independent peer review and conflicts of interest are regularly suspended when it comes to the "evidence-base" for CBT/GET in people with ME/CFS.

Consequently, as Dr Madan has stated that the Wessely School's conflicts of interests did not make any material difference, she is now being requested to explain WHY the conflicts of interest she has acknowledged exist were not recorded as required, since conflicts of interest should be recorded to enable people to make up their own mind whether or not the conflicts matter. Such an important issue is not up to Dr Madan to decide but is –or should be -- determined by the AGREE Instrument.

Even though it is in the public interest to publicise that there is a potentially dangerous guideline in circulation that was engineered by Wessely School members whose conflicts of interest in respect of the medical insurance industry are legion (and who have no expertise in infection or in inflammation or in immunology that underpin ME/CFS), the Judge will not be considering the issues surrounding the NHS Plus Guideline

It is, however, hoped that the Judge will require the particular conundrum pertaining to NICE to be explained so that straight-thinking folk can understand it, namely, why NICE

recommended interventions for “CFS/ME” for which its own paymaster (the Department of Health) has stated that there is no supportive data.

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See Also:

<http://www.meactionuk.org.uk/nicejr.htm>