

## Comments on the NICE Guideline on “CFS/ME”

Margaret Williams      29<sup>th</sup> August 2007

The National Institute for Health and Clinical Excellence (NICE) was set up in 1999 and is funded by the Department of Health, to whom it is accountable. It is not therefore “independent” of the machinery of State.

Its “consultation” processes are, according to Christopher Booker, merely an empty exercise: the Government and its bodies pretend to “consult” those affected by their actions, then carry on doing exactly what they intended in the first place. In other words, the “consultation” period is a farce, as the Government is not remotely interested in looking at the evidence (Sunday Telegraph, 20<sup>th</sup> June 2004).

As noted by Peter Kemp, topics for the Institute’s work programme are selected by the Department of Health, but once a topic has been referred, the development and communication of the subsequent advice is entirely the responsibility of the Institute. As Kemp noted: *“This seems to suggest that NICE can be told what to do. This does not sound like independence in the true sense of the word. The remit is so heavily loaded that I believe a truly independent institute would reject it out of hand. The remit is effectively telling NICE what to recommend; ie. ‘management of adjustment and coping’ and ‘rehabilitation strategies’. NICE have been told what to recommend for people with CFS/ME and judging from their draft guideline, have complied”* (ME/CFS and FM Information Exchange Forum, 21<sup>st</sup> November 2006).

It was on 23<sup>rd</sup> February 2004 that the Department of Health and the Welsh Assembly formally requested NICE to prepare a clinical and service guideline. The remit was:

*“To prepare for the NHS in England and Wales, guidance on the assessment, diagnosis, management of adjustment and coping, symptom management, and the use of rehabilitative strategies geared towards optimising function and achieving greater independence for adults and children of CFS/ME”.*

On 29<sup>th</sup> September 2006 NICE issued a draft Guideline on “CFS/ME” for consultation. There were many serious problems with the draft Guideline, starting with incorrect and confusing information about the way in which responses to the consultation Questionnaire should be submitted. The problems of terminology and classification were not addressed; some Guideline Development Group members had a published track record of supporting the psychosocial model of “CFS/ME” favoured by the Wessely School; in clear contravention of the AGREE Instrument (see below), the vested interests of Guideline Development Group members were not declared (including the fact that one GDG member had spent 15 years working for the medical insurance industry and was Chief Medical Officer for a major medical insurance company); due to the narrow confines of the remit, there was a failure to heed the biomedical evidence that disproved the psychosocial model of ME/CFS; the names of the advisers to the Guideline

Development Group were withheld (but were later confirmed by Carole Forbes, Systematic Review Project Manager at the CRD, to be the same people who had advised the Systematic Review team at the CRD, which included Simon Wessely, Anthony Pinching and Chris Clark from AfME -- from which Clark resigned in March 2006); the Questionnaire contained a series of “misprints” relating to questions 29-61, making a nonsense of responses to those questions and meaning that answers to over one third of the questions were likely to be erroneous; the way in which answers were to be provided was changed in such a subtle way as to make it unlikely that patients with cognitive impairments would notice, thereby potentially achieving results that respondents did not intend; out of an ME/CFS UK population of between 0.2 to 0.4% (ie. up to 240,000 people), only 399 questionnaires were sent out and out of these, only 219 were completed, rendering such a tiny and unrepresentative response easy for NICE to ignore statistically; the Key Questions upon which the questionnaire was based (in order to fit the NICE scope, the scope being the document that set out what the Guideline will cover) seemed designed to preclude anything other than a psychosocial model; NICE relied upon the Systematic Review provided for it by the CRD at York, when that Systematic Review had already been exposed as flawed, even to the extent that it may have contained research misconduct in that it had deleted previously published evidence in order to cast the management regime favoured by the Wessely School in a good light. Most importantly, NICE failed to conform to the AGREE Instrument (The Appraisal of Guidelines for Research and Evaluation) which requires that NICE is obliged to give equal weight to three main sources of data: “evidence-based” medicine, usually deemed to be random controlled trials (RCTs); the opinion and experience of physicians with expertise in the area, and the opinion and experience of the patient group for whom the Guideline is intended. This did not happen in its draft Guideline on “CFS/ME”.

Despite the fact that the UK medical defence unions have advised doctors that exercise regimes (which form part of a cognitive behavioural therapy regime) must be prescribed with just as much caution as pharmacological interventions, it seemed that NICE may have overlooked the implications of this advice: in its Draft Guideline on “CFS/ME”, the only recommended management regime was cognitive behavioural therapy (CBT), including graded exercise therapy (GET) and, for the severely affected, “Activity Management”.

For further analysis of the draft Guideline, see the 54 page document compiled on behalf of The 25% ME Group for the Severely Affected: [“Some Concerns about the National Institute for Health and 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”](http://www.meactionuk.org.uk/Concerns_re_NICE_Draft.htm) available online at [http://www.meactionuk.org.uk/Concerns\\_re\\_NICE\\_Draft.htm](http://www.meactionuk.org.uk/Concerns_re_NICE_Draft.htm)

Other cogent criticisms of the draft NICE Guideline included one submitted by a member of the Association of British Neurologists:

*“The draft guideline is fundamentally flawed because it presupposes certain interventions (CBT and GET) to be highly effective in CFS/ME for routine clinical use*

*despite lack of adequate evidence. The Guideline is also selective in its review of existing literature and is heavily influenced by (the) psychiatric view of the condition. Indeed, it almost seems that a select group of psychiatrists with a polarised view of this complex condition is directing the development of the guideline from 'behind the scene'. There has been no review of general and post-exercise pain. The draft guideline reflects an incomplete and psychiatrically polarised view of CFS/ME. The importance of appropriate diagnosis of CFS/ME from common psychiatric conditions has not been mentioned even once. No-where in this guideline have the exclusion criteria for CFS/ME (eg. generalised anxiety disorder, somatisation) been adequately defined and properly discussed. The guideline needs to be thoroughly revised to reflect our current understanding of this condition rather than the supposition of the psychiatrists. It would be immoral for NICE not to recognise the huge dissatisfaction about this draft guideline amongst most patients, carers and clinicians. The guideline should not re-define CFS/ME to 'fit in' CBT and GET as the recommended treatment options. Listen to patients”.*

A further submission from the Association of British Neurologists said the following:

*“(The Guideline Development Group) is tactically promoting Oxford criteria over the more widely used and recognised international CDC criteria – again, a clear evidence of psychiatrists’ influence on this group”.*

Referring to a paragraph in the draft Guideline: *“This paragraph deals with a publication (Wessely et al, Lancet 1999) which was published as a HYPOTHESIS and which remains to be proven. However, the GDG seems to have taken it as a matter of fact. Please refer to the criticisms of this article in the Lancet. Being only a hypothesis, (it) is totally irrelevant for the purpose of a dedicated guideline on CFS/ME”.*

*“The GDG should also be criticised for its total lack of reference to the neurological aspect of fatigue and its overemphasis and over-reliance on the psychiatric literature from a group of psychiatrists”.*

*“With the possible exception of some psychiatrists, most specialists prefer the international criteria to diagnose CFS/ME”.*

*“Clearly there is very little compelling evidence at present that these patients benefit from CBT and GET”.*

*“There is selective omission of research literature on reproducible neuroendocrine tests, with an overemphasis on research data from certain psychiatrists”.*

Another well-argued criticism was submitted by Dr Derek Pheby, Project Co-ordinator, National CFS/ME Observatory. For some reason, his comments were not published by NICE and he received a communication from the NICE Guidelines Co-ordinator stating: *“A number of comments and responses are still being held by the Institute and are not included in the table. These are comments which may contain defamatory or libellous wording”.* Pheby wrote back: *“Your statement is clearly defamatory of us. This is*

*completely unacceptable, and a serious slur not only upon my reputation but also upon the reputations of the prominent and highly respected academics who are involved in the Observatory project. If you wish to argue that your statement was not intended to apply to us, and that your omission of our comments was in error and unintentional, then this lack of care calls seriously into question the quality of the exercise you have undertaken”.*

Pheby’s original comments on the NICE draft guideline included the following:

*“The National ME Observatory is a research collaboration, funded by the Big Lottery Fund, comprising the London School of Hygiene and Tropical Medicine, the University of East Anglia, and the Hull-York Medical School. It was established earlier this year (ie. 2006) in order to address the serious problem about a totally inadequate corpus of scientific knowledge about CFS/ME.*

*“The belief that evidence-based guidelines can be constructed on such an inadequate evidence base is, in our opinion, misguided. Indeed, many of the recommendations in the draft guideline appear not to be evidence-based at all (and) reflect what limited research was carried out in the 1990s and before.*

*“The draft states: ‘When the adult or child’s main goal is to return to normal activities, then the therapies of first choice should be CBT or GET’. This is very misleading. It implies that there is a group of people with CFS/ME who may not have as their main goal a return to normal activities. We have never encountered this. It also implies that, of a range of possible therapeutic approaches, CBT and GET are the two which emerge as being the most effective, whereas the reality is that there has been very little clinical trial activity involving other treatment. The statement is also misleading because it does not consider the extent to which outcomes of trials of CBT and GET do not appear representative of the population with CFS/ME as a whole.*

Referring to the statement in the draft Guideline that said: *‘Healthcare professionals who are responsible for the care of (people) with CFS/ME should have appropriate skills and expertise in the condition’*, Pheby commented: *“What the document does not state is what skills and expertise are appropriate, nor how they are to be acquired. Given that CFS/ME is a relatively common condition, and that a wide range of healthcare professionals are likely to be involved, this has considerable implications for education and training (which) in turn have substantial organisational and resource implications which will have to be addressed.*

*“The diagnostic criteria detailed in paragraph 1.2.1.2 do not conform to any existing clinical case definition for CFS/ME and appear to be based on poor evidence.*

*“CBT and GET should not be regarded as the first choice of treatment or as providing a cure. To put rehabilitation before prevention or early intervention falls short of the patient-centred approach which the draft guidelines claim to be advocating.*

*“Greater evidence should be placed on medical interventions, including symptom control and improved access by patients to services, information and resources.*

*“...promoting the use of CBT and GET in severely affected people (is) extremely dubious, since there is a dearth of evidence supporting the use of these approaches in such patients, and plenty of anecdotal evidence, as well as evidence from surveys conducted by patients organisations, of these methods being at best of limited value and at worst damaging. (In relation to the use of CBT and GET in children and the severely affected, the draft guideline) states that ‘There is no evidence for the use or effectiveness of these strategies in these two patient groups’, and yet the guideline recommends that they may be used in such cases.*

*“The draft, as it stands, has obvious defects, which make it unsuitable for general application throughout the NHS. It demonstrates lack of understanding of CFS/ME (and) the evidence-base is inadequate to support the conclusions and recommendations made. The review claims to be evidence-based but in fact is mostly based on expert opinion, rather than on evidence. There is no indication that the document reflects a balanced view of expert opinion on CFS/ME. The report gives the erroneous impression that the role of these management options has been satisfactorily evidenced and widely agreed by professional and lay groups involved in this field.*

*“The recommendations serve only to underline the extent to which the existing evidence base is inadequate.*

*“We strongly recommend that the draft be rewritten to reflect more accurately the current state of scientific knowledge, and also the views of stakeholders (and) patients’ organisations, which do not appear to have been taken much into account. NICE guidance is of such importance in the NHS, and has such huge repercussions on patterns of treatment and care. It therefore needs to be accurate. Where there are differences of opinion among experts, such differences should be reflected in the document”.*

Following the decision of NICE not to publish his submission in the table of Stakeholder Comments, Pheby commented on an internet group: *“I was dismayed to find that our comments were missing from the published tables of comments, and they have clearly had no influence in the final version. I don’t like the implication that our comments may have been defamatory. It may well be that our comments said things NICE did not want to hear, but that’s an entirely different matter”.*

Other criticisms were submitted, including the following:

The Association for Psychoanalytic Psychotherapy noted the absence of any evidence that CBT is superior to other psychological interventions such as counselling.

The Royal College of General Practitioners (Wales) said: *“A guideline based on dysfunction and disability will inevitably remain focused on rehabilitation rather than on cure and prevention”.*

PRIME (Partnership for Research in ME/CFS) noted the GDG's acknowledgement that there are insufficient studies using outcomes that are important to patients (noted with thanks by the GDG) and that most studies often assess only fatigue and sleep, and that few studies include outcome measures that explore the wider impact of ME/CFS.

These illustrations give an indication of the strength of opposition to the dominant Wessely School beliefs about "CFS/ME".

Report of an "Evidence-based Commissioning Collaboration: Diagnostic Tests for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis" (The Trent Institute Report)

Pending the production of the NICE Guideline, an interim Report was produced by the Trent Institute. This Report was an illustration of the total circularity of the Wessely School influence about ME/CFS that pervades the UK, and was written to support the NICE Guideline on "CFS/ME".

It was completed on 22<sup>nd</sup> November 2004 and was produced by the Trent Institute of Health Sciences and Public Health Research, which is a collaboration between the Universities of Leicester, Nottingham and Sheffield in conjunction with other areas including Southampton, Aberdeen, Liverpool, Exeter and the West Midlands. The Evidence-based Commissioning Collaboration (EBCC) is made up of the North East Yorkshire and North Lincolnshire Primary Care Organisation; the North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium; The Trent Commissioning Consortium and the West Yorkshire Primary Care Organisation. All these bodies were collaborating on behalf of their respective Primary Care Trusts. The objective of the Collaboration was to share research knowledge about the cost-effectiveness of service interventions to inform the commissioning process.

The specific objective of this Report was "*To develop a brief report outlining the current recommendations for the use of diagnostic tests in Chronic Fatigue Syndrome*".

The Trent Report used the MRC "CFS/ME" Research Strategy and the much-criticised Royal Australasian College of Physicians Guidelines for CFS. It supported the use of the Oxford criteria for "CFS/ME", which have no predictive validity and have not been adopted anywhere but in the UK.

This Report stated: "*There is widespread controversy surrounding the existence of CFS/ME*".

The Report's conclusions were that the only laboratory tests recommended for people with "CFS/ME" are those "*aimed at detecting alternative medical conditions*".

At its Steering Group meeting held on 15<sup>th</sup> November 2004, it was documented that the Trent Report was to present “*a holding position pending the preparation of NICE guidance*”.

It was further documented that “*CFS/ME was not a disease as such*” and that the role of the report’s collaborators was to “*educate GPs*”.

It was agreed that Professor Wessely’s book should be added to the Report’s references (Wessely S, Hotopf M and Sharpe M (1999) Chronic Fatigue and its Syndromes; Oxford University Press).

The Report was supported by Mark Adams, Clinical Network Lead for CFS/ME for South Yorkshire and North Derbyshire, whose comments were: “*The content and conclusions of the report is in line with my understanding of the literature on this subject*”.

It is profoundly disturbing that those involved with this report appeared unaware of the vast body of international literature on ME/CFS that is of a very different nature from their recommended list of references: for them to prepare a realistic report that is fair to patients, that body of literature ought not to have been ignored.

#### The (finalised) NICE Guideline on “CFS/ME”: 22<sup>nd</sup> August 2007

On 22<sup>nd</sup> August 2007 the finalised NICE Guideline was published (Chronic fatigue syndrome / myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome / myalgic encephalomyelitis (or encephalopathy) in adults and children. Turnbull N et al. Royal College of General Practitioners, London, 2007.

Professor Anthony Pinching (the patients’ “champion” responsible for the much-criticised Centres that deliver only CBT and GET) is singled out by the Guideline Development Group for special thanks, as is the team from the Centre for Reviews and Dissemination. The Hooper & Reid analysis of the CRD Systematic Review was ignored, which means that the so-called “evidence-base” upon which NICE recommends CBT and GET remains intrinsically flawed, relying as it does on only seven RCTs of dubious quality, all of which exclude children and the severely affected.

However, the final Guideline is like the proverbial Curate’s egg: good in parts. It is clear that, to its credit, the Guideline Development Group has taken heed of many submitted representations but that the Wessely School has retained control of the recommended management strategies, although to nothing like the extent they sought (see below), and that even those management strategies (CBT and GET) have been modified from those previously employed by the Wessely School (which sought to force patients to change their beliefs and accept that they were not suffering from a physical disorder, about which Dr Ellie Stein – herself a psychiatrist -- said at the ME Research UK International Conference in Edinburgh on 25<sup>th</sup> May 2007: “*I would never in my practice use the*

*Wessely model of CBT – I find it disrespectful to try to convince somebody they don't have an illness they clearly have”).*

Having been given the remit by the Department of Health, NICE could hardly produce a Guideline saying that the reality is that there is no treatment apart from symptomatic (such as analgesia and anti-emetics), especially for what is clearly an immense and increasing problem. It is a reflection of existing policy that so few management options are available for those with ME/CFS.

Some of the helpful points in the Guideline include:

- recognition that the physical symptoms can be as disabling as multiple sclerosis, systemic lupus erythematosus and congestive heart failure and that the disorder places a substantial burden on sufferers, their families, their carers, and hence on society
- recognition that the healthcare professional should acknowledge the reality and impact of the condition (this addresses the fact that up to 50% of GPs still do not accept that the disorder exists)
- recognition that the WHO classifies CFS/ME as a neurological illness at G93.3, noting that some members of the GDG felt that the NICE guideline should recognise this classification but that others felt doing so did not reflect the nature of the illness and risked restricting research into causes and future treatments (the inclusion of the WHO classification seems to reflect a rejection of the Wessely School's determination not to accept the WHO classification, as well as a rejection of the Wessely School's wish to justify their PACE trials funded by the MRC for their psychosocial model of "CFS/ME")
- recognition that there is great variability of symptoms, which may fluctuate in intensity and severity
- recognition that it can cause profound, prolonged illness and disability
- recognition that treatment and care should take into account patients' individual needs
- recognition that people with "CFS/ME" should have the opportunity to make informed decisions about their care and treatment and should participate as partners in all decisions about their healthcare
- recognition that the healthcare professional should offer information about local and national self-help groups and support groups
- recognition that people with "CFS/ME" should have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their current or future care
- every person with "CFS/ME" should be offered assistance negotiating the healthcare, benefits and social care systems
- recognition that some people with severe "CFS/ME" may remain housebound
- recognition that there is no pharmacological treatment or cure for "CFS/ME"
- recognition that many people find exclusion diets helpful in managing bowel symptoms



- recognition that rest periods are a component of all management strategies for “CFS/ME”
- recognition that healthcare professionals should work with the person with “CFS/ME” to develop strategies to minimise complications that may be caused by nausea, swallowing problems and difficulties with buying, preparing and eating food
- recommendation that for people with moderate or severe “CFS/ME” a wheelchair, blue badge or stairlift should be considered as part of an overall management plan (this is particularly welcome, as people with a psychological disability will not normally qualify for a blue badge)
- recognition that advice to undertake unstructured, vigorous exercise may worsen symptoms
- recognition that strategies for managing “CFS/ME” should not include an imposed rigid schedule of activity and rest
- if chronic pain is a predominant feature, healthcare professionals should consider referral to a pain management clinic
- people with “CFS/ME” should be advised that relapses are to be expected
- people with severe “CFS/ME” may need to use community services, including nursing and respite care
- recognition that consideration of the aetiology of “CFS/ME” was outside the scope of the Guideline: for that reason, the GDG has not made recommendations about the causes of “CFS/ME” but recommends that research in this area would be very helpful
- recognition of the anecdotal evidence that CBT/GET in children and the severely affected may be harmful or not effective
- recognition that reliable information on the prevalence and incidence of this condition is needed to plan services
- recognition that when used for patients with “CFS/ME”, the aim of cognitive behavioural therapy is to support the sufferer and does not assume that symptoms are psychological (ie. the aim is not to convince patients that they do not suffer from a physical disorder as was the case with the Wessely School regime -- the Medical Research Council PACE trial states that CBT *‘will be based on the illness model of fear avoidance’*)
- recognition that in “CFS/ME”, the aim of graded exercise is to assist the patient to be as independent as possible (ie. not to force patients to “exercise back to fitness”: in the MRC PACE trial, GET *“will be based on the illness model of both deconditioning and exercise avoidance”*)
- recognition that in the NICE guideline, pacing is defined as energy management and the keys to pacing are knowing when to stop and rest by listening to and understanding one’s own body (this is anathema to the Wessely School and represents a significant rejection of their beliefs that what they call “body-watching” should be a target for intervention)
- recognition that some peoples’ understanding of pacing is as “adaptive pacing therapy” in which people with “CFS/ME” use a management strategy plan, whereas patients’ own understanding of pacing is a self-management strategy, and that people with “CFS/ME” generally support this approach

- recognition that there are different stages in the natural course of “CFS/ME”
- recognition of the need for employers and schools to be better informed
- recognition that there should be avoidance of a dogmatic belief in a particular view.

### Concerns about the published Guideline

Even though the nature of CBT and GET in relation to “CFS/ME” is explained (and is clearly different from the earlier Wessely School model in which people were admonished to exercise no matter how sick they were and to abandon their “aberrant illness beliefs”), the major problem with the NICE Guideline remains its recommendation that CBT/GET “*should be offered to people with mild or moderate CFS/ME because currently these are the interventions for which there is the clearest research evidence of benefit*”.

Not only is this misleading, because the “evidence” upon which that statement is based has been shown to be seriously flawed as was pointed out to NICE in the clearest terms (the Hooper & Reid report), but some of the recommendations remain offensive to people with ME/CFS, as well as potentially damaging.

For example, reference is still made to “*unhelpful beliefs*”, to “*the relationship between thoughts, feelings, behaviours and symptoms and the distinction between causal and perpetuating factors*” and to the fact that the CBT plan will include “*identifying perpetuating factors that may maintain CFS/ME symptoms*” and will address “*any over-vigilance to symptoms*” (which is contradictory to the Guideline’s own recommendation that keys to pacing are listening to and understanding one’s own body).

This is wholly unacceptable: it demeans people with ME/CFS and it ignores the substantial evidence (over 4,000 published studies showing underlying biomedical abnormalities) that ME/CFS is not a psychosocial disorder.

It is insufficient for the GDG to claim that consideration of the biomedical evidence did not come within its remit – it was charged with providing guidance on the diagnosis of “CFS/ME”, so the literature which demonstrates the clear biomedical aetiology should have formed part of the literature review.

The Guideline acknowledges the Canadian Consensus Definition yet ignores its message; Dr Bruce Carruthers, Fellow of the Canadian Royal College and principle lead of the international expert team that produced the highly respected ME/CFS Clinical Case Definition, states in the Overview:

*“A hypothesis underlying the use of Cognitive Behaviour Therapy (CBT) for ME/CFS is based on the premise that the patient’s impairments are learned due to wrong thinking and ‘considers the pathophysiology of CFS to be entirely reversible and perpetuated only by the interaction of cognition, behaviour, and*

*emotional processes. The patient merely has to change their thinking and their symptoms will be gone. According to this model, CBT should not only improve the quality of the patient's life, but could be potentially curative'. Supporters suggest that 'ideally general practitioners should diagnose CFS and refer patients to psychotherapists for CBT without detours to medical specialists as in other functional somatic syndromes'. Proponents ignore the documented pathophysiology of ME/CFS, disregard the reality of patient's symptoms, blame them for their illness and withhold medical treatment. Their studies have often included patients who have chronic fatigue but excluded more severe cases as well as those who have other symptoms that are part of the clinical criteria of ME/CFS. Further, their studies fail to cure or improve physiological impairments..."*

Research that indicates potential dangers of the recommended management regime was ignored

Research that directly impinges on the safety of the NICE recommendations for graded exercise (which was available to the GDG) was also excluded from consideration and / or ignored. This was a serious omission. The AGREE Instrument (Appraisal of Guidelines Research and Evaluation Instrument) with which NICE is obliged to comply in the formulation of all its Guidelines is specific: *"The health benefits, side effects and risks should be considered when formulating the recommendations"*. Of particular significance is an important paper that was published in 2005 (well within the 2004 – 2007 life of the GDG's deliberations); that paper demonstrated that exercising muscle is a prime contender for excessive free radical generation, free radicals being highly reactive molecules which can cause damage to the cells of the body. Incremental exercise challenge induces a prolonged and accentuated oxidative stress, and existing evidence has shown a good correlation between muscle pain thresholds on exercise with various blood markers of oxidative injury (Oxidative stress levels are raised in chronic fatigue syndrome and are associated with clinical symptoms. Gwen Kennedy, Vance Spence, Jill Belch et al. *Free Radical Biology and Medicine* 2005:39:584-589).

The recommended graded exercise plan specifies that the intensity of GET should be incrementally increased, leading to aerobic exercise. This is in direct contradiction to international ME/CFS experts such as Professor Paul Cheney from the US, who in 1999 explained why aerobic exercise should not be used: *"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"* (Lecture given in Orlando, Florida, February 1999, at the International Congress of Bioenergetic Medicine).

Professor Cheney has made a particular study of cardiac anomalies in patients with ME/CFS since the 1980s and emphasises the unassailable tenet that if metabolic demand (as in aerobic exercise) exceeds the impaired cardiac output of ME/CFS patients, even

very briefly, the result is death. This information was submitted to NICE and was available to the GDG, including the evidence that 82% of ME/CFS patients have abnormal cardiac impedance and that patients have a high heart rate but a low cardiac output caused by a problem with energy production, with ischaemic changes in the inner ventricular wall. If a patient has abnormal oxygen consumption, muscles will not have enough oxygen and exercise will result in relapse. Patients' ability to work is impaired, as shown unequivocally by an abnormal serial exercise stress test which is 100% objective. This information was ignored by the GDG but impacts upon the recommended management regime.

(For more information on Professor Cheney's cardiac work in ME/CFS, see [http://www.meactionuk.org.uk/Klimas\\_Wessely\\_NICE\\_-\\_Redefining\\_CBT.htm](http://www.meactionuk.org.uk/Klimas_Wessely_NICE_-_Redefining_CBT.htm) and for a summary of current research on the cardiovascular anomalies that have been demonstrated in ME/CFS, see [http://www.meactionuk.org.uk/Facts\\_from\\_Florida.htm](http://www.meactionuk.org.uk/Facts_from_Florida.htm) ).

Professor Pinching advised adapting the level of activity to levels that can include an incremental increase (page 87 of comments on chapter 1). Pinching also referred to "*the commonest co-morbidities that are well-documented in the literature*" as being depression and anxiety, yet the literature shows such levels to be no higher in ME/CFS than in disorders such as multiple sclerosis.

All these studies and conference reports have direct bearing on the safety of the recommended management regimes and as such, under the terms of the obligatory AGREE Instrument, there can be no credible excuse for NICE to have ignored them.

In endeavouring to justify CBT/GET for use in ME/CFS, the Guideline states: "*an evidence-based psychological therapy is used in many health settings, including cardiac rehabilitation and diabetes management*". This claim has been investigated by numerous people and has been found to be inaccurate, since unlike in ME/CFS, it is used as an adjunct where necessary, not as the first-line treatment of choice across the board. In no other medical disorder apart from ME/CFS are patients offered exercise as the only "treatment" option.

Although it is clear that the type of CBT now recommended by the Guideline differs from Wessely's original prescription, it cannot be known whether the CFS Centres set up by Pinching will continue to employ Wessely's version (about which there are so many adverse reports – see the RiME collations) or the more supportive version as outlined in the Guideline, nor is it known who will re-educate and monitor the existing staff in these Centres, which is a matter of real and justified concern.

The Guideline refers (on page 186) to the Wessely School mantra of "*predisposing, precipitating and perpetuating factors in CFS/ME*" as a key area upon which future research should be focused: unless this model of research is applied to all other medical conditions, it is inappropriate for this special pleading to apply only in the case of "CFS/ME" and reflects the Wessely School's discredited assertion that "CFS/ME" is a

“faulty belief system” that can be “corrected” by CBT and aerobic exercise. The reality is that more than one Coroner has accepted ME/CFS as a cause of death.

In line with the Wessely School beliefs, the Guideline restricts investigations that may be performed on those with ME/CFS and it also stipulates that thyroxine must not be administered to such patients, which ignores the evidence of thyroid dysfunction and the fact that basic NHS tests are too blunt to pick up this serious dysfunction.

The Guideline states that no research evidence was found to support the experience of some people with “CFS/ME” that they are more intolerant of drug treatments and suffer more severe adverse side effects. There is an abundance of evidence (though not RCTs) from Professor Marty Pall in the US explaining the exact mechanism of such hypersensitivity and it is notable that the Guideline Development Group accepted anecdotal evidence when it suited their aim (for example, acceptance of the “boom and bust” concept, for which there is no RCT evidence), but rejected it in other places (such as Professor Pall’s evidence), which is inconsistent.

One patient representative on the GDG who resigned just prior to publication of the Guideline is on record as stating: *“I do believe that the guideline has not fully taken into account the patient and biomedical evidence, because if it had, then it would not be recommending the widespread use of CBT and GET. It is said that patient evidence is not given high weighting due to it being biased”*. If this is true, then it is another illustration of a clear breach of the AGREE Instrument to which NICE is obliged to conform.

The Guideline recommends domiciliary support for the severely affected, yet in a climate of unprecedented financial restrictions offers no reassurance that funds will be available to implement such support.

The NICE Guideline contains examples of carelessness, for instance, the date of reference 50 is given as being “1921” when it should be “2005:19:21:38-43”, as well as other incorrect dates.

Another striking example of carelessness is to be found in the table of Stakeholders’ Comments and GDG Responses, where inexcusably, many comments from one respondent have been attributed to others, for example, comments submitted by LocalME have been attributed to both Newport Pharmaceuticals Ltd and to North Staffordshire Combined Healthcare NHS Trust.

#### Evidence that the GDG has not conceded to all the demands of the Wessely School

The Wessely School clearly endeavoured to get its own way (see quotations below from the responses submitted by Simon Wessely and Peter White to the Questionnaire) but on a number of fronts they did not succeed. The Wessely School got all its own way with the 1996 Joint Royal Colleges’ Report and were infuriated that patients’ views were

given such weight in the 2002 Chief Medical Officer's Working Group report; this time, NICE seems to have treated them on the same basis as any other stakeholder among many, to the extent that this NICE Guideline now includes the Canadian definition, in full, over several pages. That is a significant step forwards.

Specifically, the NICE Guideline does not state that ME/CFS is a behavioural disorder, a psychiatric illness, a somatic/functional disorder, and illness belief, depression or anxiety.

It emphasises the need for an individualised management plan that should be provided in ways suitable for the individual, and it highlights the importance of shared decision-making between healthcare professionals and patients.

Section 5.5 of the draft Guideline stated: *"a view held by a few individuals on the GDG was that CFS/ME could not be identified or managed unless a broader view was taken"*. This "broader view" was that a "biopsychosocial" approach to ME was required, lumping it together with other states of chronic "fatigue" and thereby affording psychiatrists the right to be involved in the care of all ME patients, regardless of whether those psychiatrist were needed or wanted. One of the patients' representatives (BRAME) challenged the fact that if only "a few" members of the GDG group held that view, why was their opinion allowed to dominate the recommended management regime?

This seems to have forced the GDG into a remarkable admission: the Guideline does not accept any of the favoured theories of the Wessely School: *"In considering the explanation for CFS/ME, we have followed the report of the Gibson Inquiry, which accepts that there is insufficient evidence to fully substantiate any of the current theories of causation, and that more high quality biomedical research is needed"*.

The conclusions of the Gibson Report were concise:

- The Canadian Criteria are *"a useful contribution in defining ME/CFS"*
- *"The opposing opinions about the nature of the disease are very problematic"*
- The Gibson Report refers to *"The inability of some in the medical profession to separate (other disorders) from genuine ME/CFS patients"*
- *"ME/CFS have been defined by the World Health Organisation as neurological illnesses"*
- *"In the UK, precedence has been given to psychological definitions"*
- *"Regarding CFS/ME as a physical illness has been marginalized by the psychological school of thought"*.

Professor Richard Baker, Chair of the Guideline Development Group, appeared to express exasperation at the polarised views about the nature of the disorder, saying in the Preface to the Guideline: *"A further problem created by the lack of adequate research evidence is the sometimes widely divergent and hotly contested beliefs about CFS/ME, including those about its cause. In developing the Guideline, we kept in mind the overall goal of improving care for people with CFS/ME, with the patient's preference and views"*

*firmly in the driving seat. Rather than aligning ourselves with one or other perspective on CFS/ME, we have sought to provide practical guidance for professionals and patients”.*

#### Quotations from the responses to the Questionnaire by some Wessely School members

Illustrations from Wessely School members demonstrate their insistence that “CFS/ME” is a behavioural disorder.

Extracts from the submission by Wessely’s Chronic Fatigue Research Unit at King’s College, London: *“We do not agree with what is written about the care of those with severe disability and CFS, and the best treatment options for that group. For example, it is stated that ‘patient experience suggests that some of these interventions may be harmful or ineffective’. We would argue on the basis of our extensive experience that what is being reported in these negative accounts is rarely either CBT or GET. It would be more accurate to state that ‘some patients’ rather than ‘patient experience’, since the latter seems to imply that it is all patient experience. It seems likely that the same approach that works in outpatients would also be successful in severely affected”.*

*“We disagree with the numerous statements in the guidelines that patients in the published CBT/GET trials are ‘mild to moderate’. Nearly all of the published studies came from secondary or tertiary care. One would expect that these will be patients with high morbidity and the data shows that to be the case”. (One can only wonder how Wessely can convince himself that people who are well enough to attend an outpatient department can be described as “severely affected”). “Overall, this is strong evidence that the published work on CBT and GET concerns those with chronic illness and substantial disability. This needs to be addressed since if this is not corrected, there is a danger than NICE will inadvertently give credence to the oft expressed but erroneous view that CBT/GET only works in those who do not have ‘real ME’, those who have psychiatric disorders, or who are not very disabled”.*

This submission goes on to assert that there is evidence of emotional instability assessed 25 years before the onset of “CFS/ME” and that this *“adds to the existing evidence that personality and depression increase the risk of CFS”* and asserts *“the statement on page 90 (of the draft Guideline) should reflect this new and definitive research”.*

The submission states: *“We note the omission of any reference to what is now a well cited and accepted body of research on the role of psychiatric disorders and CFS, which is definitely of interest to clinicians considering treatment options. It is sometimes said that depression or anxiety is merely a consequence of disability. However, there is now a well-replicated body of evidence that shows this not to be the case. It has been established that the rates of psychiatric disorder in the CFS patients are too high to be explained as a simple reaction to disability. Such is the consensus in this area that studies are no longer being performed”.*

Commenting on page 134 of the draft Guideline which related to Wessely's own paper in the Lancet (1999:354:936-939) '*CFS has been described as part of a broader condition that includes a range of disorders including fibromyalgia, irritable bowel syndrome etc*', this submission states: "*True, and this will be well received by many doctors, since it reflects their views and emphasises ways in which we can increase our knowledge of one 'syndrome', to which the GDG response was that it accepts the conclusions of the Gibson Report.*

The submission from Peter White's Chronic Fatigue Services at St Bartholomew's Hospital said: "*We think it illogical to mix symptoms and disability. We do not think the evidence supports separating severe from very severe. We emphasise that CBT and GET can also help patients who do not wish to return to normal health*".

*"There are too many symptoms included, which will encourage practitioners to attribute symptoms such as palpitations to CFS/ME"*.

*"The (draft) guideline emphasises the importance of investigations, with little guidance about examining the patient. Examination should include a proper mental state examination. The guideline could usefully provide guidance about illness insights and beliefs"*.

*"The emphasis here would be appropriate for someone suffering from an incurable chronic disease, which CFS/ME is most often not"*. The GDG response was terse: "*The Guideline Development Group had to balance a positive outlook with the recognition that some people will not recover*".

*"Equipment and aids may hinder recovery as much as help it"*, to which the GDG response was: "*The view of the GDG is that equipment can help to maintain independence*".

*"The advice regarding drug treatment should (not imply that) neuropathic pain and IBS are part of CFS/ME"*, to which the GDG response was: "*The section has been revised to reflect comments from stakeholders*".

*"Weight loss is not part of CFS/ME at any age"*, to which the GDG response was: "*The view of the GDG is that some children may lose weight and require nutritional support*".

*"Sometimes acting as an intermediary between a patient and employer may encourage dependence rather than fostering recovery"*, to which the GDG's response was: "*Facilitating a dialogue with employers about adjustments to work often helps to remove barriers for the patient*".

*"Referral to specialist care should depend on the severity of the disability, not severity of symptoms"*, to which the GDG replied: "*The GDG considered the wording to be appropriate*".



Quoting from the draft Guideline that said: “*We need reliable information on prevalence and incidence of this condition to plan services*”, Peter White’s response was: “*Do we really?*”, to which the GDG replied: “*The GDG considered the research recommendations to be appropriate*”.

As the above illustrations show, the Wessely School did not succeed in all its demands.

In the light of this submission, it is noted that on 16<sup>th</sup> August 2007, St Bartholomew’s CNCC (Clinical Network Co-ordinating Centre) issued the following Statement: “*We can confirm that Barts CNCC does not consider CFS/ME to be a psychiatric illness*”.

### Evidence that the Wessely School knows that CBT and GET provide no lasting benefit in ME/CFS

Despite their ruthless determination to implement CBT and GET across the board for people with ME/CFS, Wessely School members have previously acknowledged that there is no long-term benefit from CBT, for example:

- at the American Association for CFS (AACFS, now the IACFS/ME) International Conference at Cambridge, Massachusetts on 10-11<sup>th</sup> October 1998, Wessely School psychiatrist Michael 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, Michael 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)

- 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).

It should not be forgotten that after a course of CBT, there is no objective evidence of improvement (only subjective) and that the transient gains may be illusory (Interventions for the Treatment and Management of Chronic Fatigue Syndrome – A Systematic Review. Whiting P, Bagnall A-M et al. JAMA 2001:286:1360-1368).

#### Some initial responses to the final Guideline

Action for ME issued a Statement supporting the Guideline: “*We believe that the guidelines represent an opportunity to drive forward the improvement of services for those with ME and it is for that reason we support them*”. AfME did note that the Guidelines still contain flaws and “*are still influenced by the history of research in this area, which has produced findings that can not be generalised to all people with ME and which therefore once again place an over-emphasis on cognitive behavioural therapy and graded exercise therapy*”.

The response of the Northern Ireland ME Association noted its disappointment that these new guidelines bring us no nearer a cure, and noted that the NHS in Northern Ireland is poorly equipped to implement these new national guidelines.

Invest in ME noted that the reasons why the draft Guidelines were almost universally condemned was due to the poor quality of analysis and their lacking ability to serve the needs of people with ME and their families, and that initial reaction to the final version can be summed up as continued dismay that NICE has again highlighted CBT and GET as the most effective forms of management.

Ellen Goudsmit PhD commented on the confusion, the bias and the inconsistencies in the Guideline; she noted the dominance of the CBT School; the promotion of unproven techniques such as activity management; the lack of recognition of subgroups of “CFS”; the lack of differentiation of ME or CFS from somatisation disorder and the

recommendation that CBT should be offered to mild cases, given NICE's interest in saving money, when counselling and self-help may be enough.

Kevin Short of Anglia ME Action quoted Dr Sarah Myhill on the central problem of ME/CFS being mitochondrial failure resulting in poor production of ATP, which shows that CBT, GET and antidepressants are irrelevant in addressing the root cause of this disorder; he feared that scientific and democratic integrity are now dead in the UK, having been sold out by the Government which has placed corporate interests over and above the interests of patients and he commented: *"To be ill and abused for it is nothing less than a living hell"*.

John Greensmith PhD: replying to an article in the Daily Mail on 23<sup>rd</sup> August 2007 which said: *"Well thought-out exercise regimes can help patients overcome the debilitating symptoms, although there used to be resistance from ME campaigners to psychiatric approaches"*, Greensmith wrote: *"The NICE report with its lax terminology and its reliance on questionable experimental designs and interpretations, produced by a disproportionate number of advisers with a psychiatric backgrounds – already in favour of and using these treatments – was much too narrow to make any material difference to ME patients. ME sufferers will not, in practice, be treated as equal partners. Things will not change until the biomedical research supported by appropriate funding, comes first"*

#### Overall assessment of the Guideline

Overall, this Guideline has accepted much that was submitted by the ME/CFS community. It was, however, limited by the narrowness of its remit: as in all reports about ME/CFS commissioned to support policy, the remit seems to have been deliberately constructed in a way that would achieve the outcome desired by the Wessely School, which meant that a significant amount of published biomedical literature was not considered by the GDG, which is to the continuing detriment of patients.

On the issue of guidance about diagnosis, there can be little doubt that the Guideline has failed those with ME/CFS (although it does recommend biomedical research and does recommend the need for informed discussion around diagnosis). The ignoring of such a significant published body of biomedical abnormalities when those abnormalities clearly assist in diagnosis is indefensible, especially as that body of evidence would be invaluable in distinguishing between ME/CFS and behavioural disorders.

On the issue of "treatment", the Guideline does highlight the need for a range of treatment options to be discussed.

Key questions remain. Given that the notion of ME/CFS as a mental disorder has been so assiduously and successfully established in the perception of healthcare professionals and agencies of the State over the last 20 years by the Wessely School (and when something is repeated often enough, it becomes regarded as fact), and given that it is perception that influences people, how much notice will healthcare professionals who are deeply mired

in Wessely School misinformation about ME/CFS take of the useful parts of the Guideline?

Will they simply ignore it and carry on as at present, with many of them dismissing ME/CFS as non-existent or else as a behavioural disorder?

Will the Medical Royal Colleges accept the Guideline? It is, by definition, only a guideline.

The Wessely School did not accept the findings of the 1994 National Task Force Report and the result was the Joint Royal Colleges' Report of 1996. What will be their response to this Guideline?

Three members of the Wessely School (Peter White, Anthony Cleare and Trudie Chalder) have already made known their plans for future CBT studies in "CFS/ME" to a group of MPs (the Gibson Inquiry) and their belief that CBT can reverse the HPA axis dysfunction seen in ME/CFS.

The Wessely School has already obtained funding for their "Biomedical Research Unit" at the Institute of Psychiatry, which is funding a project called "Emotional Processing in Psychosomatic Disorders". The Section of General Hospital Psychiatry at the IoP was advertising for a psychology graduate to work on the project, which will "*involve working across the Section on Eating Disorders and the Chronic Fatigue Research and Treatment Unit*". The closing date for applications was 13<sup>th</sup> July 2007. The job reference was 07/R68.

Applicants were informed that "*The Chronic Fatigue Syndrome Research and Treatment Unit receives about 400 referrals per year. The multi-disciplinary team assesses and treats patients with chronic fatigue syndrome and carries out research into both causes and treatment efficacy. Anorexia Nervosa (AN) and chronic fatigue syndrome (CFS) are classical psychosomatic disorders where response to social threat is expressed somatically. Aberrant emotional processing is a strong candidate as a maintaining factor for these disorders. The post holder will work under the immediate supervision of Professors Ulrike Schmidt (AN) and Trudie Chalder (CFS)*".

Other IoP job advertisements for "CFS" that can be found on the website include one for a "Cognitive Behavioural Psychotherapist" for the Chronic Fatigue Research and Treatment Unit, accountable to Professor Trudie Chalder, which requires the applicant to possess "*the ability to maintain a high degree of professionalism in the face of highly emotive problems, verbal abuse and the threat of physical abuse*" and "*an understanding of the needs of people with mental health problems*".

Will anything really change for hapless ME/CFS patients as a result of this NICE Guideline?

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**See Also:**

**19<sup>th</sup> October 2006**

**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)**

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