

**Some Concerns about the National Institute for Health & Clinical Excellence (NICE) Draft Guideline issued on 29<sup>th</sup> September 2006 on Diagnosis and Management of Chronic Fatigue Syndrome / Myalgic Encephalomyelitis in Adults and Children**

Margaret Williams (Nominated Respondent with The 25% ME Group for the Severely Affected)

19<sup>th</sup> October 2006

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Prepared for a Registered Stakeholder:  
The 25% ME Group for the Severely Affected  
4, Douglas Court  
Beach Road  
Troon  
Ayrshire, KA10 66Q

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The NICE web page gives instructions for respondents to the Draft Guideline on “CFS/ME” that are misleading: it states that the Institute is unable to accept comments that are not on the correct (online) proforma. When contacted about this, NICE confirmed that the Institute favours online responses because they make things easier for NICE, but confirmed that nominated respondents without a computer *are* permitted to send in responses. However, NICE then stated that individual responses that are not sent in via a registered stakeholder will not be considered. This again contradicts the web page, which states: “Individuals and organisations not registered as stakeholders are able to comment”. Further, the web page states that the Institute is unable to accept more than one response per stakeholder and it is unclear whether or not the responsibility for collating the comments of all their nominated respondents into one single response is deemed to be the responsibility of each stakeholder. This means that from the outset of the consultation period, there are restrictions and unacceptable confusion that the sick people who are the subject of the Draft Guideline are likely to find insurmountable. Following discussions, NICE has since confirmed that submissions from stakeholders’ nominated respondents *will* be accepted in whatever format the stakeholders receive them, but it is requested that non-online submissions be typed and be submitted as soon as possible (ie. well before the end of the consultation period). It is understood that the NICE web page is to be amended to reflect this clarification.

**Introduction**

In many respects the NICE Draft Guideline on “CFS/ME” of September 2006 is a remarkable document. There are, however, technical anomalies that require correction in the final version – for example, the acronym “QALY” is not explained in the Glossary of Terms (QALY stands for Quality Adjusted Life Years and is the product of life expectancy and a measure of the quality of the remaining life years).

For identification of other significant technical anomalies in the Draft Guideline, see below.

The Draft Guideline is certainly an impressive tool for managing the biopsychosocial model of chronic fatigue. The major problem is that it fails to distinguish between authentic ME and various other states of chronic fatigue which bear little resemblance to ME. Perhaps expediently, it includes compelling evidence from sufferers who have authentic ME so it can legitimately claim to target such patients within its remit.

However, in terms of understanding the nature of ME and in terms of implementing its favoured regime of cognitive behavioural therapy/graded exercise therapy (CBT/GET) upon those with ME, the Draft Guideline comprehensively fails those with ME, as did two of its predecessors, the Report of the “independent” Working Group for the Chief Medical Officer in January 2002 and the Medical Research Council’s CFS/ME Research Advisory Group Report “CFS/ME Research Strategy” in May 2003.

To be added to the reports that fail the ME/CFS community is the new Guideline (now a published Policy Document) from NHS Plus for the Department of Health that will have a devastating impact upon those with ME/CFS who are of working age (“**Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline**” DH Publication 2006/273539). This National Guideline is clearly timed to support the NICE Draft Guideline on “CFS/ME” and has the same misapprehensions, perhaps because its own Guideline Development Group included Professor Trudie Chalder and its External Assessors were psychiatrists Professors Michael Sharpe and Peter White, all of whom believe that “CFS/ME” is a behavioural disorder.

Peter White is well-known for his belief that medicine is currently travelling up a “blind alley” by following the biomedical approach and he believes that the biopsychosocial approach is the way forwards. Whereas the biomedical model accepts that ill-health is directly caused by diseases and their pathological processes, White and other members of the “Wessely School” (see below) prefer the psychosocial approach

which incorporates thoughts, feelings and behaviour --- they believe it is what they deem to be “aberrant” beliefs that result in and perpetuate ill-health (see [www.meactionuk.org.uk/PROOF\\_POSITIVE.htm](http://www.meactionuk.org.uk/PROOF_POSITIVE.htm)).

Together with Anthony Clare, Professor of Clinical Psychiatry at Trinity College, Dublin, Peter White contributed the section on Psychological Medicine in the medical textbook that is likely to be on the desk of every GP in the UK as it won the ‘Highly Commended’ British Medical Association Award (Clinical Medicine: Kumar and Clark, 2004, 5<sup>th</sup> edition: published by Saunders: ISBN 0 7020 25798). It is promoted as “*one of the most highly respected textbooks of medicine in the world. It is used by medical students and practising doctors, as well as by many other health professionals. It has been translated into several languages*”. One of the editors is Parveen Kumar, Professor of Clinical Medical Education at Barts and The London, Queen Mary School of Medicine (ie. the same institution as Peter White).

The entry for Myalgic Encephalomyelitis directs the reader to the entry for CFS, which in turn directs the reader to Section 21 (Psychological Medicine) where CFS/ME is listed under “Functional or Psychosomatic Disorders: Medically Unexplained Symptoms”. White and Clare assert that the psychiatric classification of these disorders is “somatoform disorder”, which the authors state were previously known as ‘all in the mind’, imaginary and malingering. White and Clare state that “CFS” has two classifications (ie. in the International Classification of Diseases): one as neurasthenia in the psychiatric section and the other as myalgic encephalomyelitis in the neurological section; perpetuating factors are said to include inactivity, avoidant behaviour and maladaptive illness beliefs (statements that are insupportable).

Clare himself is known for his disparaging comments about those with ME/CFS: when he chaired the meeting that was convened to formulate the Oxford criteria, there was, he said, only one reason for calling the meeting and that was “*a group of patients with a cluster of symptoms who get a lot of publicity*”: (BMJ:1990:300:832).

Under “Conflicts of interest”, the NHS Plus Guideline states: “none declared”, yet the two external assessors (Sharpe and White) are long-time medical advisers to the insurance industry and White does consultancy work for the Department for Work and Pensions, so failure to declare such obvious conflicts of interest would seem to be a serious matter.

Also of concern is that the searches upon which so much reliance is placed are limited to those that will deliver the desired outcome: “*Due to time and resource limitations, the “grey literature” on CFS (do they mean the biomedical literature?) was not comprehensively searched. The two external assessors are experts in the field of CFS and they indicated that they were content that all relevant research had been identified in the review*”.

Unsurprisingly, this National Guideline states: “*in the past 20 years, the medical profession has increasingly come to recognise that the symptoms of individuals with CFS are not readily explained by recognisable organic disease*”. It concludes that the two treatments for which there is the greatest weight of evidence are CBT and GET and its “Key priority for implementation” states: “***Ill health retirement should be deferred until CBT/GET has been explored***”.

The timing of the appearance of these two documents seems to indicate a co-ordinated tactical strategy by the psychiatric lobby to achieve its aim of widespread implementation of psychotherapy for patients with “CFS/ME” via national guidelines.

As for the NICE Draft CFS/ME Guideline itself, it has to be said that it is exactly what was predicted. How could it be otherwise, given that the Government has already invested £8.5 million on new Centres expressly to deliver the same management regime and when previous publications from NICE have widely promoted CBT/GET as the management regime of choice for “CFS/ME”? (see “Effective Health Care” bulletin produced by the Centre for Reviews and Dissemination at the University of York (May 2002: volume 7 (4): “Interventions for the Management of CFS/ME”, published by the Royal Society of Medicine).

By any objective standards, the Draft Guideline is replete with misapprehensions, misinformation, omissions and outright bias.

Attention is here drawn to some of those underlying problems.

### **Problem: Terminology**

As has been noted many times previously, the nub of the problem is that the term “CFS” means different things to different people.

The term “ME/CFS” denotes the neurological disorder ME and acknowledges that in the World Health Organisation’s International Classification of Diseases (ICD-10), an alternative term for ME is “Chronic Fatigue Syndrome”. It is this latter term that has been foisted on the international research community since 1988 and thus the extensive biomedical research literature uses the term “CFS”.

Confusion arises because the UK psychiatric lobby (known colloquially as the “Wessely School” after its notorious prime mover Professor Simon Wessely) uses the same term “CFS” to mean neurasthenia, or chronic “fatigue” ie. a mental (behavioural) disorder.

This matter of terminology is very much a live one. Jill McLaughlin draws timely attention to the on-going battle by the psychiatric lobby to legitimise “hysteria” (Co-Cure ACT:RES: 9<sup>th</sup> October 2006) and notes that on 26<sup>th</sup> September 2006 the New York Times carried a feature by Erika Kinetz on hysteria and its newer names that include ‘neurasthenia’, ‘non-organic’ and ‘medically unexplained symptoms’: “*Hysteria has always been a perjorative term, because of its association with women*’ said Dr William E Narrow, associate director of the research division of the American Psychiatric Association. Patients with medically unexplained symptoms account for up to 40% of all primary care consultations (but) to avoid the wrath of patients, clinicians use these blander terms. *‘Hysterical patients take a bad rap in the medical profession*’ said Deborah N Black, an assistant professor of neurology at the University of Vermont. *‘We don’t like them’* Dr Black said. *‘Somewhere deep down inside, we really think they’re faking it. The other reason we don’t like them is they don’t get better’*”.

Thus for ME/CFS to be regarded as synonymous with “neurasthenia” (ie. “hysteria”) by the Wessely School perpetuates the existing culture of contempt for these patients (see below).

The Wessely School adherents seem to suffer from tunnel vision in relation to “fatigue”, apparently believing that fatigue is fatigue, whatever its provenance, and that it should be managed by a wall-to-wall behavioural modification approach. They seem impervious to the fact that fatigue is a feature of over 30 different disorders with widely differing pathology and treatment, any of which may present with “fatigue”.

On page 38, line 23, the Draft Guideline states that CBT is a psychological therapy and at line 27 states that it “*is used in many health settings including cancer*”. Whilst it is not disputed that psychological support can be helpful (and even essential) in any illness for those upon whom the demands imposed by events exceed their ability to cope, that is very different from stipulating that psychotherapy should be the first-line management regime, which is what is happening with ME/CFS. For the record, several cancer charities, including Cancer Research UK, have confirmed that CBT/GET is not routinely used as part of cancer patients’ rehabilitation programmes. Equally, the MS charities have confirmed that it is not used as a first-line management approach.

Since there is no specific psychiatric service providing compulsory corrective behaviour regimes upon fatigued cancer sufferers in order to compel them to change their “illness beliefs” that they are sick, or upon those with lupus, or on those with multiple sclerosis or other neurological disorders, how can it be justified to impose such a regime on those with ME/CFS? The answer is because Wessely School psychiatrists advise Government bodies that ME does not exist except in the minds of those who think they suffer from it, and that CFS is a behavioural disorder.

The NICE Draft Guideline asserts that the term “CFS” was adopted by the Royal College of General Practitioners in 1996 (when it appeared in the much criticised and psychiatrically biased Joint Royal Colleges’ Report CR54) but the rest of the world adopted the term in 1988. However, “ME” was recognised by the WHO as a distinct neurological disorder in 1969 and was officially recognised in the UK by the Royal Society of Medicine in 1978; in 1987 it was recognised by the Department of Health, who accepted it as an organic disorder in November that year and have repeated this acceptance numerous times thereafter. (For official evidence, see [http://www.meactionuk.org.uk/Reality\\_Check.htm](http://www.meactionuk.org.uk/Reality_Check.htm)).

However, the NICE Draft Guideline uses the term “CFS/ME”, which is diagnostically meaningless. It was coined by Simon Wessely purely to placate patients: *“In this article we discuss how illness beliefs arise and suggest principles for dealing with patients. It is only human for doctors to view the public as foolish, uncomprehending, hysterical or malingering. One challenge arises when patients have named their condition in a way that leaves doctors uncomfortable, as occurred with chronic fatigue syndrome. It may seem that adopting the lay label (ME) reinforces the perceived disability. A compromise strategy is ‘constructive labelling’: it would mean treating chronic fatigue syndrome as a legitimate illness while gradually expanding understanding of the condition to incorporate the psychological and social dimensions. The recent adoption by the UK Medical Research Council and the chief medical officer’s report of the term CFS/ME reflects such a compromise”* (ref: “Managing patients with inexplicable health problems”. B Fischhoff S Wessely BMJ 2003;326:595-597).

What disorder is the Draft Guideline therefore talking about?

**Problem: Continued refusal to heed the biomedical evidence that disproves the biopsychosocial model of ME/CFS**

No matter how much biomedical evidence about ME/CFS is submitted to UK official bodies, it is ignored, even when sent by Recorded Delivery. For illustrations of what has been submitted to various official bodies over the years, see the [www.meactionuk.org.uk](http://www.meactionuk.org.uk) website.

The only feasible conclusion is that no biomedical evidence, however relevant to ME/CFS patients’ well-being, will be allowed to displace the pre-determined agenda of imposing CBT/GET on patients diagnosed with “CFS/ME”, nor will biomedical evidence be allowed to displace the determination of the influential psychiatric lobby to re-classify ME as a behavioural disorder by subsuming it within the heterogeneous term “CFS/ME”, the intention being to drop the term “ME” as soon as expediently possible, thereby achieving Wessely’s long-held goal of “eradicating” ME (see page 20 below).

There can be no acceptable rationale for this continued ignoring by Government bodies of the evidence that ME/CFS is a multi-system, multi-organ disorder at endothelial level ie. that it is an inflammatory-mediated response causing endothelial swelling and arterial stiffness with hard evidence of raised isoprostanes not seen in any other known disorder.

Although the precise cause is yet to be determined, the symptoms of ME/CFS are not, as stated in the Draft Guideline (page 135, line 1), “medically unexplained”: as noted in our article “ME Exists: True or False?”, it remains beyond reason that the existence of so many documented abnormalities in people with ME/CFS should simply be disregarded and denied, including the following:

- abnormalities of the central nervous system include abnormalities of brain cognition, brain perfusion, brain metabolism and brain chemistry; there is evidence of low blood flow in multiple areas of the brain; neuro-imaging has revealed lesions in the brain of approximately 80% of those tested and according to the researchers, these lesions are probably caused by inflammation: there is a correlation between the areas involved and the symptoms experienced; abnormalities on SPECT scans provide objective evidence of central nervous system dysfunction; there is evidence of a chronic inflammatory process of the CNS, with oedema or demyelination in 78% of patients tested; there is evidence of a significant and irreversible reduction in grey matter volume (especially in Brodmann’s area 9) which is related to physical impairment and may indicate major

trauma to the brain (which could also explain the low recovery rate); there is evidence of seizures; a positive Romberg is frequently seen in authentic ME/CFS patients

- abnormalities of the autonomic and peripheral nervous systems: there is evidence of dysautonomia in ME/CFS patients – see, for example, “Standing up for ME” by Spence and Stewart: *Biologist* 2004:51(2):65-70; according to Goldstein, ME/CFS represents the final common pathway for a multi-factorial disorder causing autonomic dysfunction
- cardiovascular dysfunction: there is evidence of haemodynamic instability and aberrations of cardiovascular reactivity (an expression of autonomic function); there is evidence of diastolic cardiomyopathy; there is evidence of endothelial dysfunction; there is evidence of peripheral vascular dysfunction with low oxygenation levels and poor perfusion and pulsatilities; there is evidence of abnormal heart rate variability and evidence of abnormal orthostasis; there is evidence of abnormally inverted T-waves and of a shortened QT interval, with electrophysiological aberrancy; there is evidence of abnormal oscillating T-waves and of abnormal cardiac wall motion (at rest and on stress); there are indications of dilatation of the left ventricle and of segmental wall motion abnormalities; there is evidence that the left ventricle ejection fraction – at rest and with exercise – is as low as 30%; there is evidence of reduced stroke volume
- respiratory system dysfunction: there is evidence of significant reduction in many lung function parameters including a significant decrease in vital capacity; there is evidence of bronchial hyper-responsiveness
- a disrupted immune system: there is evidence of an unusual and inappropriate immune response: there is evidence of very low levels of NK cell cytotoxicity; there is evidence of low levels of autoantibodies (especially antinuclear and smooth muscle); there is evidence of abnormalities of immunoglobulins, especially SIgA and IgG<sub>3</sub>, (the latter having a known linkage with gastrointestinal tract disorders); there is evidence of circulating immune complexes; there is evidence of a Th1 to Th2 cytokine shift; there is evidence of abnormally diminished levels of intracellular perforin; there is evidence of abnormal levels of interferons and interleukins; there is evidence of increased white blood cell apoptosis, and there is evidence of the indisputable existence of allergies and hypersensitivities and positive mast cells, among many other anomalies, with an adverse reaction to pharmacological substances being virtually pathognomonic
- virological abnormalities: there is evidence of persistent enterovirus RNA in ME/CFS patients; there is evidence of abnormalities in the 2-5 synthetase / RNase L antiviral pathway, with novel evidence of a 37 kDa binding protein not reported in healthy subjects or in other diseases; there is evidence of reverse transcriptase, an enzyme produced by retrovirus activity, with retroviruses being the most powerful producers of interferon; there is evidence of the presence of HHV-6, HHV-8, EBV, CMV, Mycoplasma species, Chlamydia species and Coxsackie virus in the spinal fluid of some ME/CFS patients, the authors commenting that it was surprising to find such a high yield of infectious agents on cell free specimens of spinal fluid that had not been centrifuged
- evidence of muscle pathology: this includes laboratory evidence of delayed muscle recovery from fatiguing exercise and evidence of damage to muscle tissue; there is evidence of impaired aerobic muscle metabolism; there is evidence of impaired oxygen delivery to muscle, with recovery rates for oxygen saturation being 60% lower than in normal controls; there is evidence of prolonged EMG jitter in 80% of ME/CFS patients tested; there is evidence of greater utilisation of energy stores; there is evidence that total body potassium (TBK) is significantly lower in ME/CFS patients (and abnormal potassium handling by muscle in the context of low overall body potassium may contribute to muscle fatigue in ME/CFS); there is evidence that creatine (a sensitive marker of muscle inflammation) is excreted in significant amounts in the urine of ME/CFS patients, as well as choline and glycine; there is evidence of type II fibre predominance, of scattered muscle fibre necrosis and of mitochondrial abnormalities

- neuroendocrine abnormalities: there is evidence of HPA axis dysfunction, with all the concomitant implications; there is evidence of abnormality of adrenal function, with the size of the glands being reduced by 50% in some cases; there is evidence of low pancreatic exocrine function; there is evidence of an abnormal response to buspirone challenge, with a significant increase in prolactin release that is not found in healthy controls or in depressives; there is evidence of abnormal arginine – vasopressin release during standard water-loading test; there is evidence of a profound loss of growth hormone; even when the patient is euthyroid on basic screening, there may be thyroid antibodies and evidence of failure to convert T4 (thyroxine) to T3 (tri-iodothyronine), which in turn is dependant upon the liver enzymes glutathione peroxidase and iodothyronine deiodinase, which are dependant upon adequate selenium in the form of selenocysteine (which may be inactivated by environmental toxins)
- defects in gene expression profiling: there is evidence of reproducible alterations in gene regulation, with an expression profile grouped according to immune, neuronal, mitochondrial and other functions, the neuronal component being associated with CNS hypomyelination
- abnormalities in HLA antigen expression: Teraski from UCLA found evidence that 46% of ME/CFS patients tested were HLA-DR4 positive, suggesting an antigen presentation
- disturbances in oxidative stress levels: there is mounting evidence that oxidative stress and lipid peroxidation contribute to the disease process in ME/CFS: circulating in the bloodstream are free radicals which if not neutralised can cause damage to the cells of the body, a process called oxidative stress: in ME/CFS there is evidence of increased oxidative stress and of a novel finding of increased isoprostanes not seen in any other disorder; these raised levels of isoprostanes precisely correlate with patients' symptoms (isoprostanes being abnormal prostaglandin metabolites that are highly noxious by-products of the abnormal cell membrane metabolism); there is evidence that incremental exercise challenge (as in graded exercise regimes) induces a prolonged and accentuated oxidative stress; there is evidence of low GSH-PX (glutathione peroxidase, an enzyme that is part of the antioxidant pathway: if defective, it causes leakage of magnesium and potassium from cells)
- gastro-intestinal dysfunction: there is evidence of objective changes, with delays in gastric emptying and abnormalities of gut motility; there is evidence of swallowing difficulties and nocturnal diarrhoea; there is evidence going back to 1977 of hepatomegaly, with fatty infiltrates: on administration of the copper response test, there is evidence of post-viral liver impairment -- an increase of at least 200 in the copper level is the expected response, but in some severely affected ME/CFS patients the response is zero; there is evidence of infiltration of splenic sinuses by atypical lymphoid cells, with reduction in white pulp, suggesting a chronic inflammatory process; there is evidence that abdominal pain is due to unilateral segmental neuropathy (Gastrointestinal Manifestations of Chronic Fatigue Syndrome: H Hyman, Thomas Wasser: JCFS 1998:4(1):43-52); Maes et al in Belgium have found significant evidence that people with ME/CFS have increased serum levels of IgA and IgM against the LPS of gram-negative enterobacteria, indicating the presence of an increased gut permeability resulting in the autoimmunity seen in many ME/CFS patients; this indicates that the symptoms of irritable bowel seen in ME/CFS reflect a disorder of gut permeability rather than psychological stress as most psychiatrists believe (gastro-intestinal problems are a serious concern in ME/CFS, and 70% of the body's immune cells are located in the GI tract)
- reproductive system: there is clinical evidence that some female patients have an autoimmune oophoritis; there is evidence of endometriosis; there is evidence of polycystic ovary syndrome; in men with ME/CFS, prostatitis is not uncommon
- visual dysfunction: there is evidence of latency in accommodation, of reduced range of accommodation and of decreased range of duction (ME patients being down to 60% of the full range of eye mobility); there is evidence of nystagmus; there is evidence of reduced tracking; there

is evidence of problems with peripheral vision; there is evidence that the ocular system is very much affected by, and in turn affects, this systemic condition.

The above list is by no means comprehensive but merely gives an overview of documented abnormalities seen in ME/CFS that can be accessed in the literature, as well as in the abstracts and reports of international Clinical and Research Conferences ([www.meactionuk.org.uk/ME\\_Exists\\_-\\_True\\_or\\_False.htm](http://www.meactionuk.org.uk/ME_Exists_-_True_or_False.htm)).

The evidence is there, and to deny it is to deny reality. However, it is easier to deny the evidence if the tests necessary to prove these anomalies are proscribed.

For example, the Draft Guideline specifically recommends (5.2.8, page 107) that serology testing for viral or bacterial infections (including other chronic and latent infections) should not be carried out, yet Professor Maes et al (see above) recommend that all patients with ME/CFS should be checked by means of the IgA panel, which is another test that is not approved in the Draft Guideline.

Equally, in cases of suspected ME/CFS, informed clinicians believe that patients should be tested for borreliosis, one of most important differential diagnoses, yet this, too is proscribed, despite the fact that a leading UK microbiologist recognises that some people who are thought to have ME/CFS may actually have borreliosis. As BADA (Borreliosis & Associated Diseases Awareness: [www.bada-uk.org](http://www.bada-uk.org)) points out, it is recognised by the scientific establishment that Borrelia is able to evade immune surveillance. Lyme Disease (LD) may be misdiagnosed as multiple sclerosis, ME/CFS or other autoimmune disorders.

The symptom list for ME/CFS and for borreliosis has considerable overlap, for example: fatigue, myalgia, migratory joint pain, neuropathy (including numbness, tingling, burning and itching, hypersensitivity), tremor, muscle twitching, vision problems such as double vision, photophobia, hyperacusis, balance problems and vertigo, severe startle factor, short-term memory loss, sleep disturbance, cardiac arrhythmia, tachycardia, nausea / vomiting, adrenal dysfunction and immune system disturbances.

To reiterate: the longer the tests that reveal serious (but sometimes treatable) organic pathology continue to be disallowed, the longer the psychiatric paradigm will prevail and patients will continue to be neglected and abused by some members of the medical profession.

For illustrations of the psychiatric lobby's denial of ME/CFS as an organic disorder, see The Mental Health Movement: Persecution of Patients? by Professor M. Hooper et al, which looks in detail at the tactics used by psychiatrists of the Wessely School to deny the evidence and to claim "CFS/ME" as a behavioural disorder ([www.meactionuk.org.uk/SELECT\\_CTTEE\\_FINAL\\_VERSION.htm](http://www.meactionuk.org.uk/SELECT_CTTEE_FINAL_VERSION.htm)).

### Illustrations of biomedical anomalies

To redress the psychiatric bias and apparent ignorance that pervades the NICE Draft Guideline, a few quotations from the literature are provided about ME/CFS:

#### **1956**

**"In nearly every patient there are signs of disease of the central nervous system"**  
(A New Clinical Entity? Editorial: Lancet 26 May 1956)

#### **1989**

**"Many of the immunological and physical features of ME/CFS cannot be explained by mental illness"**  
(Stephen E Straus of the National Institutes for Allergy and Infectious Diseases, USA, Progress toward an answer to Chronic Fatigue: reported in CFIDS Chronicle, Spring 1989, pp77-78)

**1989**

**“The abnormalities we found provide evidence for central nervous system and neuromuscular involvement”**

(Carolyn L Warner: Neurology, March 1989;39:3: Suppl 1: 420; Presentation at the American Academy of Neurology Conference, Chicago, April 1989)

**1989**

**“The disabling weakness and exhaustion a patient with ME/CFS experiences is so profound that ‘fatigue’ is probably an insult”**

(J Cuozzo: Chronic Fatigue: JAMA 1989;261:5:697)

**1989**

**“The crucial differentiation between ME and other forms of postviral fatigue syndrome lies in the striking variability of the symptoms not only in the course of a day but often within the hour. This variability of the intensity of the symptoms is not found in post viral fatigue states”**

(Dr Melvin Ramsay, President, UK ME Association. ME Association Newsletter, Winter 1989: 20-21)

**1991**

**“The NK (natural killer) cell is a very critical cell in (ME)CFS because it is clearly negatively impacted. The most compelling finding was that the NK cell cytotoxicity in (ME)CFS was as low as we have ever seen it in any disease. This is very, very significant data. In (ME)CFS the actual function was very, very low --- 9% cytotoxicity: the mean for the controls was 25, in early HIV and even well into ARC (AIDS related complex, which often precedes the fully developed condition), NK cytotoxicity might be around 13 or 14 percent. (ME)CFS patients represent the lowest cytotoxicity of all populations we’ve studied”**

(Nancy Klimas, Professor of Medicine, University of Miami School of Medicine; Director of Immunology; Director of AIDS research and Director of the Allergy Clinic at Miami. Presentation: Immunological Markers in (ME)CFS. The CFIDS Association Research Conference, November 1990, Charlotte, North Carolina. Reported in CFIDS Chronicle, Spring 1991; pp 47-50)

**1991**

**“Once one is familiar with the concept of post-viral fatigue syndrome (ME/CFS), such patients are in practice not too difficult to differentiate from those with true psychiatric illnesses. The physical symptoms should be an aid to diagnosis, although they may be wrongly attributed to primary psychological illness unless care is taken in eliciting them”**

(Professor Rachel Jenkins: Assessment and Diagnosis of ME in the Psychiatric Clinic. In: Postviral Fatigue Syndrome; British Medical Bulletin 1991;47:4:241-246)

**1992**

**Patients with ME/CFS “may have been experiencing a chronic, immunologically mediated inflammatory process of the central nervous system”**

(Buchwald D, Cheney P, Peterson D et al: A chronic illness characterized by fatigue, neurologic and immunologic disorders, and active human herpes type 6 infection. Ann Int Med 1992;116:103-116)

**1992**

**“CFIDS has an organic basis; it is not a psychiatric illness. Our Surveillance Study does not support the notion that (ME)CFS is a psychiatric illness, and in fact, suggests that it has an organic basis”**

(Dr Walter Gunn, Principal Investigator of (ME)CFS studies at CDC: CFIDS Chronicle, February 1992, page 1)

**1993**

**“The worst cases have both an MS-like and an AIDS-like clinical appearance. The most difficult thing to treat is the severe pain. Most have abnormal neurological examination. 80% of cases are unable to work or attend school. We admit regularly to hospital with an inability to care for self”**  
(Testimony by Dr Paul Cheney before US FDA Scientific Advisory Committee)

**1993**

**“The performance of the CFIDS patients was sevenfold times worse than either the control or the depressed group. These results indicated the memory deficit in CFIDS patients was more severe than assumed by CDC criteria. A pattern emerged ...supporting neurological compromise in CFIDS”**

(Curt Sandman, Professor of Psychiatry and Human Behaviour, University of California School of Medicine: Memory deficits associated with chronic fatigue immune dysfunction syndrome: Biol Psych 1993;33:618-623)

**1994**

**“The spectrum of illnesses associated with a dysregulated immune system must now include (ME)CFS”**

(Paul H Levine, Research Professor of Epidemiology and Biostatistics, George Washington University, Washington DC: Summary and Perspective: Epidemiology of (ME) Chronic Fatigue Syndrome: Clin Inf Dis 1994;18: (Suppl 1):S57-S60)

**1994**

**“Abnormalities of immune function, hypothalamic and pituitary function, neurotransmitter regulation and cerebral perfusion have been found in patients with (ME/CFS). Recent research has yielded remarkable data. The symptoms of (ME)CFS have long been viewed as a neurologic pattern, as confirmed by other names such as myalgic encephalomyelitis. A link is being forged between the symptoms pattern of (ME)CFS and objective evidence of central nervous system dysfunction. The view that (ME)CFS is a primary emotional illness has been undermined by recent research”**

(Dr David S Bell: Instructor in Paediatrics, Harvard Medical School: Chronic fatigue syndrome update: Findings now point to CNS involvement: Postgraduate Medicine 1994;98:6:73-81)

**1995**

**“In my experience, (ME/CFS) is one of the most disabling diseases that I care for, far exceeding HIV disease except for the terminal stages”**

(Dr Daniel L Peterson: Introduction to Research and Clinical Conference, Fort Lauderdale, Florida, October 1994; published in JCFS 1995:1:3-4:123-125)

**1995**

**“I take great issue with the current recommendations that no additional testing should ever be done. I believe there are indications for more advanced testing”**

(Dr Daniel Peterson: JCFS 1995: 1:3-4:123-125). Peterson is a Diplomate of the American Board of Internal Medicine and it was he who first identified CFIDS during an outbreak in Incline Village, Nevada, in 1984. At the Second World Congress on ME/CFS and related disorders, held in Brussels in September 1999, Peterson said he was amazed at the misconceptions that existed about ME/CFS; he said that ten years ago, he believed ME/CFS would be resolved by science; he had now changed his mind and believed it could only be resolved by politics)

**1997**

**“The signal abnormalities in ME/CFS patients most closely resemble those seen in AIDS encephalopathy. Patients often experience rejection by family, friends and physicians. The illness is hardly ‘imaginary’ ”**

(Anthony Komaroff, Assistant Professor of Medicine, Harvard Medical School: Clinical Crossroads: Conference Report: JAMA 1997;278:14:1179-1185)

**1999**

**“The most important thing is not to have (patients) do aerobic exercise. I believe that even progressive aerobic exercise is counter-productive. If you have a defect in mitochondrial function and you push the mitochondria by exercise, you kill the DNA”**

(Paul Cheney, Professor of Medicine, Capital University, USA: Presentation in Orlando, Florida, February 1999 at the International Congress of Bioenergetic Medicine). (At the 7<sup>th</sup> AACFS International Research and Clinical Conference in Wisconsin in October 2004, magnetic resonance spectroscopy evidence was presented showing mitochondrial dysfunction similar to mitochondrial encephalomyopathy)

**2000**

**“In summary, there is now considerable evidence of an underlying biological process in most patients (which) is inconsistent with the hypothesis that (the syndrome) involves symptoms that are only imagined or amplified because of underlying psychiatric distress. It is time to put that hypothesis to rest”**

(Anthony Komaroff: Assistant Professor of Medicine, Harvard Medical School: Editorial: Am J Med 2000;108:2:169-171)

**2001**

**“In ME, there are chronic sequelae and the effects may be neurological, hormonal, autoimmune and myalgic, which may affect the myocardium”**

(Dr John Richardson: Enteroviral and Toxin Mediated Myalgic Encephalomyelitis / Chronic Fatigue Syndrome and Other Organ Pathologies. The Haworth Press Inc, New York, 2001)

**2001**

**“There is considerable evidence already that the immune system is in a state of chronic activation in many patients with (ME)CFS”**

(Anthony Komaroff, Assistant Professor of Medicine, Harvard Medical School: American Medical Association Statement, Co-Cure, 17 July 2001)

**2001**

**“New Survey reveals Chronic Fatigue Syndrome (ME) is as disabling or debilitating as lupus, multiple sclerosis and rheumatoid arthritis. Many medical professionals are acknowledging it as a seriously disabling condition. Three quarters of medical professionals responding to the survey believe that (ME)CFS, also known as CFIDS, is as or more disabling than other chronic diseases”**

(Press Release, CFIDS Association of America, 15<sup>th</sup> November 2001)

**2005**

**“Our patients are terribly ill, misunderstood, and suffer at the hands of a poorly informed medical establishment and society”**

(Professor Nancy Klimas, University of Miami, AACFS In-coming Presidential Address: Co-Cure, 21<sup>st</sup> March 2005: <http://www.co-cure.org>).

Patients with ME/CFS can indeed be “terribly ill” and “misunderstood” and without doubt do “suffer at the hands of a poorly informed medical establishment”, so on what rational basis can the NICE Draft Guideline recommend that the first line (and indeed only) management approach to such a clearly devastating disorder as ME/CFS should be one that utilises behavioural modification techniques in an attempt to convince patients that they do not have a legitimate physical disorder?

**Problem: Choice of Guideline Development Group (GDG) members**

It seems that where ME is concerned, most of those chosen to be advisers to official bodies are those with the same ideology as the psychiatric lobby, who are then assured of their pre-determined outcome. Why, for instance, would the following be appointed as members of the NICE GDG?

Dr William Hamilton has a published track record of believing that CFS/ME is a behavioural disorder. In 2001 he co-authored a paper with Dr Alison Round, a community health physician who was one of the five members of the CMO’s Working Group to walk out because they were not getting enough of their own way in that their insistence that “CFS/ME” be designated a behavioural disorder met significant resistance (the others who walked out being psychiatrists Professor Peter White, Dr Anthony Cleare, Professor Elena Garralda and former mental nurse Trudie Chalder, now Professor of Cognitive Behavioural Psychotherapy).

Hamilton et al concluded that CFS patients consulted their GP more frequently in the 15 years before the development of their condition (how such a conclusion relates to those with ME/CFS under the age of 15 years is not addressed) and Hamilton therefore concluded that behavioural factors have a role in the aetiology of CFS (ref: Frequency of attendance in general practice and symptoms before development of chronic fatigue syndrome: a case-control study. WT Hamilton, GH Hall, AP Round. British Journal of General Practice 2001;51 (468):553-558). His conclusions were attacked by Professor JC Murdoch in the BJGP, to which Hamilton took exception, asserting: “*No abnormality has been demonstrated with CFS. Extensive searches for immunological, infectious or endocrine explanations have drawn a blank*”, an astonishing assertion that is readily disproved by a survey of the scientific and medical literature. More troubling is Hamilton’s interpretation of his own study and his demand that CFS researchers and clinicians examine their beliefs against his findings and see how well they match (Co-Cure RES. NOT: 21<sup>st</sup> December 2001).

Also notable is that Hamilton has spent 15 years working for the medical insurance industry and is currently Chief Medical Officer for a major medical insurance company, The Exeter Friendly Society; it was Hamilton who drew up their exclusion clause for CFS/ME, which states: “No benefit shall be payable for investigation or treatment of chronic fatigue syndrome / myalgic encephalomyelitis or allied conditions. The allied conditions are excluded because CFS/ME has several other labels including PVFS, neurasthenia and fibromyalgia”. Other medical insurance companies have adopted the same exclusion as that drawn up by Hamilton.

It is disturbing that Hamilton appears to be unaware that ME is classified in the ICD-10 as a neurological disorder at G93.3, that neurasthenia is classified as a mental disorder at F48.0 and that fibromyalgia is classified as a soft tissue disorder at M79. They cannot be the same condition because the World Health Organisation has confirmed in writing that it is not permitted for the same condition to be classified to more than one rubric.

Why is someone with Hamilton’s known views deemed suitable to be on the GDG that is formulating the NICE national policy for patients with ME/CFS?

Lumping different disorders together and claiming -- in defiance of the evidence -- they are but one single (somatoform) disorder is simply a re-run of Simon Wessely’s 1999 paper in which he and Mike Sharpe claimed that conditions such as CFS/ME are nothing more than “*artefacts of medical specialisation*” and should “*not be dignified by their own formal case definition and body of research*” but should be managed

as a psychiatric disorder (Functional somatic syndromes: one or many? S Wessely C Nimnuan M Sharpe. Lancet 1999;354:936-939).

As Geenen et al noted in 2001: *“The apparent overlap between fibromyalgia, chronic fatigue and irritable bowel is not sufficient cause to consider all these syndromes as manifestations of a single syndrome. The objective should be to try to find pharmacological or non-pharmacological treatment of choice for specific subgroups of patients”* (see Fibromyalgia: diagnosis, pathogenesis and treatment. Geenen R, Jacobs JW. Curr Opin Anaesthesiol 2001;14 (5):533-539).

No evidence-base and no rationale exists for such lumping together of separate syndromes; to do so is both morally and scientifically unacceptable because it perpetuates diagnostic confusion to the detriment of the various patient groups. If Hamilton does not know or accept this, his input to the GDG is seriously flawed.

Dr Fred Nye is another member of the NICE Guideline Development Group. He is a consultant physician and “Clinical Champion” of the Liverpool “CFS” Clinical Network Co-ordinating Centre, whose advertisement for therapists informed applicants that “CFS” patients have perpetuating illness behaviour; that they experience barriers to understanding; that there can be significant barriers to accepting the changes needed in behaviour, which have to be overcome in therapy in order to facilitate a successful outcome; that the Fatigue Therapist will be required to modify patients’ predisposing personality style and provide motivation to patients with CFS; that some clients may be resistant to working in a psychological framework and that there may be verbal aggression (Chronic Fatigue Treatment Service: Ref: 2570. Closing date: 31<sup>st</sup> January 2005).

Following the resultant distress and offence to patients, Nye apologised publicly and the advertisement was withdrawn but the question remains how, under Nye’s leadership, such an advertisement came to be issued in the first place.

Dr Hazel O’Dowd: In the Draft Guideline Acknowledgements (page 6), Dr Hazel O’Dowd gets a special mention for her work on the behaviour section of the Draft Guideline. She is a psychologist who is a CFS “Clinical Champion” at Frenchay Hospital Bristol: like Hamilton, she is a believer in behavioural modification regimes for those with ME (to which she refers as myalgic encephalopathy, a non-classified disorder).

She states about herself: *“I was previously in adult mental health. CBT is a tool to help change and deal more effectively with problems their particular diagnosis gives them. CBT works best for people who can identify aspects of themselves or their coping style which they want to change. Changing the way you think and feel about yourself and your illness can bring about massive improvement in mood, sleep, levels of fatigue, and work. We plan to offer this type of approach in the home for the more severely disabled. However, if people don’t like the approach, they won’t do the therapy. Under those circumstances, CBT cannot be expected to produce results. Graded activity is part of the rehabilitation package we offer, combined with CBT. We do this because the research consensus is that this is the most powerful intervention currently available”* (ME Essential, October 2004, page 21).

However, her recent publication may cause Ms O’Dowd to reconsider her beliefs about the effectiveness of CBT.

She has just published a paper in which the objective was to test the hypothesis that group CBT will produce an effective and cost-effective management strategy for patients in primary care with CFS/ME; it was a double-blind, randomised controlled trial that used the Chalder fatigue scale as one of its outcome measures.

The study findings were unequivocal: *“Group CBT did not achieve the expected change in the primary outcome measure as a significant number did not achieve scores within the normal range post-intervention. The treatment did not return a significant number of subjects to within normal range on this domain (and) it did not bring about improvements in cognitive function or quality of life”* (Cognitive behavioural therapy

in chronic fatigue syndrome; a randomised controlled trial of an outpatient group programme. O'Dowd H et al. *Health Technol Assess* 2006;10(37):1-140).

The NICE Draft Guideline asks at page 154, line 20: "*Is Group CBT cost-effective relative to individual CBT?*". Will Ms O'Dowd draw her negative findings to the attention of the NICE Guideline Development Group?

### **Problem: Secret Advisers to the Guideline Development Group**

Even though the ME Association has submitted a written request for the names of these advisers, there seems to be a curious reluctance to name them and the advisers themselves seem suddenly shy. However, Carole Forbes, Systematic Review Project Manager at the Centre for Reviews and Dissemination (a co-author of the current Chambers / Bagnall et al JRSM paper) was contacted about this some months ago and she confirmed that the NICE Guideline is being formulated through NICE's own Guideline Development Group and that the Advisory Panel to the GDG is the same as the one used for the York Systematic Review in 2001 and that it includes psychiatrists Simon Wessely, Mike Sharpe and Peter White.

### **Problem: The NICE Questionnaire**

The Questionnaire was sent out on 6<sup>th</sup> February 2006 and had to be returned by 5<sup>th</sup> May 2006. NICE promised that "*The GDG will use the results to help them make decisions about the recommendations that NICE will publish for public consultation (and) the results will help to inform the GDG's decision-making*".

However, the Draft Guideline itself acknowledges (on page 52, line 14) that there were problems, quoting one respondent: "*How I, or anyone else with ME or even recovered could possibly read, digest and understand the NICE document enough to be able to answer the Questionnaire is beyond my comprehension*".

It is known that some people were simply unable to complete the Questionnaire and did not return it because the process was made too complicated and impossible for sick people to cope with, for example, how could those severely affected by ME/CFS even hold a copy of the 488 page Systematic Review update of October 2005 by Bagnall et al from the Centre for Reviews and Dissemination at York that was required to be read before answering the Questionnaire (which when sent electronically could not be downloaded because it was too large a document, causing computers to stall, so hard copies had to be sent out even to those who had requested an online version).

The nature of the Questionnaire sent to stakeholders indicates that the major decisions had already been taken by the GDG without reference to the stakeholders. Only disputed matters, where the GDG were "uncertain", have been sent for stakeholder input, which means that 80% of matters have been decided without consultation, with only a token 20% being referred.

Importantly, the Questionnaire contained a serious "misprint" relating to questions 29 – 61, making a nonsense of responses to those questions. Since there were 90 questions in total, this means that answers to over one third of questions (33 out of 90) were likely to be erroneous.

Perhaps expediently, the following section (starting with question 62 and relating to "Behavioural Approaches") changed -- without guidance or instruction -- from choosing 'inappropriate' in the previous section to choosing 'appropriate' in that section. How many people with cognitive impairment would have spotted this semantic hurdle?

On 3<sup>rd</sup> May 2006 Nancy Turnbull, Chief Executive and Project Lead, National Collaborating Centre for Primary Care which sent out the Questionnaires on behalf of NICE (based at the Royal College of General Practitioners) acknowledged in writing that there was a problem: respondents were given just two days in

which to consider, check, amend and return their Questionnaire, which for sick people was virtually impossible in such a short time scale (and which by that time had been returned anyway).

### **Problem: Respondent Statistics**

The Draft Guideline gives a suggested population prevalence of “CFS/ME” in the UK of at least 0.2% – 0.4%. The rate in 2002 Report for the Chief Medical Officer was 240,000 (ie 0.4% of the UK population) and the Draft Guideline adopts this figure (page 38, line 10).

The Draft Guideline lists 143 registered stakeholders, each of whom could nominate 5 to 50 people with knowledge or experience of “CFS/ME” to take part in the Questionnaire. If 143 stakeholders nominated 50 respondents, there would have been 7,150 potential respondents; if stakeholders nominated the minimum 5 respondents, the number of potential respondents would have been 715.

However, only 399 Questionnaires were sent out. Of these, 219 were completed, out of which only 119 were returned by patients themselves (the remainder being returned by carers or healthcare professionals), so out of a presumed patient population of 240,000, this is just 0.05%. This tiny response will be even easier for NICE to ignore, which seems to have been the intention from the beginning.

How is such a response representative of the UK ME community, also bearing in mind the fact that the incorrect wording in the Questionnaire may have resulted in erroneous responses to over one third of the questions?

### **Problem: The Key Questions upon which the Guideline is based**

NICE claims that “*The Guideline is based on the best available evidence from the research literature*”. In relation to ME/CFS, this seems to be a misleading statement. Instead of focusing on the needs of the ME community and on the research literature that supports a biomedical model of the disorder, the GDG have created their own “key questions” to fit the NICE scope (the scope being the document that sets out what the Guideline will cover). These seem to preclude anything other than a biopsychosocial model; indeed, the Draft Guideline states: “*The key questions set the basis for subsequent evidence reviews and facilitated the development of the recommendations by the GDG*” (page 41, line 25). This seems to support the notion that the key questions were designed specifically to achieve a pre-determined agenda, especially as the York Review team (whose advisers include Simon Wessely) was instrumental in the formulation of those five questions (page 41, line 28).

For example, out of the five key questions, Question 1 is: “*what are the existing case definitions for chronic fatigue syndrome in adults and children?*”. The Draft Guideline states (page 36, line 11) that the Oxford criteria are “*frequently used definitions*”, which is misleading, since the Oxford criteria have never been adopted internationally, being used only in the UK by Wessely School adherents. The Oxford criteria have been shown to have no predictive validity and have been rejected by world experts in ME/CFS.

Question 3 is: “*does the evidence show that any particular intervention is effective in treatment, management or rehabilitation of adults and children with a diagnosis of CFS/ME?*”. Since only the psychiatric lobby has been able to obtain serious funding, it follows that the literature is replete with their psychiatric studies which purport to show that the intervention of CBT/GET is effective, so on a numerical evaluation of published studies, the answer to this question is inevitable and simply feeds the self-perpetuating psychiatric paradigm.

### **Problem: The narrow aim (and remit) of the York Systematic Review team**

According to Anthony Komaroff, Professor of Medicine at Harvard and acknowledged world expert in the disorder, there are in excess of 2,000 research studies showing biological abnormalities in ME/CFS.

The York Review team seems to have ignored every single one and overstates the belief of the Wessely School that “CFS/ME” is amenable to behavioural modification.

It was in 1998 that Wessely wrote: “*Citation of the literature is influenced by (the) review authors’ discipline*” (Joyce, J, Wessely S et al: JAMA 1998;28 (3):264-266). This acknowledgement of bias seems to have been overlooked in the present literature searches upon which the Draft Guideline relies.

The Draft Guideline states (page 43, line 3): “*The aim of the literature search was to identify the most relevant published evidence in relation to the key clinical questions in order to produce an evidence review*”. This seems to be yet another example of the self-perpetuating psychiatric paradigm that, by virtue of the acknowledged lack of studies other than psychiatric that address management, inevitably assures that the literature search will produce only studies that support a psychiatric intervention.

On 26<sup>th</sup> January 2006, Sarita Tamber of the NHS Communications Executive at NICE wrote to a respondent: “*With regard to the CFS/ME Guideline, because of the lack of evidence, it was decided to use formal consensus methods within the GDG*”, adding: “*NICE Guidelines are based on research evidence (and) the systematic review (the Evidence Review) was carried out by the University of York and updates the earlier review which informed the CMO’s report*”. Given the composition of the GDG (see above), the known views of the GDG advisers and the limitations of a literature search that was bound to include only psychiatric studies, the outcome was inevitable.

#### **Problem: The ignoring of patients’ own evidence**

“Evidence-based medicine” (EBM) is often quoted as the gold standard by which all interventions are to be judged. Contrary to sound-bites emanating from the psychiatric lobby, EBM does not consist solely of random controlled trials (RCTs) but must include all three sources of evidence (1) RCTs (2) patient experience and (3) clinician experience. In the case of ME/CFS where -- due to prevailing policy -- there is a paucity of good quality evidence about non-psychiatric interventions such as dietary modification and other forms of complementary medicine, it is irrational to rely on just five RCTs that appear to support GET as the intervention of choice (page 147, line 11) whilst ignoring the other two components, especially given that the RCT study participants may not have had authentic ME in the first place and that the RCTs excluded those with severe ME/CFS.

Moreover, the sample sizes in the five RCTs ranged from just 49 to a maximum of only 148 (page 147, line 12). How relevant the health status of these few patients is to the large number of severely affected ME/CFS patients in the UK is impossible to say. It is worth recalling that Wessely himself has dismissed other researchers’ biomedical studies on the grounds that there were too few participants to be meaningful, yet the NICE Draft Guideline is promoting a national policy on what is by any standards a small and unrepresentative sample.

All Guideline Development Groups are governed by a Code of Practice stipulating that patient groups must be consulted if implementation is to succeed. There is every indication that this particular GDG will pay mere lip-service to the “consultation” process and that its mind is already made up even though the consultation period has only just started: in his summary of a NICE meeting held on Thursday 5<sup>th</sup> October 2006, the Medical Adviser to the UK ME Association (Dr Charles Shepherd) was under no illusion: “*Unfortunately I was left with the impression that the (Draft) Guideline would not be the subject of major changes at this late stage in the development process (and) I doubt if we are going to see a Guideline that the ME Association can endorse – certainly on the basis of the responses that were given on Thursday*” (at which Professor Peter White was in attendance: Co-Cure ACT: 8<sup>th</sup> October 2006).

Whilst not unexpected, this is a matter of deep concern, as the proposed CBT/GET regimes have been consistently rejected by patients because they are either ineffective or actively harmful. It is a matter of record that a substantial number of mild-to-moderately affected patients became – and have remained -- severely affected following exercise regimes.

Insistence on implementation of management regimes that patients have found both useless and harmful is contrary to the principles set out in the Department of Health booklet “The Expert Patient: A New Approach to Chronic Disease Management for the 21<sup>st</sup> Century” (2001) but the NICE Draft Guideline ignores this, stating (page 181) that CBT/GET “*should be offered to ALL adults and children with CFS/ME*”. It neglects to mention that for those who refuse this “offer” – because they may be too sick -- State and medical insurance benefits are likely to be withdrawn.

Patients may indeed know best about how to manage their own condition. Often, rest is best, despite the endless admonitions of the psychiatric lobby that rest is not to be tolerated.

Ciara MacLavery, a University graduate who became a severely affected ME patient, has written in compelling terms of her own experience:

*“It’s been 20 years since I was first diagnosed with ME and I have never had a full day’s health since then. I want to express my concerns over the widely-touted dictate that ‘total and/or prolonged rest’ is counter-productive in ME. When I was in the acute phase I was bed-bound for three years and was in pain and excruciating malaise every waking moment. The pain in my head was searing and nothing would lessen the pain. I couldn’t read, watch TV or listen to the radio. I had to wear earplugs as household noises caused surges of acid-like pain in my head. I could barely speak. If I was propped up in bed, I nearly passed out. I sometimes vomited. I often couldn’t hold a knife and fork. I longed for a bath and was mortified that my hair was unwashed for so long. When I finally started to heal it was NOT because I started ‘gentle exercise’. The pain in my head began to lessen by small degrees. I believe this slow healing within the brain happened because I gave my body the best chance. When I hear the ‘no total rest’ prescription I get exasperated as there are so many cases where this is wholly inappropriate. I recently took part in Dr Chaudhuri’s research project, undergoing a magnetic resonance spectroscopy (MRS). The brain scan (was) indicative of ongoing inflammation. I knew that the sense of brain inflammation I had in the first three years of ME was utterly crippling on a scale that is extremely difficult to convey. I just wasn’t believed. Doctors who want to prescribe ‘no total rest’ to patients in my position should start by listening to the patient. How ill must a person be when they have to shut down all meaningful interaction with life, forgo all of life’s pleasures and lie, barely moving in the dark for several years? Does that sound like a rest? Or any kind of a choice? The inability to get out of bed is not a consequence of the disease. It is the disease”.*

Patients like Ciara MacLavery who have no option but to follow their own instincts are berated and derided by the psychiatric lobby and dismissed by clinicians who have been unduly influenced by it. This compounds their despair.

If the aim is to help patients and to move toward a better understanding of best-practice and cost-effective policy, instead of the NICE Draft Guideline inflating the paucity of existing (unrepresentative) evidence to a stature that is insupportable in order to conclude that CBT/GET should be implemented throughout the UK “CFS/ME” community, it would surely be better to give more weight to the patients’ surveys which find that CBT is unhelpful and that GET is harmful. The Draft Guideline itself acknowledges this (page 56, line 3: “*graded exercise was felt to be the treatment that made more people worse than any other*”).

In considering patients’ experience of CBT and GET, a patients’ survey carried out by The 25% ME Group for the Severely Affected that was submitted to NICE is not mentioned in the Draft Guideline (Severe ME Analysis Report, March 2004). This is an important omission because in that survey, 93% found CBT unhelpful; 95% found GET unhelpful and of those who tried GET, 82% reported that they were worse afterwards.

As in the tragic case of Ciara MacLavery, even to think of imposing CBT and GET on house-bound severely affected patients makes such patients objects of derision and shows a disturbing lack of understanding of their situation. Those who are bed-bound are nowhere near “activity management” level (page 138, line 1). Many of those with severe ME/CFS may have between 10% - 20% functional ability, and Professor Mike Sharpe himself concedes that at least 80% functional ability is needed in order to engage in activity management. The proposed 90 minute sessions (a considerable percentage of which

will be via the telephone for those with severe ME/CFS) are not feasible. Many people with even moderate ME/CFS are not able to use the telephone for as much as 10 minutes at a time. How much therapeutic intervention can be delivered by telephone, especially for those who are isolated?

It is the case that ME/CFS patients, their carers, their clinicians and even their MPs have submitted evidence making plain their legitimate concerns about CBT/GET.

From what is contained in the Draft Guideline, it seems that all these submissions have been ignored, just as they were ignored by the CMO's Working Group and by the MRC.

**Problem: The refusal by NICE to listen to patients perpetrates and even sanctions the culture of contempt surrounding ME/CFS**

That there is a culture of contempt about people with ME/CFS that is perpetrated by certain members of the medical profession cannot be disputed.

In 1990 Wessely wrote: "*The description given at the Mayo Clinic remains accurate: 'the average doctor will see they are neurotic and he will often be disgusted with them'* ". (Chronic fatigue and myalgia syndromes. Wessely S. In: Psychological Disorders in General Medical Settings. Ed. N Sartorius et al. Hogrefe and Huber, 1990).

In 1994 Wessely stated: "*Patients with inexplicable physical symptoms are generally viewed as an unavoidable, untreatable and unattractive burden*" (Patients with medically unexplained symptoms. Alcuin Wilkie, Simon Wessely. British Journal of Hospital Medicine 1994;51:8:421-427).

This was further exemplified by Professor Mike Sharpe in 1999: "***Those who cannot be fitted into a scheme of objective bodily illness yet refuse to be placed into and accept the stigma of mental illness remain the undeserving sick of our society and our health service***" (ME: what do we know [real illness or all in the mind]? Lecture given in October 1999 by Michael Sharpe, hosted by the University of Strathclyde).

**Evidence of the culture of contempt surrounding ME/CFS**

For the avoidance of doubt and to clarify what the Wessely School really thinks about people with ME/CFS, some illustrative quotations are provided; note that the thread throughout the following quotations illustrates the intransigent and therefore worrying refusal to pay heed to the peer-reviewed literature that shows the Wessely School to be wrong, which ought to be of concern to policy-makers:

**1990**

Old wine in new bottles: neurasthenia and ME Simon Wessely.  
*Psychological Medicine* 1990;20:35-53

**"Suggestible patients with a tendency to somatize will continue to be found among sufferers from diseases with ill-defined symptomatology until doctors learn to deal with them more effectively"**

**1990**

Possible ME S Wessely  
*The Practitioner* 8<sup>th</sup> March 1990;234:195-198

**"ME is a description, not a diagnosis"**

**1990**

The chronic fatigue syndrome – myalgic encephalomyelitis or postviral fatigue S Wessely PK Thomas  
*In: Recent Advances in Clinical Neurology. Pub: Churchill Livingstone 1990:pp85-132*

**“It is regrettable that (ME) has become a fad”**

**1990**

Chronic Fatigue and Myalgia Syndromes Simon Wessely  
*In: Psychological Disorders in General Medical Settings Ed: N Sartorius et al Hogrefe & Huber, 1990*

**“Most CFS patients fulfil diagnostic criteria for psychiatric disorder”**

**“Other symptoms include muscle pain and many somatic symptoms, especially cardiac, gastrointestinal and neurological. Do any of these symptoms possess diagnostic significance? The answer is basically negative”**

**1991**

Postviral fatigue syndrome and psychiatry Anthony S David  
*British Medical Bulletin 1991:47:4:966-988*

**“A diagnosis of depressive illness would be appropriate. Unfortunately, this is not good enough for the patient”**

**“In summary, there is considerable direct and circumstantial support for chronic fatigue (note the title purports to refer to PVFS, or ME/CFS) being an aspect of psychiatric illness”**

**1991**

Cognitive behaviour therapy in chronic fatigue syndrome Butler S, Chalder T, Ron M, Wessely S  
*JNNP 1991:54:153-158*

**“Continuing attribution of all symptoms to a persistent ‘virus’ preserves self-esteem”**

**1991**

The psychological basis for the treatment of CFS Wessely S  
*Pulse of Medicine 14<sup>th</sup> December 1991:58*

**“The prognosis may depend on maladaptive coping strategies and the attitude of the medical profession”**

**1991**

Psychiatric management of Post Viral Fatigue Syndrome M Sharpe  
*British Medical Bulletin 1991:47:4:989-1005*

**“To exclude (patients with a psychiatric diagnosis) is practically restrictive”**

**“Psychiatric management may be defined as the assessment and treatment of the mentally ill”**

**“Personality factors (attitudes, beliefs and thoughts) and behaviour have been shown to perpetuate disability. These unhelpful or “dysfunctional” cognitions include the beliefs that recovery from the illness is not under personal control or that the illness is poorly understood”**

**“In response to the lack of acceptance of the “reality” of the symptoms of CFS, support has been sought for the existence of a disease called myalgic encephalomyelitis or ‘ME’ ”**

**“The insistence that ‘ME’ is an exclusively physical disease with a poor prognosis may have been unhelpful for sufferers (and) such a restricted conception of the problem may have perpetuated illness in some individuals”**

**“The use of extensive laboratory investigation may be psychologically harmful to the patient by reinforcing their beliefs about serious physical disease”.**

**1992**

The epidemiology of fatigue: more questions than answers Lewis G Wessely S  
*Journal of Epidemiology and Community Health 1992;46:92-97*

**“Studies usually find a high prevalence of psychiatric disorder among those with CFS, confirming that physicians are poor at detecting such disorders”**

**1992**

Eradicating myalgic encephalomyelitis (ME) Simon Wessely  
*Report of the meeting held on 15<sup>th</sup> April 1992 at Belfast Castle / Pfizer Invicta Pharmaceuticals, pp4-5*

**“It seems that ME sufferers prefer to feel that they have a ‘real’ physical disease – it is better for their self-esteem (and) the label ‘ME’ helps legitimise their dealings with doctors”**

**1994**

Predictors of chronic “postviral” fatigue Helen Cope, Anthony David et al  
*Lancet 1994;344:864-868*

**“Doctor behaviour, such as sick certification, emerged as a significant contributor to the risk of chronic fatigue” (note the title refers to postviral fatigue)**

**1994**

The Chronic Fatigue Syndrome: A Comprehensive Approach to its Definition and Study.  
K. Fukuda S.Straus M Sharpe et al  
*Ann Int Med 1994;121:12:953-959*

**“In clinical practice, no additional tests, including laboratory tests and neuro-imaging studies, can be recommended”**

**“Examples of specific tests (*which should not be done*) include serologic tests for enteroviruses; tests of immunologic function, and imaging studies, including magnetic resonance imaging scans and radionuclide scans (such as single photon emission computed tomography (SPECT) and positron**

emission tomography (PET) of the head. We consider a mental status examination to be the minimal acceptable level of assessment”

**1994**

Patients with medically unexplained symptoms Alcuin Wilkie Simon Wessely  
*British Journal of Hospital Medicine* 1994;51:8:421-427

**“Their symptoms have no anatomical or physiological basis”**

**1994**

Microbes, Mental Illness, The Media and ME: The Construction of Disease Simon Wessely  
*9<sup>th</sup> Eliot Slater Memorial Lecture, 12<sup>th</sup> May 1994*

**“I will argue that ME is simply a belief, the belief that one has an illness called ME”**

**“The Royal Free Disease itself is part of the world of myth”**

**1995**

Cognitive Functioning and Magnetic Resonance Imaging in Chronic Fatigue H Cope, Anthony David et al  
*British Journal of Psychiatry* 1995;167:86-94

**“Clinicians should avoid reinforcing unproven illness beliefs”**

**“We are critical of what we regard as the misuse of neuropsychological test results to confirm or refute an ‘organic’ basis for CFS”**

**1995**

Psychiatry in the Allergy Clinic LM Howard S Wessely  
*Clinical and Experimental Allergy* 1995;25:503-514

**“Many doctors are frequently consulted by patients with persistent unexplained symptoms attributed to allergy or chemical sensitivity”** (no evidence is provided to support this claim)

**“When patients are told there is no evidence of any underlying immunological or allergic cause, they can be difficult to manage”**

**“The epidemiology of environmental illness is reminiscent of the difficulties encountered in distinguishing between the epidemiology of myalgic encephalomyelitis (ME), a belief, and chronic fatigue syndrome, an operationally-defined syndrome”** (the World Health Organisation does not regard ME as “a belief” but as a formally-classified neurological disorder)

**“Attribution of unexplained symptoms to a ‘virus’, as happens in most patients with the label of ME, may preserve self-esteem and protect against the stigma of psychiatric disorder”**

**“These syndromes are akin to culture-bound syndromes afflicting modern developed societies where sufferers from unexplained symptoms no longer see themselves as possessed by devils or spirits but instead by toxins and viruses”**

**“Further investigations will add nothing to the management but will reinforce the patient’s belief in organic pathology”**

**“Liaison between the physician and the psychiatrist is necessary so that patient acceptance of psychiatric referrals can be facilitated”.**

### **1996**

Chronic fatigue syndrome: an update Anthony J Cleare Simon C Wessely  
*Update 1996:14 August:61*

**“Chronic fatigue may be better understood by focusing on perpetuating factors and the way in which they interact in self-perpetuating vicious circles of fatigue, behaviour, beliefs and disability”**

**“The perpetuating factors include inactivity, illness beliefs and fear about symptoms, symptom focusing, and emotional state”**

**“CFS is dogged by unhelpful and inaccurate illness beliefs, reinforced by much ill-informed media coverage; they include fears and beliefs that CFS is caused by a persistent virus infection or immune disorder”**

**“Increased symptom focusing occurs in CFS sufferers; (this) increased concern leads to selective attention and ‘body watching’: this can intensify the perceived frequency of symptoms, thereby confirming illness beliefs and reinforcing illness behaviour”.**

### **1999**

ME. What do we know (real physical illness or all in the mind?)  
*Lecture given in October 1999 by Michael Sharpe, hosted by the University of Strathclyde*

**“In my lecture this evening, I would like to talk to you about myalgic encephalomyelitis (ME), also known as chronic fatigue syndrome or CFS (which) for convenience I will refer to as CFS”**

**“CBT has been shown to have substantial benefits for patients with CFS (and) can reduce disability in most patients”**

**“I shall argue that patients themselves have played a part in denying themselves this type of treatment”**

**“The vehemence with which many patients insist that their illness is medical rather than psychiatric has become one of the hallmarks of the condition”**

**“Purchasers and Health Care providers with hard pressed budgets are understandably reluctant to spend money on patients who are not going to die and for whom there is controversy about the “reality” of their condition (and who) are in this sense undeserving of treatment”.**

Note that many people *have* died from ME, the most recent in the UK being Sophia Mirza, and her Death Certificate confirms this: <http://www.investinme.org/Article-050%20Sophia%20Wilson%2001-RIP.htm>

There is also a Memorial List of ME-related deaths: see <http://www.ncf-net.org/memorial.htm>

**2000**

Responding to Mass Psychogenic Illness. Editorial: Simon Wessely  
*The New England Journal of Medicine 2000;342:2:129-130*

**“The term ‘psychogenic illness’ and its predecessor ‘mass hysteria’ exemplify the problem. To the majority of observers, including most professionals, these symptoms are indeed all in the mind”**

**“How do you convey the message that the main mechanisms for the transmission of distress are psychosocial and behavioural? A firm public message that certain symptoms are probably psychological in origin will probably help prevent their spread”.**

**2002**

Functional Symptoms and Syndromes: Recent Developments Michael Sharpe  
*In: Trends in Health and Disability 2002, Report of UNUM Provident Insurance Company*

**“There is a great deal of confusion about what to call such illness. A wide range of general terms has been used including ‘hysteria’, ‘abnormal illness behaviour’, ‘somatisation’ and ‘somatoform disorders’ ”**

**“ The psychiatric classification has important treatment implications. Because patients may not want a psychiatric diagnosis, this may be missed”**

**“Possible causal factors in chronic fatigue syndrome:**

**“Psychological: personality, disease attribution, avoidant coping style”**

**“Social: information patients receive about the symptoms and how to cope with them; this information may stress the chronicity and promote helplessness. Such unhelpful information is found in ‘self-help’ books. Unfortunately doctors may be as bad”**

**“Obstacles to recovery:**

**“The current system of state benefits, insurance payment and litigation remain potentially major obstacles to effective rehabilitation”**

**“As the authority of medicine to define what is a legitimate illness is diminished, increasingly consumer oriented and privatised doctors will collude with the patient’s views that they have a disabling and permanent illness”.**

**2003**

Medically unexplained symptoms: exacerbating factors in the doctor-patient encounter.  
 LA Page, S Wessely  
*Journal of the Royal Society of Medicine 2003;96:223-227*

**“This paper proposes that well-intentioned actions by medical practitioners can exacerbate or maintain medically unexplained symptoms (MUS). This term is now used in preference to ‘somatisation’ ”**

**“The adoption of a label such as CFS affords the sufferer legitimacy --- in other words, it allows entry into the ‘sick role’ ”**

**“(In relation to treatment), there is evidence to suggest that harm occurs at the hands of non-medical practitioners (who) colluded with patients’ abnormal illness beliefs”**

**“If sections of the media advocate an exclusively organic model, as has happened with CFS, the biomedical model may become firmly enshrined for patients and families at the expense of psychosocial models”**

#### **2004**

Somatoform disorders: a help or hindrance to good patient care? Michael Sharpe Richard Mayou  
*British Journal of Psychiatry 2004;184:465-467*

**“The value of somatoform diagnoses is often taken simply to indicate a need to minimize access to medical care”.**

#### **2005**

Chronic fatigue syndrome: an overview Hyong Jin Cho Simon Wessely  
*Rev Bras Psiquiatr. September 2005;27:3: Sao Paulo*

**“Functional somatic syndromes refer to groups of symptoms lacking demonstrable abnormalities of structure. They include chronic fatigue syndrome”**

**“Firstly, many consider that amplification of somatic symptoms that happen in our daily lives is a core factor underpinning the perpetuation of many unexplained medical syndromes. Secondly, modification of these factors is the main focus of what are the currently most successful treatments for CFS, ie. cognitive behavioural therapy and graded exercise therapy”**

**“Several factors have been reported to be associated with the perpetuation of CFS. These include a fixed somatic attribution, which may be associated with avoidance behaviour related to exercise or activity”.**

There are many more such examples of the views of the Wessely School, which indeed flood the UK medical literature to the exclusion of biomedical papers.

#### Professor Komaroff’s view about the psychiatric model

It was on 18<sup>th</sup> November 1995 in his lecture in London that Anthony Komaroff, Professor of Medicine at Harvard and world expert on ME/CFS, went on record saying: *“Not **once** has anyone’s illness gone away with psychiatric therapy. And then there is the failure to find evidence of psychiatric disease, either before or after the onset of ME, in a large fraction of our patients. When we looked with our psychiatric colleagues we could not find evidence of psychiatric illness in the majority of ME patients”.*

What is so appalling is that this is not ignorance on the part of the Wessely School, but the deliberate and determined suppression of the available medical and scientific evidence that has demonstrated organic pathology in a very serious and complex disorder.

This is such a serious issue that questions have been raised in the literature as to whether or not the behaviour of Wessely et al amounts to scientific misconduct.

#### Illustrations of the effects of the psychiatric lobby’s dissemination of misinformation

Just a few illustrations of the ramifications of Wessely School views are provided here.

- The health writer for the web magazine “spiked” is Dr Michael Fitzpatrick, a GP and anti-ME activist well-known for presenting and promoting the views of Professor Simon Wessely and for his perverse and immoderate attacks on those with ME. One such article can be found at <http://www.spiked-online.com/Articles/00000002D3B6.htm> (SPIKED: Health: 17th January 2002: “ME: the making of a new disease”). Speaking in support of those with ME/CFS at the launch of his Working Group’s Report, Professor Sir Liam Donaldson, Chief Medical Officer, said on the record: “*CFS/ME should be classed as a chronic condition with long term effects on health, alongside other illnesses such as multiple sclerosis and motor neurone disease*” (BBC News / Health: 11<sup>th</sup> January 2002: <http://news.bbc.co.uk/1/hi/health/1755070.stm> ), only to be vilified by Fitzpatrick: “*The CFS/ME compromise reflects a surrender of medical authority to irrationality. The scale of this capitulation is apparent when Professor Donaldson claims that CFS/ME should be classified together with conditions such as multiple sclerosis and motor neurone disease. The effectiveness of the ME lobby reflects its middle-class base.*”
- Supporting Fitzpatrick, Professor Mike Sharpe said in the BMJ that doctors would not accept a particular strategy just because the CMO’s report recommended it (BMJ:2002:324:131)
- The medical trade magazines (widely distributed free to doctors, especially to GPs and to hospital libraries by the drug companies) have made a point of mocking and denigrating sufferers from ME/CFS in a way they would not dare do about patients with multiple sclerosis or other neurological disorders. These have been reflected in the national media, for example:
  1. on 1<sup>st</sup> April 1994 “GP Medicine” carried a bold banner headline proclaiming “*GPs despise the ME generation*”
  2. on 12<sup>th</sup> January 1995 “Doctor” magazine ran a feature called “Bluffer’s Guide” by Dr Douglas Carnall, in which he wrote “*Modern bluffers prefer the term chronic fatigue syndrome....if they really insist on a physical diagnosis tell them chronic fatigue syndrome is a complex disorder in which multiple biopsychosocial factors are mediated via the anterior hypothalamus ---in other words, it’s all in the mind*”
  3. on 5<sup>th</sup> May 1996, under the headline “Chronic Bandwagon Disease”, CFS was described in the Sunday Express by Jonathan Miller as “Chronic Fictitious Sickness”
  4. on 21<sup>st</sup> February 1999 Adrian Furnham, Professor of Psychology at University College, London, suggested that there was a wealth of conditions that can be fashionable excuses for lack of success, writing in the Telegraph: “*You are not dim, or work-shy or lazy. No indeed, you are a chronic sufferer from a recently discovered syndrome! Indeed, this medical problem can probably account for all the setbacks you have met in life. Chronic fatigue. There is no cure, although reclining on a sofa watching ‘Richard and Judy’ is said to alleviate the worst symptoms*” (This was the subject of a complaint to the British Psychological Society, who decided that Professor Furnham had not committed any form of professional misconduct)
  5. “Doctor” magazine ran a quiz by Dr Tony Copperfield (known to be the pseudonym of a GP in Essex) in which GPs were asked to choose from four possible answers to the question “*What would be your initial response to a patient presenting with a self-diagnosis of ME?*” The correct answer was “*For God’s sake pull yourself together, you piece of pond life*”. (This was the subject of a complaint to the General Medical Council)
  6. on 20<sup>th</sup> October 2001 “Pulse” ran a series called “Choices for the new generation of GPs”. The approach provided by Dr Mary Church (a Principal in a practice in Blantyre, Scotland and a member of the British Medical Association medical ethics committee) was particularly contemptuous but is not untypical: “*Never let patients know you think ME doesn’t exist and is a disease of malingerers. Never advise an ME patient to make a review appointment*”

7. on 23<sup>rd</sup> March 2001 in “GP” magazine Dr Marko Boganovic, research registrar, Merton College, Oxford, wrote about patients with CFS/ME: *“The provision of disability services and benefit payment is controversial because illness beliefs may be reinforced (and) services and benefits constitute secondary gain”*

- The issue of “secondary gain” is important. It is an often-repeated assertion by the Wessely School for which not a shred of evidence exists. Patients are desperate to get better and to resume their former lives and their independence. What “secondary gain” can possibly compensate for the loss of health, employment, financial security, social life and – far too often – the loss of home, partner, family and friends? If “adopting the sick role” and “symptom amplification” bring people with ME/CFS to the point of such despair that they consider or commit suicide, how can it be thought to be “rewarding”? The psychiatric lobby persistently fails to address this issue: at a conference held in London on 31<sup>st</sup> October and 1<sup>st</sup> November 2002 on the biopsychosocial model of illness, the question of secondary gain was raised, and Professor Michael Von Korff said: *“If we start with the assumption that (ME/CFS) patients are motivated largely by secondary gain....”* (for a detailed report, see [www.meactionuk.org.uk/PROOF\\_POSITIVE.htm](http://www.meactionuk.org.uk/PROOF_POSITIVE.htm)). To depend on such an assumption defies logic, so the question therefore needs to be repeated: where are the published studies which demonstrate that such patients obtain secondary gain? As Von Korff made plain, the psychiatrists’ view is an assumption -- with reputations and careers being built on it -- but assumptions are hardly “evidence-based medicine” upon which Wessely et al purport to place such store

8. in early in 2002, at Wessely’s instigation the BMJ ran a ballot asking doctors to vote on what they considered to be “non-diseases” that are best left medically untreated: Wessely proposed ME. Along with freckles and big ears, ME was voted a “non-disease” and in April 2002 both broadsheet and tabloid newspapers ran banner headlines proclaiming that ME is a non-disease.

- In 2001 a major report by the charity Action for ME (AfME) found that 77% of sufferers experienced severe pain; over 80% had felt suicidal as a result of ME/CFS; 70% are either never able, or are sometimes too unwell, to be able to attend a doctor’s clinic; 65% (nearly two out of three) have received no advice from their GP on managing this illness and 80% of those who are currently bed-ridden by ME report that a request for a home visit by a doctor has been refused. (Severely Neglected: ME in the UK: AfME, March 2001)
- AfME also published some comments of doctors to ME/CFS patients including the following:
  1. “Throw away your crutches – it’s your head that needs them, not your legs”
  2. “Women of your age imagine aches and pains -- are you sure you’re not attention-seeking?”
  3. “You are a menace to society”
  4. “You have the audacity to come here and demand treatment for this self-diagnosed illness which does not exist”
  5. “Stop feeling sorry for yourself – I have patients with real illnesses”
  6. “ME is a malingerers’ meal-ticket”

7. "I'm not going to further your career of twenty years of being ill"
  8. "If you go on like this you will be struck off (the GP's list)"
  9. "I was told I was a disgrace"
  10. "I was told that I was a nutter"
  11. "He laughed me out of the surgery"
- These quotations come from the ME Action (now AfME) magazine in 1989 (InterAction: Spring 1989:2:78) but due to the assiduous efforts of the Wessely School, there is little evidence of any improvement in doctors' attitudes 17 years later: ME/CFS patients are still accused by doctors of refusal to get better and of not wanting to work. One patient was recently taunted: "If you're able to get to my surgery, you're able to get a job. Don't confuse me with facts. My mind is made up" (Co-Cure: 10<sup>th</sup> October 2006). Another was sworn at and told she was abusing the NHS and ought to be ashamed of herself (this patient had worked in a senior clinical capacity in the NHS for longer than the GP concerned and was assessed by Social Services as requiring 24 hour care)
  - Unknown numbers of severely sick people with ME/CFS have been removed from GP's lists, often with no prior warning. After the BMJ poll on non-diseases, one very sick ME patient was brusquely informed that "This practice does not treat non-diseases" and was removed from the list
  - Many doctors still do not believe in ME/CFS: on 10<sup>th</sup> July 2006 in his oral evidence to the Gibson Parliamentary Inquiry on ME/CFS, consultant physician and ME expert Dr William Weir pointed to a big problem – pervasive medical ignorance. He stated his belief that 90% of doctors believe ME/CFS is a psychiatric disorder.

If NICE persists in disregarding patients' evidence and in accepting the indisputably biased "evidence" of the psychiatric lobby, this culture of contempt is set to continue.

#### **Problem: Apparent misinterpretation of the "evidence" by the York Review team**

The machinations of NICE have not escaped the attention of the Gibson Parliamentary Inquiry: "*There are a number of themes that are eliciting concern and debate*", says Dr Ian Gibson MP, Chairman of the Inquiry. "*Are the NICE Guidelines for diagnosis effective? And what evidence base was used to form the guidelines?*" (A new look at CFS/ME. Ian Gibson. J Clin Pathol 2006: published online 25<sup>th</sup> August doi:10.1136/jcp.2006.042432).

In its present deliberations on ME/CFS, NICE would do well to heed the message from a former Editor for 20 years of the BMJ, Dr Richard Smith. Interviewed by Claire O'Donnell (Irish Times, 1<sup>st</sup> October 2006) about his new book entitled "The Trouble with Medical Journals", Smith is categorical:

**"Don't believe all you read in a medical journal. All medical journals publish rubbish, and quite a lot of it. I think it would be good for the world at large to realise just what a dodgy process peer review is. Most doctors are not equipped to critically appraise the evidence".**

#### **No evidence of long-term benefit from CBT**

The York Review team seems to have overlooked the evidence that CBT intervention is already known not to work:

- at the AACFS International Conference at Cambridge, Massachusetts on 10-11<sup>th</sup> October 1998, Mike Sharpe went on record stating that the benefits of CBT faded with time

- in a personal communication dated 12<sup>th</sup> October 1998 to Professor Fred Friedberg, Mike Sharpe stated about his often-quoted 1996 study (BMJ 1996:312:22-26) that outcome measures have begun to decline 17 months after treatment termination (quoted in JCFS 1999:5:3/4:149-159)
- on 3<sup>rd</sup> November 2000, Sharpe again confirmed “There is a tendency for the difference between those receiving CBT and those receiving the comparison treatment to diminish with time due to a tendency to relapse in the former” ([www.cfs.inform.dk](http://www.cfs.inform.dk) )
- the very modest benefit in only some patients who have undergone CBT has been shown to last for only 6-8 months and “*observed gains may be transient*” (Long-term Outcome of Cognitive Behavioural Therapy Versus Relaxation Therapy for Chronic Fatigue Syndrome: A 5-Year Follow-Up Study. Alicia Deale, Trudie Chalder, Simon Wessely et al. Am J Psychiat 2001:158:2038-2042)
- in his Summary of the 6<sup>th</sup> AACFS International Conference in 2003, Charles Lapp, Associate Clinical Professor, Duke University and Director, Hopkins-Hunter Centre, NC, stated about CBT that Dr Daniel Clauw (who had studied 1,092 patients) found that at 3 months there were modest gains, but at follow-up at 6 and 12 months, those modest gains were lost (this being an example of “evidence-based” medicine that seems to have escaped the York Review team)
- Wessely himself is on record stating that CBT doesn’t work for all: in his Editorial (JAMA 19<sup>th</sup> September 2001:286:11) he stated that CBT and GET are only “*modestly effective*” and that neither is “*remotely curative*”
- Wessely is also on record as stating: “*It should be kept in mind that evidence from randomised trials bears no guarantee for treatment success in routine practice. In fact, many CFS patients, in specialised treatment centres and the wider world, do not benefit from these interventions*” (The act of diagnosis: pros and cons of labelling chronic fatigue syndrome. Marcus JH Huibers and Simon Wessely. Psychological Medicine 2006:36: (7): 895-900).

#### International concern about UK psychiatrists’ reliance on CBT

International experts are on record as being very concerned about the stance of UK psychiatrists re CBT/GET:

1. Professor Charles Lapp (USA) stated: “**In my opinion, CBT is widely but unfairly maligned because of the British approach, which presumes (ME)CFS has no organic basis and is therefore contradictory to most patients’ perspectives and (to) current science. This type of CBT assumes somatic symptoms are perpetuated by errant illness beliefs and maladaptive coping**”
2. Professor Nancy Klimas stated: “**I don’t take the British point of view that CBT is the one thing you can do to effectively treat (ME)CFS**”
3. Dr David Bell stated: “**I don’t refer (ME/CFS patients) to outside CBT therapy**”
4. Dr Daniel Peterson stated: “**Sending patients to therapists who don’t understand (ME)CFS isn’t something I’d comfortably do**” (The CFIDS Chronicle Science and Research Special Issue, 2005-2006).

Notwithstanding that the efficacy of CBT has not been proven, the UK Government is committed to rolling out CBT across the board: the Prime Minister himself confirmed this in a Parliamentary Reply on 15<sup>th</sup> June 2005: **“The Department of Health is working on proposals for extending the range of treatments offered under the NHS to people with mental health problems, focusing on greater availability of the so-called Cognitive Behavioural Therapies”** (Hansard). Questions have been asked as to who advised the Prime Minister, as it is known that Professors Wessely and White are influential advisers to Departments of State and that they are involved in policy-making. (For evidence, see [www.meactionuk.org.uk/PROOF\\_POSITIVE.htm](http://www.meactionuk.org.uk/PROOF_POSITIVE.htm) ).

Despite their best efforts, North American researchers have been unable to replicate the beneficial effects of CBT/GET claimed by British psychiatrists of the Wessely School.

Friedberg, for example refers to “widely divergent clinical presentations”:

*“Descriptive studies of CFS patients in England, the US and Australia suggest that the CFS patient population studied in England shows substantial similarities to somatization patients, while the US and Australian research samples have been clearly distinguished from primary (psychiatric) patients and more closely resemble fatiguing neurological illnesses. Because the ‘successful’ trials have all been conducted in England, a replication of these findings in a well-designed US study would be necessary before a general recommendation for CBT could be made”.* (A Subgroup Analysis of Cognitive-Behaviour Treatment Studies. Fred Friedberg. JCFs 1999:5:3/4:149-159).

Further, in 2003 a Report from New Zealand regarded CBT as out-dated and the UK attitude towards it as distorted: *“Possibly resulting from the psychiatric bias, or from the out-dated research base, it was felt that this guideline showed a bias towards the now out-dated management practices of CBT and GET. The reviewers commented that the research about CBT is ambiguous and inconsistent and that GET may cause relapse and is thereby potentially harmful. The reviewers also commented that a particular shortcoming of the CMO report is the Anglocentric nature of the research base and the consequent omission of relevant evidence from international studies. It was also felt that there was too strong an emphasis on psychological issues and approaches (as a result of) extreme professional positions. **(It is necessary to) avoid making recommendations shown by more recent research to be ineffective or even harmful, as has been the case with some of the reviewed guidelines”.*** (Analysis of Chronic Fatigue Syndrome Guidelines. Report to the Ministry of Health. New Zealand. November 2003).

Clearly, this cuts no ice with NICE because it has its own agenda, as noted in a lecture delivered on 1<sup>st</sup> March 2006 to the Humanities and Mental Health Research Network in Nottingham (Truth, Politics and Psychological Therapy) by clinical psychologist David Smal: *“None of the factors I had always taken as being important receive any real consideration, or influence the NICE evaluation of the so-called evidence. The NICE version of things may not be valid or remotely true but it is certainly useful in enabling central control and direction of professional activity, whether in research or practice. This is an exercise in transfer of costs between departments, justified by a projection that (it) will be a cost-neutral exercise with major social benefit. What all this amounts to is that we have lost any semblance of pursuing scientific inquiry. Control of behaviour seems to me a disreputable aim. Thatcherism introduced a world, now firmly established, in which the operation of crude economic interest plays almost the only role. **The devastation this has caused is maintained by a web of nearly impenetrable institutional power obscured by psychobabble”.***

The JRSM article by Chambers and Bagnall et al that publishes the views of the York Systematic Review team upon which the NICE Draft Guideline relies states: *“No severely affected patients were included in the studies of GET”,* yet NICE will recommend that the severely affected should be subjected to what would amount to barbaric regimes and it advocates strategies which are potentially damaging for those with severe authentic ME/CFS in whom there is already a degree of cardiac failure (Interventions for the treatment, management and rehabilitation of patients with chronic fatigue syndrome / myalgic encephalomyelitis: an updated systematic review. Chambers D, Bagnall A-M et al. JRSM 2006:99:506-520)

To implement such regimes without any prior monitoring of such patients for cardiac failure -- whilst ascribing the cardiac symptoms to “deconditioning” -- is perilously cavalier.

#### Over-diagnosis of somatisation disorder

The psychiatric lobby repeatedly asserts that patients’ “attributions” and “cognitions” perpetuate the illness, as does the “attributional bias” of those physicians who take patients with ME/CFS seriously. The evidence suggests the reverse ie. it is the attitude of the interviewer, not the symptomatology, that determines the rate of somatisation diagnosed.

Wessely, for example, often suggests that he is controlling for physical symptoms by eliminating one symptom – fatigue – from the list, but he then attributes all the other symptoms to psychiatric diagnoses.

Johnson et al expose the inappropriateness of this in cases of ME/CFS: *“The diagnosis of somatisation disorder (SD) is extremely problematic in terms of its validity because it involves a series of judgments that can be arbitrary and subjective. If the examiner recognises that the patient’s (ME)CFS symptoms indicate a physical illness, the diagnosis of SD may not be made. Conversely, if the examiner does not consider (ME)CFS a medical illness, (this) may lead to the diagnosis of SD. Factors that contribute to this variability are the interviewer’s orientation (and) the heterogeneity of the population. The difficulty in distinguishing somatic symptoms that are psychiatric versus organic in origin can result in overdiagnosis of SD in medical illness, particularly chronic illness. Several studies have performed a recalculation, changing (ME)CFS from a psychiatric to a physical disorder, which greatly reduced the number of subjects with SD. Prevalence rates of SD ranged from 0% to 98% depending on whether (ME)CFS symptoms were coded as being due to physical illness or not. The present study found a reduction from 55% to 12% in SD rate when (ME)CFS symptoms were coded as physical. Using the strict DSM-III-R definition identifies very few (ME)CFS patients as having SD. Although (ME)CFS patients frequently endorse symptoms thought to indicate SD, they do so only after the onset of (ME)CFS and thus do not show the history thought to be characteristic of SD. If (ME)CFS is considered an organic disease, then (ME)CFS patients cannot have SD. Furthermore, screening out chronic psychiatric disorders in our population did not result in a decrease in somatic symptom reporting compared with previous (ME)CFS studies. **These results strongly suggest that psychiatric factors alone are not a sufficient explanation for the broad array of somatic symptoms reported in (ME)CFS.** The present study illustrates that the terminology used to interpret the symptoms (ie. psychiatric or physical) will determine which category (ME)CFS falls into (but) a diagnosis of SD may be so arbitrary as to be rendered meaningless in illness such as (ME)CFS. Labeling of a condition is not trivial because it can affect treatment services”.* (Assessing somatization disorder in the chronic fatigue syndrome. Johnson SK, DeLuca J, Natelson BH. Psychosomatic Medicine 1996;58(1):50-57).

#### High drop-out rates ignored

All patient surveys of ME/CFS patients report that a high percentage are made worse by GET, yet the published trials that underpin the NICE Draft Guideline never report adverse events. Why not? The high drop-out rates cannot be ignored: to claim no adverse effects in trials with such high drop-out rates is implausible.

#### Discrepancies in data

Dr Mary Schweitzer, a qualified statistician, raises cogent concerns about the “Statement of principal findings” in the JRSM paper mentioned above that was designed specifically to support the NICE Guideline. The paper claims: *“A number of RCTs suggest that behavioural interventions, including elements of CBT, GET and rehabilitation, may reduce symptoms and improve physical functioning of people with CFS/ME”* and Dr Schweitzer comments: *“That was not how I read their own measurement of success or failure (a ranking where 0 is a total failure and 20 is total success) in the table included with the study. There were eight studies using CBT. The quality of scores ranged from 1 to 18. The method of scoring apparently did not take into account the problem of the number of patients withdrawing from the studies, and it is also well to remember the controversy swirling around GET with regard to studies that*

'cherry-pick' their patients (ie. choose only those patients well enough to be able to exercise in the first place). I remain perplexed at the conclusions that they drew. **Either there was something wrong with their methodology (their scoring system) or the conclusions they drew had nothing to do with the study they conducted**" (Co-Cure RES:ACT: 6<sup>th</sup> October 2006). Dr Schweitzer notes: "I guess they feel perfectly safe publishing one thing in their tables, and yet something else entirely in the text – they know that all anybody is going to do is read the text and perhaps quote from it" (personal communication, 13<sup>th</sup> October 2006).

#### Academic critique of the York Review by Bagnall et al of October 2005

Despite Nancy Turnbull (Project Lead) having confirmed in writing that it had been received and discussed, the Guideline Development Group seems to have ignored an important analysis that pointed out the inadequacy of the evidence base relied upon by the York Systematic Review team.

In January 2006 Professor Malcolm Hooper and Horace Reid published a critique exposing the inadequacy of the evidence base of RCTs relied upon by the York team (Inadequacy of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base, Comment on Section 3: the Diagnosis, treatment and management of CFS/ME in adults and children: Work to support the NICE Guidelines") available online at [www.meactionuk.org.uk/FINAL\\_on\\_NICE\\_for\\_Gibson.html](http://www.meactionuk.org.uk/FINAL_on_NICE_for_Gibson.html)

It is one of the most damning indictments of the Wessely School paradigm that has ever been mounted.

It noted that the York Systematic Review team downplayed the small size of the evidence base upon which it relied; that the Review team also downplayed the fact that the evidence upon which they rely originated and has been used only in the UK, and the extent to which American, Australian and Canadian experts in the disorder -- all world renowned -- dissent from that alleged evidence.

The necessity for the NICE Guideline Development Group to read and heed the Hooper /Reid analysis cannot be emphasised enough.

However, for convenience, extracts from that analysis are produced here.

#### Introductory Comment

*"As a summary of evidence-based medicine for the treatment of (ME)CFS, Section 3 of this systematic review from Bagnall et al is a failure. The reviewers have (1) failed to realise the limitations of the RCT evidence base; (2) failed to integrate the great body of literature on individual clinical expertise, and (3) failed to fully reflect the rights, preferences and choices of the patient community".*

#### Section 1: Inadequacy of the RCT evidence-base

##### 1.2 Deficiency of RCTs cited by the Bagnall et al.

*They are old, ranging from 1992 to 2001. Bagnall reviewed much the same papers in 2001.*

*They are mostly UK based, "Anglocentric" according to one New Zealand authority.*

*They are small in number.*

*They have small sample sizes.*

*They have questionable methodology.*

*The sole multicentre trial had excessive drop outs in each treatment arm.*

*The sole 5-year follow-up trial suffered from corrupt data, and its results may be meaningless.*

### 1.3 Inadequate foundation for definitive guidelines.

*By itself the RCT evidence base is not an adequate foundation for definitive guidelines. If NICE base their deliberations only on the Bagnall systematic review, then they will make binding recommendations for tens of thousands of UK patients on an evidence base totalling only 777 patients where there was high drop out from treatments, averaging 18.5%, and where there was little lasting benefit at 5-year follow-up.*

#### Section 2: Concerns about RCTS on GET and CBT

*In this 2005 review Bagnall et al. reviewed RCTs by Fulcher, Powell, Wearden, Deale (1 & 2), Sharpe, Prins and Lloyd. In 2001 another Bagnall team jointly compiled a systematic review of the same RCTs, which was published in JAMA.*

*Negative comments on the RCTs, published by Bagnall and American co-authors in 2001, are listed below. For some inexplicable reason, the greater part of this negative comment has disappeared from the 2005 version. Considering that the same RCTs were scrutinised, and that Bagnall was a member of both teams, this is all the more puzzling. (These adverse comments by Bagnall et al refer to methodological inadequacy; study withdrawal; drop-out rates for CBT; drop-put rates for GET; unacceptability of treatments; reported improvements may be illusory; no objective evidence of improvement; little lasting benefit from CBT. All have disappeared from the updated 2005 review of the same studies, with no explanation. In both the 2001 and the 2005 update, two important issues were apparently undetected: (i) corrupted data and (ii) follow-up revealed relapse after CBT).*

Sections 3 and 4 record the concern of American, Australian, Canadian and New Zealand researchers and clinicians about CBT: the take home message is *“British psychiatric management of “CFS/ME” is a poorly-informed, counter-productive, parochial aberration”*.

Section 5 deals with publication bias, noting that Bagnall et al (2005) and Bagnall et al (2001) have markedly different approaches to the same data. In 2001, Bagnall et al suspected that most of the papers they reviewed suffered from publication bias, but in their 2005 update they confine their suspicion of bias to just one study.

This same section notes the way Wessely and Sharpe tailor their comments on “CFS/ME” to cater for different audiences:

Wessely in the UK:           *“substantial improvements in measures of fatigue and physical functioning”*  
(BMJ 2000:320:292-296)

Wessely in the USA:       *“modestly effective”; “neither approach is remotely curative”; “not the answer to CFS”* (JAMA 2001:286)

Sharpe in the UK:           *“the overall treatment effect was substantial”; “a return to normal functioning is possible in most cases”* (BMJ 1996:312:22-26)

Sharpe in the USA:       *“CBT is not a panacea”; “many, if not most, patients continue to complain of excess fatigue”* (Am J Med 1998:105: 3A)

The key message from Section 5 is:

- ***“UK research on CBT and GET may suffer from bias. NICE should not take the York Review team’s findings at face value”.***

Section 6 is entitled *“Imposed Top-Down Therapy Initiatives are Rejected by CFS/ME Patients”*.

This section addresses patient dissatisfaction; psychiatrists’ refusal to engage with patients; coercion of patients (known to mitigate acceptance of Guidelines); the wounding allegations of mental illness and the

permanent loss of trust in psychiatry: by falsely labelling CFS/ME patients as mentally ill, Wessely School psychiatrists have alienated patients from mental health professionals.

Section 6 also draws attention to the deceit perpetrated upon patients by Wessely: having announced an apparent “ceasefire” in the *Lancet* (12<sup>th</sup> January 2002:359:9301), patients discovered that Wessely was clandestinely endeavouring to reclassify ME/CFS as a mental disorder in the WHO Guide to Mental Health in Primary Care. It took intensive efforts by patients themselves for his attempt at reclassification to be thwarted by WHO Headquarters in Geneva and for the UK Department of Health to acknowledge that the correct WHO classification for ME/CFS remains neurological.

Section 7 addresses the evidence on counselling, and the key message is that CBT therapists are scarce, expensive, and will face resistance, whereas counselling is cheaper and more readily acceptable. The document notes: “*It may be relevant to note that Professor Wessely has an aversion to professional counsellors*” (BMJ 1996:313:158-160).

Section 8 addresses treatment choice and notes that UK patients are robbed of choice and consent, and that they are permitted only psychiatric interventions for their primary organic disorder.

Section 9 considers whether the authors of the updated York Review are guilty of research misconduct.

The Hooper/Reid document is unambiguous:

*“One remit of Bagnall et al. was to determine **“How effective and safe are interventions for the treatment and/or management of CFS/ME in adults and children?” (Question 3).***

*They have signally failed to address either issue in this heading.*

*We are left with a bald one-word assessment that GET is “promising”. The reviewers demonstrate no curiosity respecting high drop-out rates. There is no risk-benefit analysis. We are not told whether GET is safe.*

*For answers to this fundamental issue, we must look beyond the 2005 York review.*

### 9.2 United States.

*Dr. Leonard Jason does not share his British colleague's enthusiasm for GET:*

*“Our reluctance to endorse graded activity arises from our vastly different clinical experience in the United States”*

*“Our clinical experience suggests that Graded Activity/CBT for clients who do not exhibit fear-based avoidance may be counterproductive and trigger symptom flare-ups”*

*Dr. Jason is the author most cited by Bagnall et al. Their reference page lists 17 of his publications, an indication of his international stature as a researcher. When Bagnall et al. consult him so frequently, why did they fail to mention his reservations about GET?*

### 9.3 Canada.

*“Exercise programmes must be entered cautiously as clinical studies have indicated that symptoms worsened in approximately half of the ME/CFS patients.”*

*(Canadian National Guidelines).*

#### 9.4 Australia.

*"Many (CBT & GET) studies have significant refusal and drop-out rates, which may reflect on the acceptability of the treatment regimens."*

*(Australian National Guidelines).*

*Bagnall et al. list the Canadian and Australian guidelines among their references. Why then do they fail to discuss their contents?*

*The Australian guidelines express significant reservations about GET and CBT. Why are these concerns not reflected by Bagnall? The guidelines were endorsed by the Royal Australasian College of Physicians, subjected to a long period of public consultation, and published in the peer-reviewed Medical Journal of Australia. What possible exception could Bagnall et al. take to their comments on GET?*

#### 9.5 New Zealand.

*"GET may cause relapses and is thereby potentially harmful."*

*(New Zealand Guidance Group)*

#### 9.6 Eminent critical comment excluded.

*Bagnall et al. are assumed to be neutral assessors. They are expected to canvass and assess a wide variety of expert opinion, and assist their clients to a balanced judgment. But what in fact seems to have happened is that only positive comment on GET has been included. All negative comment, no matter how eminent the source, has been excluded.*

#### 9.7 Bagnall et al. suspend critical faculties.

*There are times when Bagnall et al. (2005) seem to suspend their critical faculties entirely. Referring to the multicentre Prins trial (on CBT), they say that this RCT "showed very high drop out rates of between 20 and 40%. Drop out rates were highest in the CBT group. Reasons for drop outs were not stated and no adverse effects from treatment were reported." (Reasons for drop out were in fact stated). They then make no further comment.*

*A review team charged with ascertaining treatment efficacy and safety might have shown more curiosity about a drop out rate of 40%. One reason for high refusal rates was reported explicitly in the body of the article. "Many CFS patients eagerly expect a medical solution for their complaints and are quite sceptical about psychological treatments", said the authors. Consumers had so little faith in the therapy that 99 (26% of those eligible) refused to enter the trial from the beginning. This pushed the overall refusal and drop out rate to 50.66%.*

#### 9.8 British reports on efficacy and adverse effects of GET.

*As for GET, again Bagnall et al. take a rose-tinted view. GET trials had a high drop out rate of 18%. We have that figure from Bagnall et al. (2001), but curiously Bagnall et al. (2005) omit mention of it. There are other examples of their creative approach to GET statistics. Referring to the Wearden GET trial, they state that "11 participants dropped out". Examination of tables elsewhere in the document reveals that in the treatment arm there were in fact 25 drop outs, an attrition rate of 36%.*

#### 9.9 Self-censorship.

*In their older JAMA systematic review, doubtless subject to rigorous American peer scrutiny, Bagnall et al. (2001) were more forthright on the implications of high withdrawal rates with GET and CBT:*

*"Dropout rates may be important indicators of the acceptability of an intervention."*

*"Where dropout rates are higher in the intervention group than in the control group it may be the case that there is something about the intervention that trial participants find unacceptable."*

*"When deciding what treatments should be given to patients it is important to take adverse effects, especially those which are so severe as to cause patients to discontinue treatment, into consideration."*

*Not only have these caveats disappeared from the 2005 version, but citation of the JAMA article in which they appeared has also been deleted. In 2001 Bagnall's work appeared in one of the world's most prestigious medical journals. But now she disowns it. What rationale could possibly underlie this astonishing act of self-censorship?*

#### 9.10 Improper External Influence.

*There are a number of intriguing hints that Bagnall et al. have been subjected to covert external influence:*

*On p. 28 they refer to "depression and fibromyalgia" as illnesses "related" to CFS. In fact, depression and CFS/ME have long been differentiated. But there is a well-known school of psychiatry in London which insists they are linked.*

*On p. 37 they assert that "graded activity is normally considered an integral part of CBT for CFS/ME." This is not the case, and prominent American researchers take a different approach.*

*But, as before, there is a school of psychiatry in London which promotes this characteristic view.*

*Bagnall first made the same gaffe in the pages of JAMA: describing a controlled trial by one of Jason's associates, Bagnall et al. (2001) remarked:*

*"The CBT used in the controlled trial differed from that used in the four RCTs, focusing more on limiting activities rather than trying to increase activity, and so it is questionable as to whether it should be classified as CBT."*

*This pejorative and uninformed comment betrayed an unfamiliarity with North American practice - and with the nature of CBT. Again, Bagnall et al. (2001) seem to have adopted the distinctive opinions of a familiar English psychiatrist.*

#### 9.11 Implications for York Centre for Reviews and Dissemination.

*It would be most unfortunate if a powerful outside influence has been able to impose his own concepts on a team of supposedly neutral reviewers.*

*The York Centre should not allow anything to put at question their independence, integrity, and authority.*

*Unfortunately there is abundant evidence that in 2005 Bagnall was prevailed upon to dilute or delete opinions she held in 2001.*

#### Key Messages for NICE:

***Internationally, a number of prominent researchers have strong reservations about GET.***

***Bagnall et al. have either failed to locate these references, or have failed to include them in their review.***

***Concealing evidence of adverse clinical events constitutes research misconduct.***

Section 10 notes that there are a number of disturbing features in the Bagnall et al (2005) review that forms the basis of the NICE Draft Guideline:

*(1) In confining themselves to RCTs and CTs, the authors have in fact committed themselves to just a small number of papers, of some antiquity and of questionable scientific validity, the bulk of them originating in Great Britain, and all restricted to one treatment option and its associated philosophy. They have denied themselves a much larger archive of expert opinion, most of it in the USA, with some in Australia, Canada and New Zealand.*

*The authors may have been restricted by their remit. But if that is the case, then the inadequacies of their brief have now been exposed.*

*Be that as it may, it was still the duty of Bagnall et al. to point out how small and dated the RCT evidence base was, and to draw attention fully to the internal limitations of each paper, and conclusions that might be drawn from them.*

*(2) In 2001 another Bagnall et al. review team surveyed the same corpus of research. As was required of them, they commented in detail both positively and negatively on each paper, and its clinical implications.*

*It is blatant that in the 2005 version, all positive comment on the GET and CBT RCTs has been retained, and much negative comment has been deleted.*

*(3) In the 2001 Bagnall review, counselling was mentioned as a viable treatment option. In the 2005 version, an important reference to a counselling RCT has been omitted.*

*(4) Bagnall et al. (2005) were asked to establish the safety of potential treatments. They almost completely failed to mention the known adverse effects of GET.*

#### 10.2 One lobby benefits.

*All of these curious omissions and restrictions become more coherent if one considers the possibility that they are calculated to benefit the interests of one interested party - the psychiatric lobby.*

*The defects of the British CFS/ME research base have been widely discussed internationally, and are admitted by its own authors. But in 2005, Bagnall et al. gave it a clean bill of health. Eminent international criticism of therapies endorsed by the UK psychiatric lobby has been excluded. All mention of counselling - a viable cheaper alternative to psychiatric treatments - has vanished.*

*If a medical researcher concealed negative findings, or failed to alert colleagues to adverse events, this would constitute research misconduct. What are we to think of the authors of a systematic review making similar omissions?*

#### 10.3 Déjà vu.

*In 1996 the current Editor of the "Lancet" made unfavourable comment on dubious tactics used by psychiatrists in formulating the Royal Colleges' report on CFS/ME.*

*"The authors of the report included 8 psychiatrists out of a membership of 16."*

*"The College representatives interpreted every piece of evidence pointing to a biological cause - for instance a virus - in a negative light."*

*"The evidence shows a total failure of antidepressants in these patients. Surprisingly, though, the Royal Colleges 'endorse the use of antidepressants' "*

*"The last word of an American review on chronic fatigue is "compassion". One struggles to find this word in the UK report."*

*"Medical paternalism seems alive and well in Britain today".<sup>i</sup>*

*Ten years on, nothing has changed for the CFS/ME community in the UK.*

*The same individual doctors, displaying the same attitudes, are making the same mistakes, with the same negative consequences for ME/CFS patients. A decade has been wasted, and they are hell-bent on wasting another.*

**Key Message:** *NICE should beware of repeating the debacles of 1996 & 2002. They should treat Section 3 of the Bagnall et al. (2005) systematic review with extreme caution.*

As mentioned above, in order to avoid a charge of supporting a pre-determined agenda, it is imperative that the NICE Guideline Development Group pays due heed to the Hooper/Reid analysis.

**Problem: Anomalies in the updated Review by Chambers and Bagnall et al in the JRSM**

Other considerations arising from the latest JRSM review by Chambers and Bagnall et al that forms the basis of the Draft Guideline recommendations (JRSM 2006:99:506-520) include:

*"Additional references were sought by contact with experts"* (the "experts" are not identified but could not have included experts in ME/CFS such as Professor Nancy Klimas, Professor Lenny Jason or Professor Anthony Komaroff)

*"Graded exercise and cognitive behaviour therapy appeared to reduce symptoms"* (if an intervention only "appears" to reduce symptoms, its efficacy remains uncertain)

*"The aetiology of CFS/ME remains uncertain"* (in which case it has not been conclusively shown to be somatisation disorder)

*"The most widely-used (case definitions) being the US CDC and the UK Oxford criteria"* (the Oxford criteria are not widely used, being used only by the handful of UK psychiatrists who formulated them)

*"Study design – only randomised or controlled clinical trials were eligible for inclusion"* (the Americans have concentrated on areas such as epidemiology and aetiology, their logic being that a disorder cannot be cured until it is (i) defined (ii) its cause is understood. In the UK, it is considered unnecessary to address these issues before imposing psychiatric management regimes)

*"70 (items) met the inclusion criteria for the review"* (of the 70 selected, only a few refer to CBT and GET)

*"No severely affected patients were included in the studies of GET"* (thus the NICE recommendations cannot be applied to the severely affected)

*"There is limited evidence about adverse effects associated with behavioural interventions"* (All surveys of ME/CFS patients consistently report a high percentage of patients are made worse by GET, yet the published trials never mention this: are they failing to report adverse events?)

*"The reasons for withdrawal (from the study) were not reported"* (given the high withdrawal rates, not to investigate or report the cause seems a curious omission. Were participants even asked for the reasons?)

*"A number of RCTs suggest that behavioural interventions may reduce symptoms of people with CFS/ME"* (the use of the words "suggest" and "may" is noted)

*“Publication bias needs to be considered and may be present in the CFS/ME literature”* (publication bias has been demonstrated – see above for the way in which withdrawal rates are treated)

*“Heterogeneity made it impossible to combine studies by meta-analysis”* (this might be interpreted as meaning that the evidence base is poor and that no reliable conclusions can be drawn from it; instead, the authors assiduously create the impression that they are recommending well-researched, effective treatments)

*“Development of objective outcome measures remain largely unmet goals”* (the only proof of effective treatment is objective evidence of increased productivity in the home or at work)

*“There is also a lack of long-term follow-up data for most interventions, although a five-year follow-up of the RCT of CBT by Deale and colleagues showed maintained benefit of the intervention for several outcomes”* (for most outcome measures, Deale and Wessely demonstrated no maintained benefit at five years and Chambers and Bagnall are thus misleading their readers. The study actually found no differences in physical functioning, fatigue, general health, symptoms, relapses, or the proportion of participants who no longer met “CFS” criteria)

*“The studies included in our review show a lack of uniformity in terms of case definitions (and) it is therefore difficult to assess the generalizability of the findings of many of these studies”* (the question arises as to why such firm recommendations for CBT and GET have been made on the basis of such a defective body of evidence)

*“The recommendations for children and young people were largely developed by consensus”* (despite a near-total lack of evidence-base, NICE still recommends CBT and GET for these ages groups)

*“Future trials should be designed to collect long-term data on effectiveness and adverse events”* (which means that the present “evidence base” has failed in these crucial areas, yet the NICE Draft Guideline stipulates on page 181 that CBT should be offered to “all adults and children with CFS/ME”)

*“A number of issues may limit the availability of effective interventions for CFS/ME. Behavioural interventions require the participation of trained therapists and this may raise issues both of cost and of the availability of personnel”* (so whilst recommending CBT, it is admitted that its own recommendation cannot be implemented. On the issue of costs involved in CBT, Tony Johnson, Deputy Director of the MRC Biostatistics Unit at Cambridge, is unequivocal that “a major limitation is its cost” -- see Clinical Trials in Psychiatry: background and statistical perspective. T Johnson. Statistical Methods in Medical Research 1998;7:209-234)

*“The project was funded by the National Institute for Health and Clinical Excellence. The funding source had no influence on the interpretation of the data”* (given the different interpretation of the same evidence in the updated review from that in the original 2001 review, and given the known aims and influence of members of the NICE GDG Advisory Panel, there are those in the ME community who find this assurance implausible).

### **Problem: The myth of the biopsychosocial model**

As Dr Weir informed the 4<sup>th</sup> Oral Evidence Session on 10<sup>th</sup> July 2006 of the Gibson Parliamentary Inquiry into ME/CFS, there is a long history of the biopsychosocial model of disease being discarded once the evidence is obtained that disproves it – the psychosocial model is a default posture which some people embrace when they do not know what is going on or do not understand the science.

In “The myth of the biopsychosocial model”, psychiatrist Niall McLaren exposes once and for all the myth upon which the so-called “biopsychosocial” model of illness so favoured by Wessely School psychiatrists depends (Australian and New Zealand Journal of Psychiatry, March 2006;40:277).

McLaren points out that psychiatrists have made a mistake in crediting Engel as author of the biopsychosocial model of disease, when Engel did not write any such model. All Engel did was to plead for “a more considerate type of medicine”.

McLaren notes that psychiatry seems to have mistaken Engel’s call for a more considerate model with an assumed existence of such a model. To quote McLaren: “Nothing (Engel) wrote constituted a coherent series of propositions that generated testable predictions relating to the unseen mechanisms by which mind and body interact, ie. a scientific model for psychiatry”.

McLaren presented a paper entitled “The biopsychosocial model and scientific fraud” at the annual congress of the Royal Australian and New Zealand College of Psychiatrists in May 2004, which is available from the author at Northern Psychiatric Services, Darwin, Northern Territory, Australia.

Pertinent to the intransigent refusal of Wessely et al to heed the advances of modern medicine to the extent that they appear to remain tethered by an obsession to equate ME/CFS with neurasthenia (claiming it as a biopsychosocial disorder), no matter what the quality and quantity of contrary evidence, McLaren points out: *“preconception, bias and prejudice may determine what we see. In turn, what we see often serves to inform what we believe. By this means, science can slip into self-justification”* and McLaren observes how an individual’s need to believe something determines what he sees.

In 1998 McLaren showed that the biopsychosocial model was a mirage (ref: A critical review of the biopsychosocial model. Australian and New Zealand Journal of Psychiatry 1998:32:8692) and in his 2002 paper he showed how reliance upon such a non-existent model is nothing but illusion (ref: The myth of the biopsychosocial model. Australian and New Zealand Journal of Psychiatry 2002:36:5:701).

McLaren notes that some psychiatrists repeatedly invoke Engel’s biopsychosocial “model” and that they accept without demur (or references) that it is a reality, when nothing could be further from the truth.

He asks: *“Why do these intelligent people (ie. psychiatrists), their reviewers, their editors and, above all, their readers, continue to pay homage to something that does not exist?”*

Wessely School psychiatrists, however, are certain that their own beliefs and their reliance upon the biopsychosocial model are right. They have built their careers upon it, so they must be right.

To quote McLaren: *“A Medline search of the word ‘biopsychosocial’ yielded nearly four hundred references, not one of them critical. Indeed, the Journal of Psychosomatics now uses the terms ‘psychosomatic’ and ‘biopsychosocial’ interchangeably. In its present form (it) is so seriously flawed that its continued use in psychiatry is not justified. **In a word, the officially-endorsed biopsychosocial model is pure humbug because it does not exist.** Psychiatrists have long attempted to convince the general public, the funding bodies and, most significantly, the younger generations of students and psychiatrists that the profession has articulated a rational model which grants it special and unique knowledge of the aetiology of mental disorder. **It is my view that we are guilty of the grossest intellectual neglect or of outright scientific fraud.** I believe there is a serious risk psychiatry as we know it will no longer exist in as little as fifteen years”* (ref: The Biopsychosocial Model and Scientific Fraud. N McLaren. May 2004; available from the author at [jockmcl@octa4.net.au](mailto:jockmcl@octa4.net.au) ).

McLaren is not the only psychiatrist to raise concerns about the lack of attention by certain psychiatrists to causal research. Per Dalen, a Professor of Psychiatry in Sweden, comments as follows:

*“There is a theme that not only survives inside the medical culture in spite of an almost total lack of scientific support, but actually thrives there due to the support given by leading circles. This is the use of psychological theories as a means of reclassifying bodily symptoms as mental problems in cases where conventional medicine is at a loss for an explanation, particularly patients with so-called new diagnoses”.*

*“Since I am a psychiatrist, I have for a long time been intrigued by the extraordinary use of psychiatric causal explanations for illnesses that not only go with predominantly somatic symptoms, but also lack any basic similarity to known mental disorders”.*

*“Research into causes is making no progress in important areas: there is no real research into causes”.*

*“Today it is common to talk about somatization as if this were something that is really understood. It is supposed to be a condition with psychological causes, where looking for somatic explanations is useless (and) should be avoided, because it may make the patient even more preoccupied with bodily complaints”.*

*“(Somatization) is hardly a natural category, but was pieced together by stretching earlier assumptions. The result is a rather pretentious thing”.*

***“It must be noted that there is no proof that it is justified to apply the label of somatization to such conditions as chronic fatigue syndrome and several more illnesses that established medicine has so far failed to explain scientifically”.***

*“The boundaries of somatization largely coincide with the current limits of received medical knowledge”.*

*“Only a few decades ago, borreliosis was a “non-existent” disease, and many patients were then regarded as psychosomatic cases, just because of medical ignorance. It didn’t matter that they often had acutely inflamed joints, as well as other indisputably somatic symptoms”.*

*“Many doctors would never let themselves be caught with woolly ideas about the possible causes of cancer, multiple sclerosis or cardiovascular diseases. But just mention the word somatization and they will feel free to engage in uncritical speculation”.*

***“Don’t hesitate to ask questions about the scientific evidence behind this talk about somatization. Be persistent, because a diagnosis of somatization is definitely not an innocuous label. It will close various doors and lead (to) treatments that usually get you nowhere. But be prepared: ‘resistance’ against the diagnosis will be taken as confirmation that it is correct”.***

*As a psychiatrist, I have to say that it is distressing how unconcernedly certain colleagues are allowing interests other than those of the patients to take precedence, (but) only a minority of psychiatrists are involved”.*

*“It is useful for you to make plain that you will not be impressed by specious arguments”.*

(For Per Dalen’s 38 page document, see [http://www.art-bin.com/art/dalen\\_en.html](http://www.art-bin.com/art/dalen_en.html) ).

Members of the NICE Guideline Development Group would do well to take due heed.

### **Problem: Flawed process**

It is clear that both the updated Review carried out by the York team and the Draft Guideline that relies upon that Review are characterised by serious flaws, misapprehensions and inadequacies.

Concerns have been raised as to whether Bagnall et al are open to a charge of research misconduct because the Systematic Review seemed to have research misconduct as one of its hallmarks: information was skewed or even deleted in order to cast CBT/GET in a good light.

Despite many admitted flaws in their “evidence-base”, the York team and the NICE GDG still make confident recommendations on treatment.

They confuse ME/CFS with psychiatric (behavioural) disorder.

They entirely ignore the abundant evidence of organic pathoaetiology in ME/CFS.

They place undue reliance on the Oxford criteria, which specifically include psychiatric disorder but specifically exclude ME (which is classified by the WHO as a neurological disease).

They focus on the single symptom of “fatigue”, whilst ignoring the cardinal symptoms of ME/CFS that other researchers have found differentiate ME/CFS patients from other states of chronic fatigue, including nausea, shortness of breath, palpitations, chest pain, dizziness, muscle weakness, parasthesiae, pain in multiple joints, night sweats, blurred vision, allergies, rashes, hair loss, mouth ulcers, frequency of micturition with nocturia and sensitivity to alcohol. For example, muscle weakness was found in 93% and arthralgias in 73% in one study (see Improving the diagnostic criteria and procedures for chronic fatigue syndrome. C. King, L. Jason. Biological Psychology 2005:68:87-106).

The belief that CBT and GET are the only interventions shown to be effective is unsustainable (the evidence is weak; the populations studied were selected using different case definitions; the population was heterogeneous, which means they should not be included in the same analysis and the authors advocate their own hypothesis for which there is no scientific basis).

NICE’s own criteria dictate that their recommendations should be realistic, affordable and acceptable to the client group. This Draft fails on all three counts: it is unrealistic to recommend CBT/GET when there is a national shortage of CBT therapists (why recommend CBT when the therapists do not exist and would cost a fortune to recruit and train?) and CBT/GET has already been shown by the national ME charities and by international studies to be ineffective and unacceptable to the targeted patients and in many cases to have resulted in significant deterioration.

The Draft Guideline stresses the need to supply patients with correct evidence-based information but singularly fails to do so: it supplies “evidence” that is carefully selected to support its own agenda but which has been publicly shown to be biased.

The only worthwhile “clinically objective outcome measures” are: is the patient cured? Are they restored to health? Can they return to work? The answer to all these questions is a resounding no.

The NICE Draft Guideline seems to be proclaiming that biomedical evidence that has been scientifically proven should be ignored in favour of nothing more than the Wessely School’s own selective ideology.

As it stands, the Draft Guideline will do nothing whatever to dispel the misapprehension that ME/CFS is a behavioural disorder. In this, it does a grave disservice both to medical science itself and above all, to countless desperately sick people who for too long have been abused by certain influential members of the medical profession and those who unquestioningly accept their dogma.

Given the intimation mentioned above that there will be no major changes to the Draft Guideline, it is a matter of grave concern that on 16<sup>th</sup> November 2005 Professor Anthony Pinching, Chair of the NHS “CFS/ME” Service Investment Steering Group, informed the All Party Parliamentary Group on ME that “Services will implement the NICE guidelines after these are announced in April 2007”.

**Problem: More misinformation that supports the NICE Draft Guideline**

Reference has been made above to the new Centres that have been set up specifically to deliver CBT/GET for those with a diagnosis of “CFS/ME”; reference has also been made to the job advertisement for behavioural therapists at the Centre of which a member of the NICE Guideline Development Group (Dr Fred Nye) is the Clinical Champion.

Dr Nye's Centre was not alone in placing such damaging advertisements: the one placed by Epsom and St Helier NHS Trust was equally inexcusable:

*"Patients referred to the service may have difficulty accepting and be hostile to the rationale for adopting a cognitive-behavioural approach to the management of their fatigue"*

*"Engaging these patients requires skilled multidisciplinary management"*

*"The CFS Service aims to extend services to those patients who have challenging presentations, interpersonal difficulties and mental health problems"*

*"Input will be based on the appropriate use of data from a variety of sources, including psychological tests and semi-structured interviews with clients, family members and others involved in the client's care"*

*"This involves utilising a range of skills including delivering complex concepts to patients; managing challenging group dynamics; managing and containing patients in a highly sensitive manner (and) implementing a range of psychological interventions"*

*"Where patients present with severe mental health problems, (the therapist will) liaise with mental health services to enable effective case management"* (Reference HJUK/ZP/238; closing date 18<sup>th</sup> March 2005).

Another illustration comes from the CFS Service at Sutton, Surrey, which stated that the position was for a clinical psychologist to work with patients ***"for whom medical intervention is no longer appropriate"***.

If such a programme were to be provided as the first line of management for (and imposed upon) people with multiple sclerosis or Parkinson's disease or motor neurone disease or cancer, there would rightly be an outcry.

#### Official endorsement of the new centres for "CFS/ME"

To the surprise of few in the ME community, a (currently unavailable) Press Release to announce the launch of the "CFS/ME Programme Report" stated:

*"Friday 15<sup>th</sup> September 2006 sees the launch of the CFS/ME Service Investment Programme Report – 'Enabling People'. This describes the first two years of this ongoing programme to implement multi-disciplinary services in the NHS in England to support patients who have this disabling condition"*

*"The tremendously successful move to set up new services for people with CFS/ME has come about through initial investment by Government of £8.5 million over two years 2004 – 2006"*

*"The Report outlines some of the creative and contemporary models of clinical care and support that have been established across the country"*

*"The programme has fulfilled its aims and has created a new national multi-professional team to provide accessible diagnosis and care for the re-enablement of patients with CFS/ME"*

*"Chairman and lead clinician for the programme is Professor Anthony Pinching, a clinical immunologist and Associate Dean for Cornwall at the Peninsula Medical School. He commented: 'The Programme is all about enablement – enabling patients, enabling carers, enabling healthcare professionals: each enabling each other. By creating a fresh, multi-professional and national collaborative team for CFS/ME patients, we now have a framework on which to base enhanced awareness and education' "*

*"Chief Medical Officer Sir Liam Donaldson said: 'I am very grateful to the way in which Professor Pinching has led this programme. The Government's £8.5 million programme to improve services for people with chronic fatigue syndrome/ME has been a tremendous success and has fulfilled its aim to*

*establish clinical networks of expertise. While 65% of the country now has a specialist CFS/ME service, we are keen that the rest of the country follows suit' ”.*

*“Professor John Tooke, Dean of the Peninsula Medical School commented: ‘The Peninsula Medical School is proud to have been the host for this important initiative and commends the achievement of Professor Pinching and his colleagues across England for developing services for such a disabling condition. The teamwork and patient-centred approach chimes closely with the philosophy of the Peninsula Medical School’ ”.*

The phrase “patient-centred approach” has a particularly hollow ring, because these glowing endorsements contrast sharply with the experience of patients who have attended such Centres which, in the real world, have been little short of disastrous for those with ME/CFS. It must be noted that these clinics come under “mental health” administration, even though ME/CFS is not a mental disorder.

For full details of patients’ adverse and often harrowing experiences at the new Centres, see the information collected by Research into ME (RiME) in their numerous newsletters at [www.erythos.com/RiME](http://www.erythos.com/RiME)

Some examples include:

- “Running a clinic using a purely psychosocial approach for people with a neurological illness is wholly unacceptable and no other group of neurologically ill people would put up with it. The treatments offered at these clinics are based on flawed research”
- “ME is treated as a psychological problem”
- “Everything about the Manchester Centre suggests a stitch-up. The leading figure is a psychiatrist (who) promotes a psychosocial model. Once again, ME patients are neglected and sidelined”
- “I fear for the welfare of all ME/CFS patients who are being sent to these Centres. Sufferers (report) being told during CBT sessions they have a ‘fear of activity’ and ‘motivation problems’ (which) is making people worse and in some cases pushing people over the edge”.

In the Press Release Professor Pinching refers to “CFS/ME” as a ‘beastly illness’, but the UK ME community knows that Pinching has a troubling track record in relation to ME/CFS in at least three significant areas:

- in 1989 the Royal College of Physicians agreed to produce a Report that was designed to discredit alternative and complementary medicine approaches to the treatment of allergies and hypersensitivities (which are commonly seen in ME/CFS). Pinching, then at Barts in London, was on the committee that produced this Report. By the autumn of 1991, the Report committee had produced a first draft (Allergy: Conventional and Alternative Concepts). A leading member of HealthWatch (the campaigning organisation to which both Simon Wessely and Charles Shepherd belong that is known for its anti-complementary medicine stance) illegally used the draft Report as evidence against a plaintiff in a High Court action even though on 18<sup>th</sup> October 1991 solicitors for the Royal College of Physicians (Field Fisher Waterhouse) had written a letter forbidding use of the draft report, saying: “The College is not in a position to endorse the contents or conclusions of the draft”. The draft Report that Pinching helped formulate was never released: it came under massive critical review and had to be re-written, as Fellows of the Royal College described it as “wildly inaccurate” and misleading. However, the Judge accepted the unauthorised draft, on the strength of which he found against the Plaintiff
- During his time as Deputy Chair of the Chief Medical Officer’s Working Group, Pinching published an article that effectively pre-empted the conclusions of the CMO’s Working Group Report, ie. that the treatment of choice for “CFS/ME” was to be CBT/GET. Pinching stated (i) that CFS was “*not related to ongoing exertion*” (ii) that the Oxford criteria were “*too narrow*” (the

Oxford criteria being the case definition of “CFS” that expressly includes psychiatric fatigue but expressly excludes neurological disease); (iii) that “*over-investigation can be counterproductive to the management of these patients, causing them to seek abnormal test results to validate their illness*”; (iv) that “*it is helpful to establish with the patient a way of thinking about the illness*”; (v) that “*the benefits of graded exercise have been shown by randomised controlled trials*”; (vi) that “*complementary therapists reinforce unhelpful illness beliefs*” and (vii) “*the essence of treatment is activity management and graded rehabilitation*” (Chronic Fatigue Syndrome. Anthony J Pinching. Prescribers’ Journal 2000:40:2:99-196)

- Also during his tenure of the Deputy Chairmanship of the CMO’s Working Group Report, Pinching asserted --- in defiance of ever-increasing calls from international experts in ME/CFS for urgent sub-grouping of the heterogeneous label “CFS” – that there was no need for such sub-grouping, which he claimed was nothing more than “semantics” (see CMO’s Report, Annex 4). For illustrations of the call by international experts for sub-grouping, see [www.meactionuk.org.uk/Subgroups.htm](http://www.meactionuk.org.uk/Subgroups.htm)

Despite – or possibly because of – this track record, Pinching was appointed Chairman of the CFS/ME Service Implementation Steering Group for the new Centres, as well as being Lead Adviser on CFS/ME to the Department of Health.

In the NICE Draft Guideline, Pinching is singled out for special acknowledgement. To those of a sceptical disposition, this would appear to be history repeating itself, especially given Pinching’s known preference for CBT/GET in “CFS”. This prediction is supported not only by his confident prophecy in November 2005 to the All Party Parliamentary Group on ME concerning the implementation of the NICE Guideline, but also by his oral submission on 10<sup>th</sup> July 2006 to the Gibson Parliamentary Inquiry on ME/CFS. From the notes taken by those who attended that session (and from their personal reports), Pinching openly and confidently said that he promotes the NICE Guideline and fully supports the biopsychosocial model and the implementation of CBT/GET. This confidence suggests prior knowledge of the outcome of the final Guideline. It was reported that Pinching also emphasised the need to make sure the new NHS services for “CFS/ME” continue to receive on-going funding, and said that the NICE Guideline (due in April 2007) would have an effect on how the Centres “manage” CFS/ME patients, ie. that the Centres would be needed to implement the NICE Guideline. It was reported that Pinching was very proud of the Centres and said that what was now needed was to extend and strengthen the current service by increasing patient through-put, which does not auger well for those with ME/CFS.

### **Comments on specific statements in the Draft Guideline**

#### Executive Summary and Recommendations

Page 21, lines 7/8: “*The Guideline Development Group developed this guideline with the aim of increasing recognition of CFS/ME*”

“CFS/ME” is not the same disorder as ICD-10 ME/CFS (and as defined in the Canadian criteria)

Page 22, lines 4 + 8: “*To facilitate shared decision-making the healthcare professional should provide information on the aetiology, nature, course and approaches towards CFS/ME*”

The Draft Guideline fails to provide any information on the biomedical anomalies that have been demonstrated in ME/CFS and it fails to mention that ME/CFS is classified in the WHO ICD-10 as a neurological disorder. These are significant omissions, and are exactly the same omissions as in the “independent” Report by the Chief Medical Officer’s Working Group in 2002

### Clinical Care Pathways

Page 28, line 11: *“Patient experience suggests that some of these interventions may be harmful and/or not effective”*

Despite acknowledging their harm and ineffectiveness, the Draft Guideline nevertheless promotes these interventions and stipulates (on page 181) that they should be offered to ALL adults and children with “CFS/ME”

Page 29, line 1: *“We need reliable information on prevalence and incidence to plan services”*

What is needed is that due attention be paid to the Canadian definition

### Development of the Guideline

Page 30, line 8: *“The guideline provides recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness”*

This has been shown to be profoundly untrue

Page 31, line 25: *“clinical case definition”*

The Draft Guideline fails to inform its clients that there are now 10 case definitions for ME/CFS and that the Oxford criteria (on which the Guideline relies) specifically excludes those with neurological disorder but specifically includes those with psychiatric disorder, or that the most accurate and informed case definition is the Canadian definition

### Introduction to CFS/ME (or encephalopathy)

“Myalgic encephalopathy” is not a classified or recognised disorder

Page 35, lines 5/6/7

Even though purporting to include “ME”, the cardinal feature of the disorder is omitted

Page 35, line 15: *“the MRC has made research on CFS/ME a priority”*

On the contrary, the MRC has not made research on ME/CFS a priority but has focused on funding yet more research into behavioural disorders that disingenuously claim to be studying ME

Page 36, line 11: *the Oxford criteria*

The Oxford criteria are not “frequently used”: they have been shown to have no predictive validity; they are used by only a handful of UK psychiatrists and have been rejected by world experts on the disorder

### Identifying the evidence

Page 43, line 21/22: *“The GDG recognised that the surveys from self selected respondents are subject to bias”*

The surveys are subject to no more bias than the cohorts selected by Wessely School psychiatrists for inclusion in their own studies

The experience of people with CFS/ME

Pages 55 - 76

The experiences of people with ME/CFS are consistently disregarded: how could any rational person believe that such profound illness as depicted in these pages should not be appropriately investigated and that the first line management approach for such patients should be behavioural modification?

General principals of care

Page 79, line 5: *“people with CFS should be able to access accurate information”*

Indeed they should, but the Guideline fails to provide accurate information about ME/CFS and provides only “evidence” that has been shown to be biased and incorrect

Support

Page 82, line 11/12: *“people with CFS/ME should have the opportunity to make informed decision about their care”*

Indeed so, but the Guideline pays lip-service only to this ideal, stating on page 181 that all adults and children with “CFS/ME” are to be offered CBT/GET

Making a diagnosis of CFS/ME

Page 88, line 5: *“Reaching a diagnosis can be a particular problem”*

As noted above on page 9 above, according to Professor Rachel Jenkins, Principal Medical Officer, Department of Health and herself a psychiatrist, this is not necessarily so. It will be recalled that in 1991 she stated: *“Once one is familiar with (the disorder), such patients are in practice not too difficult to differentiate from those with true psychiatric illness such as depressive illnesses, anxiety, hypochondriasis or hysteria. The physical symptoms should be an aid to diagnosis, although they may be wrongly attributed to primary psychological illness unless care is taken in eliciting them”* (Assessment and Diagnosis of ME in the Psychiatric Clinic. Rachel Jenkins. BMB 1991:47:4:241-246)

Further, correct diagnosis would be less difficult if the international research evidence were to be made available to UK physicians in the UK medical journals instead of being deliberately suppressed, dismissed and misrepresented by the psychiatric lobby (as has been shown to be the case for the last two decades).

Page 88, line 18: *“CFS/ME cannot be diagnosed by any test currently available”*

That may be true for “CFS/ME” but it is not true for ME/CFS: although there is as yet no single, definitive and specific test, there is a recognised pattern of reproducible abnormality on the appropriate testing that, if positive, is virtually diagnostic

Page 90 (in box): *“Evidence Statements: there is limited evidence for a wide range of risk factors including higher social class in childhood”*

This is untrue: there is ample published evidence that ME/CFS affects all social classes

Page 105 (box): *“The following should be regarded as ‘red flags’, indicating suspicion of serious underlying pathology: abnormal neurological signs (and) features of cardiovascular problems”*

There is abundant published evidence of substantial neurological deficit in the ME/CFS literature. Both neurological signs and cardiovascular abnormalities are well-documented features of ME/CFS and the

Draft Guideline acknowledges on page 112, lines 2/3/4 that the Canadian definition requires such features to be present

Page 105 (box): *“before diagnosis of CFS/ME, assessment of mental health should be carried out”*

ME/CFS is just as much a physical disorder as cancer, lupus or multiple sclerosis, in none of which is a mental health assessment obligatory before diagnosis, so why is there special pleading for ME/CFS?

Page 124 (box): *“some will recover fully”*

This is misleading, as the statistics show that only 4% had full remission (not recovery) at 24 months (US CDC statistics)

Page 126, line 1: *“Spatial disorientation is not generally characteristic of CFS/ME and is indicative of brain damage”*

Spatial disorientation is documented in the ME/CFS literature: see, for example:

- Neuropsychological Deficits in CFS. Sheila Bastien. CFIDS Chronicle Fall 1989:24-26 (abnormalities consistent with organic brain syndrome)
- Alteration of spatial-temporal parameters of gait in CFS. Saggini R et al. J Neurol Sci 1998:154:1:18-25 (abnormalities consistent with involvement of the central nervous system)
- Patterns of Neuropsychological Abnormalities and Cognitive Impairment in Adults and Children. Sheila Bastien. In: the Clinical and Scientific Basis of ME/CFS; ed. BM Hyde, J Levy and Paul Levine; pub. The Nightingale Research Foundation, Ottawa, 1992: 453-460
- Neuropsychological Function in Patients with Chronic Fatigue Syndrome, Multiple Sclerosis and Depression. Ella Daly, Anthony Komaroff et al. Applied Neuropsychology 2001:8(1):12-22 (spatial abnormalities consistent with brain alteration in ME/CFS)

#### A Conceptual Framework

Page 133, line 16: *“There is little understanding of the nature of the disease”*

This is an astonishing statement, as there is a significant body of scientific literature that documents the multi-system, multi-organ dysfunction that over the last 50 years has been demonstrated in ME/CFS (for example, the vascular abnormalities that have demonstrated a novel finding not seen in any other known disorder)

Page 133, line 24/ 25: *“there are no objective abnormalities to account for the illness experienced”*

This is untrue: there are numerous indisputable abnormalities, but these are seen only on appropriate testing, not on basic screening (which is the only permitted level of investigation on ME/CFS patients in the UK NHS)

Page 134, lines 14 – 16: *“CFS has been described as part of a broader condition that includes a range of disorders including fibromyalgia, irritable bowel syndrome....”*

There is no doubt that this statement is here intended to refer to somatisation disorder but there is no credible evidence to support such an assertion: it is singularly unscientific and is merely the belief of the Wessely School psychiatrists. There is, however, a school of thought that believes such disorders may all be metabolic or neuro-immune in origin.

The compilers of the NICE Draft Guideline appear ignorant of the scientific evidence, for example:

there are significant differences between laboratory findings in ME/CFS and FM, and of foremost significance is the fact that whilst ME/CFS is classified in the ICD-10 as a neurological disorder at G93.3, fibromyalgia is classified as a distinct entity in the ICD-10 at M79.0 under Soft Tissue Disorders. It is not permitted for the same condition to be classified to more than one rubric, since ICD categories are mutually exclusive, as confirmed in writing by the World Health Organisation itself.

In 1994, the British Medical Journal published information from Dr Darrel Ho-Yen, a well-known and respected virologist and researcher into ME, who stated the following: “The distribution and number of tender points in fibromyalgia are different from the chronic fatigue syndrome, **and the management of the two conditions is different. Patients with (ME/CFS) should be advised not to increase their activities gradually until they feel 80% of normal, whereas patients with fibromyalgia may benefit from a regime of increasing activity**” (BMJ 1994:309:1515).

It is a matter of record that Whiting and Bagnall et al expressly excluded fibromyalgia studies from the systematic review of the literature that was commissioned by the Policy Research Programme of the Department of Health and carried out by the Centre for Reviews and Dissemination at the University of York for the CMO’s Working Group on CFS. The systematic review is unequivocal: “**Studies including patients with fibromyalgia were not selected for the review**” (see Interventions for the Treatment and Management of Chronic Fatigue Syndrome. Penny Whiting, Anne-Marie Bagnall et al. *JAMA* 2001;286:11:1360-1368).

The literature itself is quite clear that up to 70% of those with ME/CFS have *concurrent* FM, and those who have both FM *and* ME/CFS have worse physical functioning than those who have ME/CFS alone.

Fibromyalgia has been documented for the last 150 years and has a uniform set of symptoms and signs that can be readily distinguished from other causes of musculo-skeletal pain (see Fibromyalgia and Related Syndromes. DL Goldenberg. In: Rheumatology. Ed. Klipper & Drieppe, 2<sup>nd</sup> edition 1998).

In his Update of August 2003 (Improving Services for Patients), the UK Chief Medical Officer referred to fibromyalgia as a discrete medical entity.

The literature is unambiguous about the distinctions between ME/CFS and FM

1991: in spite of some overlap, FM and ME/CFS do not represent the same syndrome. (Primary fibromyalgia and the chronic fatigue syndrome. AJ Wysenbeek et al *Rheumatology Int* 1991;10:227-229)

1996: “*fibromyalgia appears to represent an additional burden of suffering amongst those with (ME)CFS*” (Fibromyalgia and Chronic Fatigue Syndrome – similarities and differences. Dedra Buchwald and Deborah Garrity. *Rheum Dis Clin N Am* 1996;22:2:219-243)

1997: levels of somatomedin C are lower in FM patients but higher in ME/CFS patients (Somatomedin C (insulin-like growth factor) levels in patients with CFS. AL Bennett, AL Komaroff et al. *J psychiat Res* 1997;31:1:91-96)

1998: “*recent studies suggest that (co-existent FM and (ME)CFS) may bode much more poorly for clinical outcome than CFS alone. In contrast to (significantly) elevated CBG (cortisol binding globulin) levels in patients with CFS, no differences were observed in FM patients. Differences in secretion of AVP may explain the divergence of HPA axis function in FM and (ME)CFS*” (Evidence for and Pathophysiologic Implications of HPA Axis Dysregulation in FM and CFS. Mark A Demitrack and Leslie J Crofford. *Ann New York Acad Sci* 1998;840:684-697)

1998: there is no evidence for elevated Substance P in patients with ME/CFS, whereas levels are elevated in patients with FM (CFS differs from FM. No evidence for altered Substance P in cerebrospinal fluid of patients with CFS. Evengard B et al *Pain* 1998;78:2:153-155)

2001: patients with FM are NOT acetylcholine sensitive (Investigation of cutaneous microvascular activity and flare response in patients with fibromyalgia. AW Al-Allaf, F Khan, J Moreland, JF Belch. *Rheumatology* 2001;40:1097-1101)

2004: patients with ME/CFS ARE acetylcholine sensitive (Acetylcholine mediated vasodilatation in the microcirculation of patients with chronic fatigue syndrome. VA Spence, F Khan, G Kennedy, NC Abbot, JF Belch *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2004;70:403-407)

2003: endothelin-1 is RAISED in fibromyalgia (Increased plasma endothelin-1 in fibromyalgia syndrome. Pache M, Ochs J et al *Rheumatology* 2003;42:493-494)

2004: endothelin-1 is NORMAL in ME/CFS (Plasma endothelin-1 levels in chronic fatigue syndrome. Kennedy G, Spence V, Khan F, Belch JF *Rheumatology* 2004;43:252-253)

In the light of so much evidence, there can be no justification for regarding CFS/ME as part of a “broader condition that includes FM”.

Page 135, lines 16-18: “*the concept of CFS through a biopsychosocial model*”

ME/CFS is not a “concept”: it is a formally classified nosological entity that is organic, not psychosocial, in aetiology and nature

Page 134, lines 25/26: “*Terminology used by doctors such as ‘functional syndrome’ and ‘medically unexplained symptoms’ are part of common usage in clinical practice today*”

Such terms are used in relation to perceived psychiatric disorders only, never to medical disorders

Page 134, line 27: “*The terms have arisen to describe non-conventional diseases*”

ME is not a ‘non-conventional’ disease: it is a formally classified neurological disease and has been so since 1969

Page 134, line 29 / page 135, lines 1/2: “*Although the term ‘functional’ has been found to be more acceptable with patients than terms such as ‘psychosomatic’ or ‘medically unexplained’, some terminology has become derogatory with use*”

Terminology should be accurate, so to describe an organic disorder as a psychiatric disorder is indeed derogatory to patients who are the subjects of such misdiagnosis, especially as patients are well aware that all these terms are meant to convey that they are suffering from a mental illness when, in the case of primary ME/CFS, this is erroneous

Pages 137 – 255 (“Management”)

The issue of CBT/GET has been addressed above, but four points need to be considered:

- on page 188 (in the box), the statement recommending planned increases in duration of physical exercise, especially aerobic exercise, is not accepted by international experts such as Professor Paul Cheney who, in 1999, emphasised that: “*The most important thing about exercise is not to have them do aerobic exercise. I believe that even progressive aerobic exercise, especially in phase one and possibly in other phases, is counter-productive. If you have a defect in the mitochondrial function and you push the mitochondria by exercise, you kill the DNA*” (see page 11 above: Cheney lecture, International Congress, Orlando, Florida, 5<sup>th</sup> – 7<sup>th</sup> February 1999)
- on page 199 (in the box), the recommendation that when experiencing a set-back, the patient should “*talk to supporters / family / friends*” is both unrealistic (there is virtually no professional support network for those with ME/CFS throughout the UK) and insensitive (countless numbers

of severely affected exist in extreme isolation); equally, to refer (on page 200) to “*guidance from the CFS/ME support team*” is ludicrous when most of the country has no such thing. Many people with severe ME/CFS require 24 hour care, but have to endure endless battles with and abysmal minimal input from Social Services

- on page 229 the statement “*Thyroxine should not be prescribed when the adult or child is biochemically euthyroid*” is open to question in patients with ME/CFS because it has long been known by experienced physicians that ME/CFS patients are often clinically hypothyroid, especially at tissue level, even if biochemically euthyroid. There may be conversion problems or receptor resistance problems not detectable on routine tests. If there is a receptor blockage, there could in fact be an excess of T3, which is then converted to Reverse T3 (which is useless to cells). As reported by Professor Kenny De Meirleir from Belgium, it is known that ME/CFS patients have a much higher level of a protein that is 98% identical to T3. Because this “foreign” protein can bind to T3 receptors, T3 cannot bind to its own receptors and is therefore ineffective in its role of activating cellular metabolism. Thus the bioavailability of T3 needs to be investigated. In ME/CFS, T3 levels are often low, or at the low end of the normal range, so selenium levels need to be investigated in patients with ME/CFS who have reduced T3 levels: this is because selenium (as selenocysteine) is an integral component of two important enzymes, glutathione peroxidase and iodothyronine deiodinase; it is expressed in the liver and it regulates the conversion of thyroxine (T4) to the active and more potent T3. Individuals who have a deficiency of 5’ deiodinase cannot produce T3 from T4, thus it is necessary to establish baseline levels of selenium in ME/CFS patients whose T3 levels are low. TSH levels may vary from week to week. Ultrasound often shows shrinkage of the thyroid. NeuroSPECT scans tend to be grossly abnormal. It is essential to do thyroid antibody tests. Thyroid pathology is but part of a generalised autoimmune dysfunction (The Complexities of Diagnosis. Byron Hyde. In: Handbook of Chronic Fatigue Syndrome. Leonard Jason et al. John Wiley & Sons, 2003)
- on page 253 (in the box), it states: “*There are no complementary therapies that treat CFS/ME and their use is not recommended*”. This is a sweeping and unsubstantiated assertion; moreover, many patients with ME/CFS have found real benefit from complementary interventions and the Draft Guideline itself acknowledges that such interventions “*may be helpful for individuals as part of their own management*” (see also patients’ surveys referred to in the Draft Guideline)

#### Pages 256 – 265 (“Severely affected”)

Given the apparent understanding of severe ME/CFS outlined in this short section, it is a matter of concern that the severely affected should nevertheless be deemed “*able to access the same therapeutic options as those who are not severely affected*”, an oxymoron which seems to call into question the probity of the NICE Guideline Development Group members and their advisers, since the only two recommended management regimes (CBT/GET) have already been shown to be harmful and to convert moderately affected ME/CFS patients into being severely affected. How can this be ethical?

It seems increasingly inescapable that, where ME/CFS is concerned, neither ethical considerations nor scientific evidence plays any part in the present Government’s policy-making.

#### **Comments from other ME/CFS charities on the NICE Draft Guideline**

The UK ME Association has already published its view that the Draft Guideline is unfit for purpose and is not willing to endorse it (see Co-Cure ACT: 18<sup>th</sup> October 2006).

The charity Invest in ME likewise is preparing a detailed rebuttal of the Draft Guideline, as is the charity MEResearch UK.

### **Technical anomalies in the NICE Draft Guideline**

Background information: NICE was set up in 1999 to advise Ministers in England and Wales on which treatments (including drugs) should be available on the NHS on the basis of both clinical and cost effectiveness. The Government's stance at the time was that it would be "entirely inappropriate" to overrule the decisions made by NICE, and that NICE should operate without political interference.

NICE promotes itself as an "independent" body, but this requires clarification, because NICE was set up by the Department of Health; it is also accountable to – and funded by – the Department of Health.

As there is now a policy of "open access" between Departments of State (for example, between the Department of Health and the Department for Work and Pensions), it is inevitable that there will be a unified policy underpinning the workings of these Departments, especially in relation to cost control in such chronic disorders as "CFS/ME" (which, according to the charity Invest in ME, is five times more prevalent in the UK than HIV/AIDS).

Given these behind-the-scenes associations, it is difficult not to think of NICE as little more than an expensive public relations edifice (at vast cost to tax payers) to enable the Government to call the shots and achieve its desired outcomes without being overtly implicated in unpopular decisions by virtue of being seen to be relying for advice on an "independent" body.

The present NICE Draft Guideline on "CFS/ME" would seem to be a case in point, because NICE is obliged to conform to certain standards in the production of its Guidelines, which in the case of this Draft "CFS/ME" Guideline it has signally failed to do.

### **The AGREE Instrument**

NICE is a party to the Appraisal of Guidelines Research and Evaluation Instrument (known as the AGREE Instrument). This originates from an international collaboration of researchers and policy makers working together to improve the quality and effectiveness of clinical practice Guidelines. The AGREE Collaboration started in 1998 as a project funded by the European Union, the main objectives being to develop an appraisal instrument to assess clinical Guidelines themselves and to harmonise Guideline development across Europe to ensure the dissemination of high-quality Guidelines.

The resulting Guidelines are intended to be "*systematically developed statements to assist practitioner and patient decision about appropriate healthcare for specific clinical circumstances*". Their purpose is "*to make explicit recommendations with a definite intent to influence what clinicians do*" (The AGREE Collaboration, September 2001, attached to "Analysis of Chronic Fatigue Syndrome Guidelines: Report to the Ministry of Health", New Zealand, November 2003).

Because the intent is to influence what clinicians do (which immediately impacts on patients), there are rigorous criteria (currently 23) which policy makers and Guideline developers must observe in the production of a Guideline.

The most important criteria in relation to the Draft Guideline on "CFS/ME" seem to be:

- **There should be an explicit statement that all group members have declared whether they have any conflicts of interest** (in the present Draft Guideline, has GDG member Dr William Hamilton, for example, openly declared his conflict of interest by stating that he is Chief Medical Officer for a medical insurance company?)
- **The patients to whom the Guideline is meant to apply should be specifically described** (the present Draft Guideline completely fails this criterion as there is no such disorder as "CFS/ME": the Wessely School believe that "CFS" is synonymous with neurasthenia, which is a classified mental disorder at ICD-10 F48, but ME/CFS is a classified neurological disorder at ICD-10 G93.3)

and fibromyalgia is a classified soft tissue disorder at ICD-10 M79; to lump different disorders together as one single disorder is in defiance of established taxonomic principles)

- **The Guideline Development Group should include individuals from all the relevant professional groups** (the present Draft Guideline fails this criterion in relation to ME: whilst physiotherapists, occupational therapists, clinical psychologists, occupational health physicians, nurses, dieticians, general practitioners, and liaison psychiatrists are represented on the Guideline Development Group, and whilst there is a neurologist and an immunologist listed, their experience of patients with ME/CFS is not known. Conspicuous by their absence, however, are a virologist, a clinical allergist, a microbiologist, an endocrinologist, a pharmacologist, a rheumatologist, a molecular biologist, a biochemist, a biostatistician, and experts in vascular medicine, nuclear medicine and genomics, all of whose input is essential to understanding the nature of ME/CFS)
- **The patients' views and preference should be sought and the patient /carer members must have equal status on the GDG** (the present Draft Guideline pays lip-service to the need to listen to patients' views but the recommendations then entirely ignore patients' views)
- **The health benefits, side effects and risks should be considered when formulating the recommendations** (the present Draft Guideline fails in this respect: all relevant patient surveys consistently report that a high percentage are made worse by GET and failure to report such adverse events is a research crime)
- **The potential cost implications of applying the recommendations should be considered** (the present Draft Guideline fails this criterion: assessment of cost-effectiveness must be carried out in respect of maximising health gain so that resources are not employed in interventions that are not cost-effective, but it is already known that the only recommendations in the Draft Guideline – CBT/GET – have very limited [and certainly not lasting] benefit and are not in any way curative, as recognised by even the keenest advocates of the recommended interventions. Moreover, there is evidence that patients with ME/CFS are actually made worse by these recommended interventions. Further, as mentioned above, the cost implications of recruiting, training and supervising an army of behavioural therapists would be considerable. How therefore can the recommendations be considered cost-effective?)
- **There should be an explicit link between the recommendations and the supporting evidence** (the present Draft Guideline fails this criterion: the alleged “evidence-base” is exceptionally weak yet it is given more weighting than the patients' evidence, when there should be equal weighting)
- **The Guideline should be editorially independent from the funding body** (does NICE pay its editorial and other advisers with funding received from the Department of Health?)
- **Systematic methods should be used to search for evidence** (this is a serious issue: for example, the integrity of the York Systematic Review that purports to support the recommendations may be suspect, since evidence that militates against the recommendations has been omitted, with the result that the favoured recommendations appear in a better light than is justified by the totality of the evidence. Anne-Marie Bagnall, for example, published different conclusions from the same material: ie. JAMA 2001 and the update in JRSM 2006 that underpins the Draft Guideline, but she does not explain how she now reaches different conclusions using the same evidence-base).

When Guidelines are based on such highly inconsistent literature, the recommendations that are based on that literature become invalid, not least because the severity of ME/CFS is deliberately obscured and patients' rights to appropriate care are obliterated (which contravenes the AGREE Instrument).

NICE has been trusted to produce a Guideline that is accurate but has failed to do so, partially because the York Review team has misled NICE in that the shortcoming of CBT/GET that they themselves highlighted

in JAMA in 2001 have now been diluted and deleted from the current update that purports to be a comprehensive and balanced scrutiny of the relevant literature.

Given that Bagnall herself contributed to both JAMA 2001 and York 2005, this is an extraordinary omission from JRSM 2006, especially as the JRSM paper states: “*Our review was designed to be as comprehensive as possible, with the objective of identifying **all** published studies of interventions for CFS/ME*”. What could be the reason for Bagnall et al now claiming “*There is limited evidence about adverse effects associated with behavioural interventions. Withdrawal from treatment is often difficult to interpret*” when she herself knew exactly how high the drop-out rates were as long ago as 2001? And what explains the statement of principal findings, ie. “behavioural interventions, including elements of CBT and GET and rehabilitation, may reduce symptoms and improve physical functioning of people with CFS/ME”?

Given the use of the word “may” in the above sentence, how has the NICE Guideline Development Group translated this into the diktat that **all** adults and children who wish to get better are to have behavioural interventions and nothing else (page 181)?

The assertion of Wessely School psychiatrists that mixing ‘fatiguing illnesses’ will clarify the pathophysiology of ‘fatigue’ has not held up: on the contrary, it has failed to yield any meaningful diagnostic or therapeutic protocols (Co-Cure ACT: 12<sup>th</sup> October 2004).

The Wessely School’s vociferous claim that they will accept only “evidence-based medicine” in relation to “ME/CFS” has been exposed as duplicitous, since their own so-called “evidence” and their own studies that claim to provide this “evidence” have, for over a decade, been exposed in the literature as methodologically flawed, for example, unrepresentative selectivity of cohorts; outright bias; manipulation of cited references, for example, leaving out findings from cited studies that were inconsistent with their own conclusions; excessive self-references; distorted interpretation of results, such as presenting assumptions and taking for granted what still needs to be explained; generating conclusions before generating the data to support such conclusions; using mixed populations but failing to disaggregate the findings; mischaracterisation of the facts; using different timing measures, for example, drawing conclusions across different studies, eg. equating simple fatigue of 30 days with chronic severe fatigue lasting decades; use of different diagnostic instruments: use of different definitions of improvement; failure to assess the adequacy of the analyses performed; failure to address the very high drop-out rates; misrepresentation of study results, for example, in one cited study, an overwhelming majority of participants who had been categorised by the authors as ‘recovered’ rated themselves as only slightly improved and less than halfway back to pre-morbid health levels; studying ‘fatigue’ but then claiming their results relate to ME/CFS – when the literature plainly states that that such results cannot be so interpreted (see Arch Intern Med 1995:155:2105-2110; see also QJMed 1997:90:723-727).

For the York Systematic Review team to have used such flawed studies as the basis of the recommendations to NICE may well amount to research misconduct. (For a more detailed discussion of the flawed methodology of the Wessely School, see [www.meactionuk.org.uk/consideration.htm](http://www.meactionuk.org.uk/consideration.htm) ).

### **Conclusion**

If only one item on ME/CFS were to be read by the Guideline Development Group, it should be “Complexities of Diagnosis” by Byron Hyde, which is chapter 3 in Handbook of Chronic Fatigue Syndrome by Leonard Jason et al, John Wiley & Sons, 2003 (referred to above). Anyone reading that chapter could be left in no doubt that ME/CFS is far removed from chronic “fatigue”.

The on-going tragedy for those with ME/CFS and their desperate families is that the clear indications are that no matter what scientific evidence is submitted which disproves the favoured psychosocial model and no matter what the patients’ experiences of overwhelming and sometimes catastrophic illness (which are fully supported by the biomedical evidence), all will be comprehensively disregarded, as so often before.

It is little short of sinister for Departments of State to refuse to accept the world-class evidence that ME/CFS can be differentiated from chronic “fatigue”, especially the novel evidence that in ME/CFS, the higher the RNase L activity, the lower the patient’s ability to function, and the further evidence that these patients also have a low molecular weight 37kDa RNase L which is not found in healthy controls *or* in fibromyalgia patients (Suhadolnik, 7<sup>th</sup> AACFS International Clinical and Research Conference, Madison, Wisconsin, October 1994), as well as the evidence of increased isoprostanes (highly noxious by-products of abnormal cell membrane metabolism) that have never been seen in any other known disorder (Oxidative stress levels are raised in chronic fatigue syndrome and are associated with clinical symptoms. G Kennedy, VA Spence, JJF Belch et al. *Free Radical Biology & Medicine* 2005;39:584-589).

What can be so important to this Labour Government and its Departments of State that they must refuse to recognise the irrefutable validity of this evidence?

For all the reasons set out above, the 25% ME Group for the Severely Affected is unable to endorse the NICE Draft Guideline on “CFS/ME” as it has no application for those with ME/CFS. This is in contravention of NICE’s obligation to observe the criteria set out in the AGREE Instrument, particularly the criterion that requires the patient population for whom the Guideline is intended to be specifically described. To equate the heterogeneous condition “CFS/ME” (which is based on nothing more than ideology as opposed to medical science) with the nosological entity ME/CFS is in defiance of the internationally accepted classification rubric.

Should NICE fail to amend the Draft Guideline to incorporate a significantly modified understanding of the nature of ME/CFS, it is intended to seek Judicial Review.

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