**Knowledge or Belief?**

**Margaret Williams 9th October 2010**

Four forthcoming events may significantly affect the lives of people with ME/CFS: the results of the MRC PACE Trial on "CFS/ME" are expected to be published soon; the General Medical Council (GMC) is shortly to decide whether or not to launch a full inquiry into the alleged misleading of the High Court during the Judicial Review of the NICE Clinical Guideline 53 by a member of the NICE Guideline Development Group (GDG); on 29th November 2010 the Fatigue Service at St Bartholomew's Hospital will hold a training day and a birthday party in the Great Hall of Barts to celebrate 25 years of Professor Peter White's services to those with "CFS/ME", and in December 2010, using the same GDG members, NICE is to consider if there has been any new research that necessitates a revision of its much criticised 2007 Guideline CG53 on "CFS/ME".

The common thread between these events is, of course, the beliefs of the Wessely School about ME/CFS (which they invert and refer to as "CFS/ME") and their continued refusal to engage with the extensive biomedical and scientific knowledge about ME/CFS that identifies damage, deficits and dysfunction in major bodily systems, particularly in the neurological, immune, endocrine and cardiovascular systems.

At the Barts Fatigue Service celebrations, Professor Wessely's talk is entitled: "Where we were then, where we are now" and Professor White is to speak on: "PACE Trial: is knowledge more useful than belief?"

Is knowledge more useful than belief? Not, it seems, where ME/CFS is concerned.

Why not? Because where the Wessely School is *now* in relation to ME/CFS is little different from where it was 25 years ago – their beliefs remain static and they have resolutely <u>not</u> moved forwards in the light of knowledge.

They perversely and irrationally reject the ever-increasing body of biomedical knowledge that ME/CFS is a serious neuroimmune disease and continue to believe that it is a somatoform disorder

which is curable by their favoured interventions of cognitive restructuring and incremental aerobic exercise. Professor Peter White claims that ***"a full recovery is possible"*** (Psychother Psychosom 2007:76(3):171-176); the PACE Trial CBT participants' Manual informs people that the PACE Trial therapies are curative, and it is elsewhere asserted that "*many people have successfully overcome their CFS/ME"* with such behavioural interventions ("Information for relatives, partners and friends", page 123). Such a belief is not supported by knowledge.

With the publication of the PACE Trial results being imminent, it is worth recalling the already-published results of its sister trial, the FINE Trial (Fatigue Intervention by Nurses Evaluation) that was funded entirely by the MRC and had 296 participants: the FINE Trial was a resounding failure on all fronts, so it is difficult to see how the PACE Trial results might be glowingly successful.

The FINE Trial results clearly showed that "pragmatic rehabilitation" (PR, based on CBT/GET) was minimally effective in reducing fatigue and improving sleep: it did so only whilst participants were engaged in the programme and there was no statistically significant effect at follow-up. Furthermore, pragmatic rehabilitation had no statistically significant effect on physical functioning; equally, its effect on depression had diminished at follow-up. Moreover the other intervention being tested ("supportive listening" or SL) had no effect in reducing fatigue, improving physical functioning, sleep or depression.

Notwithstanding, the investigators are already seeking further funding to test their hypothesis that providing more sessions might improve the effectiveness of pragmatic rehabilitation which they state "*will inform the next phase of our work….The first phase of this work will be in conjunction with the Greater Manchester CFS Service"*.

The PACE and FINE Trials, as well as the recommendations in the NICE Guideline CG53, were predicated on the Wessely School's beliefs, not on existing biomedical knowledge.

The existing knowledge is that the interventions do not work, but the belief of the investigators is that they ought to work, thus belief triumphs over knowledge.

Of particular note is what Professor Wessely said on 26th July 2010 during the final of "Debating Matters" filmed in India. The subject was "*Alternative Medicine is Quackery"*; discussing people who make what he regards as false claims about the success of alternative medicine and comparing them with the scientific rigour of modern medicine, Wessely said, apparently without a trace of insight: "*They do not change their beliefs or their practice on the basis of the evidence, that's the difference that we're talking about. It's the ability to move from dogma to science and to say yeah, it sounded*

*good at the time, but the evidence shows that it isn't, so we move on, we research, we try and progress, that's the difference we're talking about"* (http://www.spike.com/video/alternative-medicine/3439367). It has been said, and might still be said, that this is precisely the argument that has been levelled against the Wessely School in relation to ME/CFS – the behavioural modification approach may have sounded good at the time, but the evidence shows that it isn't, so it's time to move on. They, however, refuse to do so and steadfastly hold on to their own blind beliefs. The tragedy for people with ME/CFS is that the Wessely School seem unable to apply the same logic they require of others to themselves.

In relation to the GMC, if the complaint about the GDG member is upheld, it would, according to one of the lawyers "*be strong grounds for re-opening the (Judicial Review) and would seriously undermine NICE".*

Eight years before the NICE Clinical Guideline 53 was published, the British Medical Journal carried a compelling article on Clinical Guidelines (Potential benefits, limitation, and harms of clinical guidelines; Steven H Woolf et al; BMJ 1999:318:527-530).

The article provides a clear warning of the dangers arising from an uncritical adherence to clinical guidelines:

"*Over the past decade, clinical guidelines have increasingly become a familiar part of clinical practice. Every day, clinical decisions…and health spending by governments and insurers are being influenced by guidelines".*

*"Many believe that the economic motive behind clinical guidelines is the principal reason for their popularity".*

***"The most important limitation of guidelines is that the recommendations may be wrong".***

*"Practices that are sub-optimal from the patient's perspective may be recommended to help control costs, serve societal needs, or protect special interests (those of doctors…or politicians, for example)".*

*"**The promotion of flawed guidelines by practices, payers, or healthcare systems can encourage…the delivery of ineffective, harmful or wasteful interventions**".*

*" **Recommendations that do not take due account of the evidence can result in sub-optimal, ineffective, or harmful practices**".*

*"Flawed clinical guidelines harm practitioners by providing inaccurate scientific information and clinical advice, thereby compromising the quality of care….**Outdated recommendations may perpetuate outmoded practices**".*

*"**Guidelines can harm medical investigators and scientific progress if further research is inappropriately discouraged**".*

*"Guidelines developed by specialists may seem to be self-serving (and) biased".*

*"**Naïve consumers of guidelines accept official recommendations on face value, especially when they carry the imprimatur of prominent professional groups or government bodies. More discerning users of clinical guidelines scrutinise the methods by which they have been developed**".*

***"…those concerned with improving quality should redirect their efforts to identify the specific barriers…that stand in the way of behaviour change**".*

The evidence for retroviral involvement in ME/CFS is becoming impossible for NICE to dismiss, for example, from 1st November 2010 there is to be a lifetime ban in the UK on people with ME/CFS donating blood, a paradigm shift that was reported nationwide and worldwide, even in The Himalayan Times(http://www.thehimalayantimes.com/fullNews.php?headline=ME+sufferers+banned+from+donating+blood&NewsID=260959) so NICE cannot claim to be unaware of the significance of it. Moreover, given the known intercourse between the UK and the US about ME/CFS, NICE can hardly be unaware that world experts in ME/CFS such as Professor Nancy Klimas (principal investigator of the National Institute for Health's Centre for Multidisciplinary Studies of (ME)CFS Pathophysiology at the University of Miami) are clear: *"…there is a chronic inflammation, neuro-inflammation, and it upsets the whole balance of your systems…the patients become terribly ill…. The immune system is really cranked up; it's a tremendous amount of inflammation. I think that if doctors could get this in their heads that it's sort of like lupus or one of these really inflammatory disorders…it is that level of inflammation. There's a tremendous amount of inflammatory stuff going on, and there's a lot of inflammation in the brain itself*" (http://www.litemiami.com/spotlite/index.aspx)

The evidence of inflammation in people with ME/CFS is important because the incremental aerobic exercise recommended by the Wessely School and encapsulated in NICE's Clinical Guideline 53 is contra-indicated in cases of inflamed and damaged tissue and inevitably results in post-exertional relapse with malaise, which is the cardinal symptom of ME/CFS.

Can NICE credibly continue to ignore the warning that was carried in the BMJ eleven years ago about the harm caused by flawed guidelines, or will it continue to prefer belief to knowledge?

Do entrenched beliefs that continue to be held in defiance of knowledge cause harm to patients?

Countless people with ME/CFS and their families know the answer to that question.