

## A NICE DILEMMA?

Margaret Williams 15<sup>th</sup> December 2008

### ME/CFS in the US

In the Summer 2008 issue of The CFIDS Chronicle published by The CFIDS Association of America, Anthony Komaroff, Professor of Medicine at Harvard, editor-in-chief of Harvard Health Publications and senior physician at Brigham and Womens' Hospital, Boston (who has published more than 230 research papers on ME/CFS) wrote an article listing the top ten biomedical research findings in ME/CFS.

These are summarised at <http://www.prohealth.com/library/showarticle.cfm?libid=14063> and include evidence that (1) many patients with ME/CFS have no diagnosable psychiatric disorder and that ME/CFS is not a form of depression; (2) there is a state of chronic, low-grade immune activation, with evidence of activated T cells and evidence of genes reflecting immune activation, as well as evidence of increased levels of cytokines; (3) there is substantial evidence of poorly-functioning NK cells (white blood cells that are important in fighting viral infections); (4) there is evidence of white and grey matter abnormalities in the brain; (5) there is evidence of abnormalities in brain metabolism (and evidence of dysfunction of energy metabolism in the mitochondria); (6) there is evidence of abnormalities in the neuroendocrine system, particularly in the HPA axis but also in the hypothalamic-prolactin axis and in the hypothalamic-growth hormone axis; (7) there is evidence of cognitive difficulties, especially with information processing, memory and/or attention; (8) there is evidence of abnormalities in the autonomic nervous system (including a failure to maintain blood pressure, abnormal responses of the heart rate, and unusual pooling of blood in the legs, as well as low levels of blood volume); (9) there is evidence of disordered gene expression, especially in those genes that are important in energy metabolism and in genes connected to HPA axis activity, to the sympathetic nervous system and to the immune system; (10) there is evidence of frequent infection with viruses, especially herpesvirus and enteroviruses.

Former top ME/CFS researcher at the US Centres for Disease Control (CDC), Dr Suzanne Vernon, stated on 5<sup>th</sup> December 2008 that there are now more than 5,000 peer-reviewed articles in the biomedical literature that tell us a lot about the disrupted biology of ME/CFS, about what happens to the immune and endocrine systems and to the autonomic and central nervous systems (<http://www.prohealth.com/library/showArticle.cfm?libid=14167> ). When asked why this information had not been harnessed, her reply was that there is no good reason why it has not been translated to the medical community, saying: “no-one is filling that gap between the bench research and the bedside”. She noted that ME/CFS is “ultimately described as immune dysregulation and neuroendocrine disturbance”. Dr Vernon stated that

*“infection is the key to initiating/triggering ME/CFS and the immune system is central to sustaining (it). Hormones are critical in modulating the immune response. A unifying theme is disturbed cell signalling and cell metabolism. We know that low cortisol occurs in some patients with ME/CFS. Cortisol is a critical molecule for regulating the HPA axis and is essential for modulating the immune response”.*

The results of a new study by Courjaret et al are unambiguous and straightforward: *“no direct relationship between the chronic fatigue syndrome and personality disorders was shown”* (J Psychosom Res 2009;66:13-20).

### ME/CFS in the UK

The Courjaret study will doubtless cut no ice with those who are committed ME/CFS deniers: on 12<sup>th</sup> March 2008, one such denier (Frank Furedi), in an item entitled “The seven deadly personality disorders” stated: *“Sloth has been medicalised, too. The creation of such conditions as chronic fatigue syndrome invites people to make sense of their lassitude through a medical label”*

(<http://www.spiked-online.com/index.php?/site/article/4862/> ).

As customary, when any biomedical aspects of ME/CFS are highlighted internationally, they fall on deaf ears in the UK, a case in point being the current issue of PULSE, which publishes the views of psychiatrist Dr Christopher Bass under the heading: “Need to know – somatoform disorders”. In his article, Bass specifically includes “CFS” as a somatoform disorder. PULSE is a medical trade magazine widely distributed throughout the NHS and Dr Bass is a liaison psychiatrist who, with Simon Wessely, worked at Kings College Hospital before moving to Oxford (another hotbed of ME denial, where psychiatrist Michael Sharpe worked before he moved to Edinburgh).

Bass makes unsubstantiated claims and he repeats, vacuously, the Wessely School mantra, for example: *“A cognitive behavioural therapy approach is helpful in patients with somatoform disorders because it addresses the predisposing, precipitating and perpetuating factors. CBT has been shown in many (sic) trials to be helpful in patients with medically unexplained symptoms such as chronic fatigue syndrome. Most patients with medically unexplained symptoms lasting for more than six months will have a somatoform disorder. Psychiatrists tend to use terms such as somatoform disorders while GPs and non-psychiatrist physicians use terms like chronic fatigue syndrome. The official diagnostic criteria for somatoform disorders—which include hypochondriasis, recently renamed as health anxiety to reduce stigma -- include symptoms that are caused or maintained by psychosocial factors”.*

In his PULSE article, Bass states that CBT has been shown to be helpful in “many” trials in patients with “CFS”, but even NICE itself in its now infamous Guideline on “CFS/ME” (CG53) could find only five such trials and it is not difficult to demonstrate that those five trials were methodologically flawed, a fact acknowledged by the team at the Centre for Reviews and Dissemination (CRD) at York who actually carried out the

systematic review of the literature specifically to support the work of NICE on “CFS/ME”.

### CBT/GET does not prevent death from ME/CFS

There have been a number of high profile deaths from ME/CFS in the UK. There can be few in the international ME community who have forgotten the harrowing death three years ago of 32 year old Sophia Mirza, who was forcibly but illegally detained under the Mental Health Act and who subsequently died from ME/CFS and whose autopsy revealed severe inflammation of the dorsal roots in her spinal cord. These are the sensory nerve roots, so she must have been in considerable pain for many years.

The most recent death is that of Lynn Gilderdale who died on 4<sup>th</sup> December 2008 aged 31, having suffered extremely severe ME from the age of 14. Lynn had been on a very potent combination of opioid and neuropathic pain medication via a subcutaneous pump and, sadly, her mother was arrested on suspicion of murder, so although Lynn had made a Will stating her wishes that her organs and tissues should be used after her death, her mother was in police custody and was unable to ensure that Lynn’s wishes were carried out at the time. The only organ that was retrieved immediately after Lynn’s death was the brain, and this was sent to Kings College Hospital, London (where Simon Wessely works). This exceptionally tragic case gained much media coverage, not only in the UK but also in countries including South America, the Czech Republic; Spain, Belgium, CNN Europe and Croatia.

Other recent deaths include that of Sue Firth from Yorkshire, who left two teenage sons, and Nicola McNougher from Bromsgrove, who also left two young sons. Like Lynn Gilderdale and Mrs Firth, Mrs McNougher suffered from severe ME; she was unable to tolerate the degree of pain and illness, so she went to Switzerland and chose to end her life there. Notably, Mrs McNougher was a psychotherapist; as such, she would, one imagines, have had the insight to practice cognitive behavioural techniques to her own advantage – if, that is, such techniques actually work. The evidence is that they do not work.

If CBT is so successful, where, then, was the involvement of the Wessely School psychiatrists, especially Professors Simon Wessely and Peter White, and even Professor Bass himself, in these tragic cases? Peter White is on record as affirming that CBT/GET can cure “CFS/ME” (“Is full recovery possible after CBT for CFS?”; Hans Knoop, Peter White et al; *Psychotherapy & Psychosomatics* 2007;76:171-176). Professor Michael Sharpe is also on record as asserting: “*There is evidence that psychiatric treatment can reduce disability in CFS. In some cases, it can be curative*” (“Psychiatric Management of Post Viral Fatigue Syndrome”; Michael Sharpe; *British Medical Bulletin* 1991;47:4:989-1005) and Simon Wessely himself is also on record as confirming that significantly more patients met the criteria for full recovery and that: “*seven (23%) of the CBT patients were deemed completely recovered*” (“Long-term outcome of cognitive behavioural therapy versus relaxation therapy for chronic fatigue syndrome: a five-year

follow up study”; Deale A, Chalder T, Wessely S et al; Am J Psychiat 2001;158:2038-2042). For the record, that same year (2001) Wessely is also on record as stating that CBT is not “*remotely curative*” (Editorial; JAMA 19<sup>th</sup> September 2001:286:11). Wessely does not clarify how the same intervention can result in complete recovery even though it is not remotely curative.

None of these trials, of course, included anyone who was severely affected by ME/CFS; indeed, it is entirely possible that there was not a single patient with ME/CFS in any of those studies, since most of the trials used the Oxford criteria and those criteria expressly exclude people with neurological disorders but do specifically include those with psychiatric disorders (which often have “fatigue” as a problematic symptom).

### NICE “Guidelines” are to become legally enforceable in 2009

In an attempt to justify its reliance on those few (and methodologically flawed) RCTs in its Guideline on “CFS/ME”, it is anticipated that on 11<sup>th</sup> and 12<sup>th</sup> February 2009 NICE will have to explain its reasons for doing so before a High Court Judge, more particularly so given the recent announcement that “*GPs will have to prove they follow NICE Guidelines or face the possibility of suspension, prosecution or the closure of their practice. Baroness Young, chair of the Care Quality Commission, revealed that guidance from NICE would become legally enforceable from 2009, with doctors to face tough annual checks on their compliance. Baroness Young told last week’s NICE annual conference that policing clinical guidance was set to be a key part of the CQC’s work, and admitted the commission had been handed ‘draconian’ powers by Ministers*” (PULSE: “Threat of legal action if GPs fail to follow NICE”; Nigel Praities; 11<sup>th</sup> December 2008).

Before it can start wielding these draconian powers in relation to ME/CFS patients, NICE may be required to explain to the satisfaction of the Judge why it relied upon an evidence-base of just one systematic review that comprised only 18 clinical trials, not all of which were random controlled trials (RCTs), of which just five were RCTs of CBT and a further five were RCTs of graded exercise therapy, making a grand total of just 10 RCTs, all on a patient base of just 1,448 patients who may or may not have had ME/CFS.

This should be compared with NICE’s Clinical Guideline on multiple sclerosis (CG8), which had an evidence-base that contained 80 systematic reviews of approximately 1,107 RCTs on a patient base of 89,230 MS patients. It will be recalled that the Government states there are 240,000 with “CFS/ME” in the UK, which far exceeds the number of people with MS.

Clearly there was insufficient evidence upon which to predicate a national Guideline for “CFS/ME”, so – according to the rules – NICE should have chosen the OIR option (Only in Research), which would have been the correct procedure for the Guideline Development Group (GDG) to have followed. It chose not to do so, thereby fuelling the

perception that the GDG was intent on recommending CBT/GET whatever the evidence or lack of it.

### Some failures by NICE to adhere to its own Guideline Development Manual

It is anticipated that NICE will also be required to explain to the Judge why it failed to adhere to its own Guideline Development Manual in the production of its Clinical Guideline 53 on “CFS/ME” in numerous other important areas.

For example, there was the unfortunate “misprint” in the printed version of the Questionnaire that respondent stakeholders were required to complete prior to the publication of the draft Guideline, a “misprint” that potentially skewed the answers to over one third of the questions in that the instructions were misleadingly worded and seemed deliberately ambiguous, even to a clear-thinking person, let alone an ME/CFS patient with cognitive difficulties. Perhaps expediently, the instructions for the following section (starting with question 62 and relating to “Behavioural Approaches”) changed – without guidance or notification – from choosing to tick “inappropriate” in the previous section to choosing to tick “appropriate” in that section. Without having attention drawn to this important change, few people with cognitive problems such as are found in ME/CFS would have spotted this hurdle. When notified of this, respondents were given just two days by Nancy Turnbull to correct their responses (see email sent on 3<sup>rd</sup> May 2006 at 2.26pm from Nancy Turnbull to Participants), which was an impossibility, since many completed Questionnaires were likely to have been posted back by then. NICE did not seem concerned, but perhaps this was because the outcome was a forgone conclusion, so whatever information patients submitted was of little value to the GDG, who are on record as affirming that patients’ evidence was deemed to be “biased” (J Inf 2007: 55:6:569-571) and therefore of little value, which is in direct contradiction to the Expert Patient programme rolled out in 2001 by NICE’s own paymaster, the Department of Health, in which patients with long-term diseases are to be acknowledged as experts in their own conditions).

Then there was the curious matter of NICE quietly dropping the required second consultation on the draft Guideline; although NICE instituted a nominal “consultation” period (which for some reason was over the 2005/6 Christmas/New Year break) on their wish to drop the second consultation, many stakeholders were unaware of it, even though they were required to be notified of it by NICE. The Manual is unambiguous that Guidelines in preparation that were beyond a certain stage of development (as was the case with CG53) were to continue under the old rules (which stipulated not one but two consultations). This did not happen with CG53.

### Introduction of “Consensus” for CG53

A notable innovation in the production of CG53 was the use of “consensus” by the GDG (said to be because the evidence-base was so poor). By letter dated 26<sup>th</sup> January 2006, a

NICE Communications Executive (Sarita Tamber) confirmed: *“With regard to the CFS/ME guideline, because of the lack of evidence it was decided to use formal consensus methods with the GDG. As you are aware, NICE guidelines are based on research evidence but NICE is aware of the lack of evidence on CFS/ME”*. Consensus methodology is rigorously defined, but in the case of CG53, NICE decided to use its own “modification” that was specially formulated for this particular Guideline (as confirmed by Dr Mercia Page of NICE in her evidence to the Gibson Inquiry). The person who advised the GDG about the consensus methodology to be used was Professor Rosalind Raine, Professor of Health Services Research at University College, London. Professor Raine’s published views on “CFS/ME” just happen to be that it is a behavioural disorder that should be managed by CBT/GET. Her views are to be found, for example, in the BMJ 2002:325:1082 (“Systematic review of mental health interventions for patients with common somatic symptoms”) and the BMJ 2004:328:1354-1357 (“General practitioners’ perception of CFS and beliefs about its management”).

After reviewing many of the same studies assessed by the York Review team for “CFS”, Raine’s main conclusion in her 2002 paper is that patients in secondary care with chronic fatigue syndrome may benefit from CBT.

In her 2004 paper, CBT was described as *“effective clinical management”* for chronic fatigue syndrome and she warned that GPs’ perceptions *“may be a barrier to mental health approaches”*.

The Medical Adviser to the ME Association, Dr Charles Shepherd, was one of the hundred or so respondents in the e-BMJ Rapid Responses: *“As a doctor who likes to receive balanced information in the BMJ, I was concerned at what appears to be a clear bias by the authors in favour of the psychosomatic explanation for ME/CFS”* (<http://www.bmj.com/cgi/eletters/328/7452/1354#61348> ).

Also in 2004, Raine published “An experimental study of determinants of group judgments in clinical guideline development”, Lancet 2004:364:429-437. It was funded by the MRC, so perhaps unsurprisingly, *“cognitive behavioural therapy, behavioural therapy, psychodynamic interpersonal therapy, and antidepressants for irritable bowel syndrome and chronic fatigue syndrome were selected for study”*.

Raine explains in this article that CBT *“is provided by CBT therapists who aim to modify thoughts and beliefs with the expectation that emotional and behavioural changes will follow”* and that behavioural therapies focus on *“the modification of behaviour to positively reinforce healthy behaviours”* which *“emphasise the role that social factors can play in the development and maintenance of functional somatic complaints. The goal is to identify and reinforce ‘well’ behaviours while reducing reinforcement for somatic behaviours eg. excessive diagnostic testing or restricting mobility”*.

Although not technically a member of the GDG, Professor Raine was in charge of the voting system used by the GDG and must have wielded considerable influence on the

outcome. That the “consensus” method used was in reality little more than a voting system has been confirmed by GDG member Dr Fred Nye (J Inf 2007: 55:6:569-571).

Another curious failure on the part of NICE was the outright refusal of the GDG to accept the WHO international classification of ME/CFS as a neurological disorder as listed in the ICD-10 at G93.3. This makes it all the more notable that in November 2007 the Customer Service Centre at the Department of Health sent out correspondence which stated: *“The Government has long recognised the World Health Organisation (WHO) classification of CFS/ME as a neurological disease, and this is the definition used in the final clinical practice guidelines published by NICE on 22<sup>nd</sup> August”*. That was an outright lie. It is a lie that is being perpetuated, because on 25<sup>th</sup> November 2008, the Northern Ireland Minister for Health, Social Services and Public Safety, Michael McGimpsey MLA, confidently stated: *“There have been a number of studies and reports in recent years clarifying that (ME) is a very real and debilitating neurological condition. Most recently this has been established in a NICE clinical guideline on the diagnosis and management of ME and CFS issued in August 2007”* (ref: COR/1471/2008). The NICE Guideline specifically and perversely refused to accept “CFS/ME” as a neurological condition, so it is unacceptable that NICE’s own paymasters (the DoH) should be advising constituents otherwise.

#### Failure of NICE to adhere to the Guideline Development Manual in the selection of GDG members

Perhaps the most rampant failure of procedure (and evidence of bias) is to be found in NICE’s disregard of the Manual’s directions about the required composition of the GDG. Bias may have been inevitable from the outset, because two people who were involved in the selection of the GDG members were Professor Anthony Pinching and Patricia Noons, who “advised” the GDG chairman Professor Richard Baker (who was himself chosen by Nancy Turnbull, Chief Executive of the National Collaborating Centre for Primary Care). Pinching was chairman of the CFS/ME Service Implementation Steering Group and Pat Noons was Programme Director of the CFS/ME Service Investment; both therefore had a clear interest in ensuring that CBT/GET was to be recommended by the NICE GDG. Pinching’s views are well-known: *“The clinical features are fatigue not related to on-going exertion. Over-investigation can be harmful and counterproductive to the management of these patients, causing them to seek abnormal test results to validate their illness. The benefits of graded exercise have been shown by randomised controlled trials (citing four Wessely School studies). A behavioural response is crucial. The essence of treatment is activity management and graded rehabilitation”*. (Anthony J Pinching. Prescribers’ Journal 2000:40:2: 99-106). Patricia Noons has a reputation of being unhelpful to ME/CFS patients, for example, internet notice boards contain the following: *“Patricia Noons came to one of our steering group meetings and she was less than helpful. All she was interested in was -- just get these clinics set up as soon as possible...it doesn’t matter what the patients think”*; *“Even if the Clinical Champion (CC) wanted to be different, it was almost impossible for them to be so, as the Department of Health and the CNCC (Clinical Network Co-ordinating Centres) set the*

*agenda. I have seen with my own eyes the pressure that was placed to conform to the 'rules' by the ex-coordinator from the Department of Health (Pat Noons)".* Even more tellingly, in 2004 Patricia Noons was involved with Trent Report, which was unambiguous: "*CFS/ME was not a disease as such*". She was also involved with the 2006 NHSPlus Guideline "Occupational Aspects of the Management of CFS: A National Guideline" which has been rejected by 25 ME charities as unfit for purpose. That Guideline was developed in consultation with stakeholders, DWP, NICE and Pat Noons at the Department of Health, as documented in the official Minutes of the All Party Parliamentary Group on ME held on 17<sup>th</sup> May 2007 at the House of Commons.

Possibly because of the intention that CBT/GET was to be the primary management regime to be recommended by the NICE Guideline, not a single disease-specific expert who does not subscribe to the Wessely School behavioural model of "CFS/ME" was permitted to be a GDG member (their written applications were rejected by NICE in writing).

This was in direct contradiction to NICE's own Guideline Development Manual, which stipulates the need for a balanced membership of a GDG.

NICE disingenuously claims that the GDG was representative of the wide body of professionals who deal with "CFS/ME" on a day-to-day basis, but that statement is to be challenged in the High Court.

#### Consideration of the known views of members of the Guideline Development Group (GDG)

The GDG chairman, Professor Richard Baker, a general practitioner for two days a week, had no prior knowledge or experience of "CFS/ME" whatever. Although he failed to declare it, he is described as "*a pioneering thinker in Primary Care Mental Health*". In his evidence to the Gibson Inquiry on 10<sup>th</sup> May 2006, Baker pointed to the MRC PACE trial as a good example of work being undertaken in the UK, to which Dr Ian Gibson MP responded by pointing to the criticism that has been voiced about the MRC trial and its underlying research, which some have accused of being biased towards a psychiatric model of "CFS/ME". Baker's response was telling: he reaffirmed that, after talking to the MRC trial researchers (ie. the Wessely School), he did not believe this to be the case.

Jessica Bavinton (physiotherapist) previously worked with psychiatrist Professor Peter White at St Bartholomew's Fatigue Clinic; she is involved in the MRC PACE trial (reporting to the trial's Principal Investigator, Professor White) and is a treatment leader, having written the GET manual for that trial; with Peter White, she is involved in the medical insurance industry (for example, with Scottish Provident and Swiss Re, of which Peter White is Chief Medical Officer) to carry out "assessments" on "CFS/ME" claimants, for whom she carries out "*lots*" of such assessments. Letters dated 7<sup>th</sup> August

2007 from Scottish Provident (i.e. before publication of the Guideline) are unequivocal: one is addressed to Jessica Bavinton at Conan Doyle Consulting Rooms, 2 Upper Wimple Street, London W1G 6LD and says: *“Dear Jessica, I would appreciate it if you would visit Mrs W at home. We are looking for your assessment of (her) inability to perform any occupation together with any other observations / thoughts that you may have”*. Another letter to the client says: *“We are arranging for a claims visit. This will be done by Jessica Bavinton who specialises in performing home visits of this nature”*. On 13<sup>th</sup> August 2007 the client spoke to Miss Bavinton on the telephone and made a transcript of what Miss Bavinton said: *“She told me she specialises in ME; she does ‘lots’ of these assessments for insurance companies; she refused to tell me what ‘treatments’ she advocates for ME patients; the insurance company may well fund (Miss Bavinton’s) treatments”*.

Miss Bavinton is not only a physiotherapist, she has been working for a Diploma in Human Givens therapy with the Human Givens Institute, aiming to work privately in this field. Human Givens therapy has been described by a medical practitioner as “dodgy psychobabble”. It purports to deal with “mental distress” in people who are depressed, anxious, phobic, or who have problems with addiction. In 2004, Miss Bavinton published an article called *“The mended fin”* (Human Givens Publishing, 2004: volume 11, no.1) which claims to show how the human givens approach empowers patients by promoting emotional health and clear thinking. In a TimeBank article published in 2002 (for which the web page is no longer available), Miss Bavinton said: *“I get a greater understanding of people and their responses to life, deepening my understanding of myself, but one of the most special feelings is knowing I directly contribute towards the number of people smiling in my community and that makes me smile”*.

Miss Bavinton is also in private practice working for Positive Health Strategies Ltd at King Edward VII Hospital, Midhurst, West Sussex. The Director of Positive Health Strategies is Dr Brian Marien, a psychologist and CBT therapist who for ten years worked with Peter White at the Chronic Fatigue Clinic at St Bartholomew’s Hospital, London and who is now the Clinical Lead for the Sussex NHS “CFS” service. The company information describes her as *“currently leading on a project involving the dissemination of good practice to therapists nationwide. Jessica is a Human Givens Therapist, which enables her to take a fully integrated approach incorporating management of emotional health”*

(<http://web.archive.org/web/20060118223755/www.phsmedical.co.uk/theteam.html> ).

Miss Bavinton also facilitates fee-paying instruction classes on GET for health professionals on “How to introduce GET for patients with ME/CFS as recommended in the NICE Guideline”, one of which took place at Frenchay Hospital Bristol, on 12<sup>th</sup> September 2008. This was the first phase of Graded Exercise Therapy Training. An advanced course is scheduled for December 2008. This training event was also held in Manchester in July 2008.

It is notable that Miss Bavinton was deemed by the GDG selectors to have more clinical expertise in “CFS/ME” than NHS consultants with a professional lifetime’s experience of

ME/CFS, such as infectious diseases expert Dr William Weir, neurologist Dr Abhijit Chaudhuri (jointly nominated by consultant neurologist Professor Leslie Findley and the Medical Adviser to the ME Association, Dr Charles Shepherd), paediatrician Dr Nigel Speight, consultant clinician Dr Jonathan Kerr, Professor Julia Newton and Dr Charles Shepherd. It is also notable that no representative of either the ME Association or the 25% ME Group for the Severely Affected was permitted to be a member of the GDG, and that their written applications were perversely rejected by NICE. This refusal by NICE to permit any representative from the ME Association, or from the 25% ME Group for the Severely Affected should be compared with NICE's Guideline on multiple sclerosis (CG8), where the GDG was replete with MS charities' representatives.

Consultant paediatrician Dr Esther Crawley is a leading supporter of CBT/GET and is dismissive of the regular and consistent patient reports which identify adverse effects; she is now Medical Adviser to AYME (Association of Young People with ME), which has adopted the psycho-social model and actively promotes CBT/GET. As that charity's founder, Jill Moss, was a GDG "expert co-optee", this effectively gave that charity two bites at the same cherry, whilst denying any representation from the other children's charity TYMES Trust (The Young ME Sufferers' Trust) which does not support the behavioural model of "CFS/ME".

It is a matter of record that AYME (and its sibling adult charity Action for ME) have been the recipients of a Section 64 grant, which would require the charities' promotion of CBT/GET for "CFS/ME" and would preclude their openly supporting a Judicial Review of the NICE Guideline on "CFS/ME". A S64 grant is the way in which the Secretary of State for Health, through Section 64 of the Health Services and Public Health Act 1968, has the power to make grants to voluntary organisations in England whose activities support the Department of Health's policy priorities (in this case, CBT/GET for "CFS/ME").

Dr Tony Downes is described simply as a "GP", but this is misleading, because his special interest is in Primary Care Mental Health Services. He sits on the Executive Committee of the Mental Health Research Network, Wales, alongside Professor Richard Bentall, Professor of Clinical Psychiatry at Bangor University. (Professor Bentall and his co-author, GDG member Dr Fred Nye, contributed two of the 18 trials that constituted the NICE "evidence-base"). In 2006, the Royal College of General Practitioners' Mental Health Task Group issued a curriculum statement (No.13) designating CFS as a mental health disorder that was suitable for treatment in Primary Care. (For the record, one of the authors of the RCGP's curriculum statement No.13 was Wessely's wife, Dr Clare Garada, who was a Senior Policy Adviser to the Department of Health). In addition to his involvement with WaMH (the Wales Mental Health Group in Primary Care), Dr Downes is involved with the Centre for Mental Health, whose Manifesto "Speaking our Minds" contains the following: *"The Centre will place high emphasis on mental health"* and it quotes Dr Tony Downes at the beginning: *"A well mind is a healthy person and a healthy people is a well nation. Mental wealth (sic) is key to a nation's economic health and a*

*'feel good' culture is vital to successful government. Government policy should promote mental wealth (sic) creation and distribution. Government and the people should work as co-producers of mental health and share in the resulting mental wealth".* The Manifesto quotes Wessely almost verbatim: *"Up to 50% of hospital outpatients have symptoms unexplained by modern medicine (medically unexplained symptoms, somatisation). The health and social costs resulting from wasted time through the acquisition of an unhelpful label and the inappropriate investigations and referrals for functional disorders and syndromes (ie. mental disorders) are considerable"*. (Wessely and the medical insurance industry refer elsewhere to ME as an unhelpful label, as it implies real, organic disease, so dropping the label ME was helpful for the insurance industry, and the Royal College of General Practitioners' [Wales] submission to NICE was unambiguous: *"Please use the term CFS and stop perpetuating ME"*). On page 5 the Manifesto talks about *"respect for the roles of social, economic (and) occupational problems in determining and shaping psychological disability"*.

It can thus be seen that for Dr Tony Downes to be described by NICE as simply an innocuous "GP" was disingenuous, to say the least.

Consultant neurologist Dr Richard Grunewald has a special interest in the interface between neurology and psychiatry, especially "functional" neurological symptoms. He is associate editor of "Behavioural Neurology", whose editors regard *"behavioural neuroscience"* as *"exciting and expanding fields of research"*. In 2005, he published a paper in the JNNP:2005:76:307-314 on *"predisposing, precipitating and perpetuating factors"* (a Wessely School phrase that permeates the NICE Guideline) and he stressed the need for the involvement of liaison psychiatrists (Wessely is a liaison psychiatrist). Grunewald emphasised that the term "functional" is more acceptable to patients than the terms "psychosomatic" and "medically unexplained". He also emphasised that *"functional symptoms can be classified as manifestations of somatoform disorders"* and noted that *"functional symptoms were previously called 'hysterical' "*. He went on to talk about *"feigning illness or exaggerating symptoms"*.

On 14<sup>th</sup> October 2006 at a Sheffield ME Group Conference organised by Mrs Ute Elliott, Chair of the Sheffield ME Group (who was one of the three patients on the GDG), Dr Grunewald spoke about ME. Amongst other things, he said: *"There is widespread ignorance about ME and the literature doesn't help"*. That is an insupportable assertion, because there are over 4,000/5,000 peer-reviewed papers on ME/CFS. Grunewald continued: *"When the NICE Guidelines are published I hope this will be the beginning of a sea change. ME is always the result of stress. The way that has been found most effective is to address this with a multi-disciplinary approach including graded activity programmes and addressing psychological issues. Some models (of ME/CFS) are unhelpful such as the virus model. There doesn't seem to be any doubt that for the majority of people there is not a viral trigger"*. Again, this is an insupportable statement, because there is an extensive international literature about viral involvement in ME/CFS, especially enteroviruses. Grunewald continued: *"The symptoms of ME are so physical but I'm afraid (the questioner) will not find a physical cause. I find the development of*

*the NICE guidelines exciting because they represent a change that's coming in the NHS approach".*

In 2007, Grunewald published a paper in the journal *Psychotherapy: Theory, Research, Practice, Training* ("Engagement in psychological treatment for functional neurological symptoms – barriers and solutions", 2007:44:3:354-360) in which he reiterated his views about "predisposing, precipitating and perpetuating factors" for "functional neurological symptoms", saying such symptoms are "*costly to health services and the economy*" but that "*patients with functional neurological symptoms are often hostile to the idea of psychological treatment for symptoms, which they typically attribute to an undiscovered physical cause*" (quoting Wessely School psychiatrist Michael Sharpe) and that "*it has long been recognised that patients with a long history of chronic symptoms and entrenched support systems reinforcing illness behaviour can be particularly difficult to engage*" because such patients "*were concerned that compliance would prevent further medical investigations which they felt were necessary*". Grunewald's solution was that these patients should receive psychotherapy (as the NICE Guideline CG53 recommends).

Also in 2007, Grunewald published another paper extolling the virtues of psychotherapy for people with somatoform disorders, especially for "non-neurological functional symptoms" (in which he specifically includes CFS), in which he concluded: "*Psychotherapy may be a cost-effective intervention for patients presenting with functional neurological symptoms*" (*J Psychosom Res* 2007:63:625-632). Citing his own (2005) work, Grunewald asserted: "*It is likely that some functional neurological symptoms are factitious or malingered*"; citing Michael Sharpe (2004), he asserted: "*Patients with functional symptoms are much more likely than patients with 'neurologically explained' disorders to attribute their problems to purely physical causes rather than to emotional or social difficulties*"; citing Simon Wessely (2002), he asserted: "*Functional symptoms are costly to the health service and to the economy*".

Grunewald's view about the estimated cost-effectiveness of his favoured psychotherapy would have endeared him to NICE: "*the described therapy is inexpensive, especially because cost savings from withdrawal of inappropriate medical treatment were not factored into the estimation of cost-effectiveness*".

Dr William Hamilton is listed as a GP and researcher. However, he is a long-standing collaborator with Professor Peter White (*Family Practice* 2005:22:383-388; *JRSM* 2004:97:571-575) and is a leading proponent of CBT/GET for "CFS/ME", which he regards as psychogenic. He is Chief Medical Officer of two medical insurance companies (Exeter Friendly Society and Liverpool Victoria, which took over Permanent Health); LV in particular actively discriminates against "CFS/ME" patients. As such, he was unfit to sit on the GDG: the Guideline Development Manual requires that anyone with vested and conflicting interests must declare those interests before being appointed to a GDG, so it is anticipated that the Judge will enquire whether Dr Hamilton failed to declare such interests, or whether he did so, but the chairman (Professor Richard Baker) failed in his duty by permitting Hamilton to sit on the GDG.

Hamilton's views about CFS are unequivocal: *"The higher number of GP consultations in patients who develop CFS can be explained by perceiving symptoms more readily as illness. Cognitive behavioural therapy, which addresses beliefs about symptoms and illness, in particular those that can block recovery, is the only treatment shown to be helpful. We consider that more emphasis should be given to this area, both for funding treatment and for research on CFS"* (British Journal of General Practice 2001:51 (468):553-558).

Hamilton's conclusions were attacked by Professor JC Murdoch in the BJGP, to which Hamilton took exception. He replied by 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).

In an earlier paper, Hamilton stated that his information came from an insurance company records. Contrary to the international evidence, his own study found no specific viral or immunological explanation for CFS and he concluded: *"abnormal illness behaviour is of greater importance than previously recognised"* (JRCP Lond 1998:32:44-48).

It seems to be the case that Dr Hamilton was head-hunted to be a member of the GDG under the chairmanship of Professor Baker specifically because of his published views on CFS/ME. This is clear from the R&D (Research and Development) annual reports by NHS organisations in England for 2006:

*"Dr Hamilton's CFS/ME work has generated publications that have been widely read and his work generated the invitation to join the NICE guideline development group for the treatment of CFS/ME which is due to report in 2007"* (<http://www.nrr.nhs.uk/2006AnnualReports/Section2A-2E.asp?O=582>).

Community Dietician Judith Harding was a member of the CNCC Collaborative 2004 – 2006, CFS/ME Service Investment Programme 2004 –2006, "Enabling People": Implementation of Clinical Service Developments for Multi-Disciplinary Chronic Disease Management, Peninsula Medical School, CFS/ME Programme (Clinical Lead: Professor Anthony Pinching; Programme Director: Patricia A Noons).

Dr Fred Nye, Clinical Champion of the Liverpool "CFS" Clinical Network Co-ordinating Centre, achieved notoriety in 2005 when an advertisement for "therapists" to work in his Centre caused justified offence. The advertisement informed applicants patients with "CFS/ME" 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).

In 2001, Nye published his view in the BMJ (2001:322:387-390) that "CFS" patients "*develop a strong physical perception of the condition*" and that "*Extensive research has failed to identify any serious underlying pathology*". Such a statement is easily shown to be erroneous. Nye continued: "*Reduction in activity results in cardiovascular and muscular deconditioning, which exacerbates symptoms. We have developed a treatment for CFS (that) involves educating patients about the medical evidence of physical deconditioning*". The article re-iterated the take-home message: "*No serious underlying pathology has been identified in patients with CFS. Cognitive behaviour therapy targeted at changing illness beliefs and graded exercise helps some patients*". However, Nye was compelled to concede that an intention to treat analysis showed that 32% of patients still complained of fatigue one year later.

In a follow-up study published in the British Journal of Psychiatry in 2004:184:142-146, Nye had not changed his beliefs about CFS/ME. Despite his own acknowledgement in 2001 that 32% of patients in the trial still complained of fatigue at one year, the 2004 study stated that at one year, "*treated patients showed significantly greater improvement in measures of fatigue*". He was obliged to record that "*One patient who had received treatment died by suicide in the follow-up period (but) it seems unlikely that this was an adverse reaction to the treatment*". Nye also had to record that patients who withdrew from treatment were not followed up. Nevertheless, his take-home message was: "*Providing patients with physiological explanations of symptoms of chronic fatigue syndrome to encourage graded exercise produces long-term benefits in outcome*".

Both papers used the Oxford criteria, so no conclusions can be drawn about the efficacy of Nye's interventions for people with ICD-10 ME/CFS.

Of relevance is the fact that Nye failed to make a full disclosure of competing interests to the extent that the independence of the GDG's decision-making process was called into question: two of his research projects were cited in the York Systematic Review and were approved of by himself as a member of the GDG, so in effect Nye was supporting and voting for his own work. Not declared either was the fact that two of Nye's co-authors are currently in receipt of a £824,129 MRC grant for "CFS/ME" research.

It is clear from his letter in the Journal of Infection (2007:55:6:569-571) that Nye is actively hostile to patient opinion, and there are disturbing reports of abrasive treatment of patients attending his CFS/ME clinic. For someone who is a committed Anglican lay preacher (at St Faith's, Great Crosby, Liverpool, where his wife, Mrs Linda Nye, is the parish Child Protection Officer), this is especially disquieting.

Ms Amanda O'Donovan is a clinical psychologist at St Bartholomew's Hospital. In March 2005 she was appointed CNCC co-ordinator for the CFS/ME Centre based at Barts, headed by Professor Peter White; as Lead Clinical Psychologist, she is heavily involved with the psychosocial model of "CFS/ME" and she promotes the use of CBT/GET for "CFS/ME". She has attempted to justify its use by insisting that CBT is used in other "physical" conditions such as stroke, diabetes, chronic pain and cancer (<http://health.groups.yahoo.com/group/IMEGA-e/message/24450> ). However, Cancer Research UK has confirmed in writing that they are unable to accept that this is the case. In the other conditions mentioned by Ms O'Donovan, CBT is used as adjunctive support, not as the primary (and only) management intervention as is the case in ME/CFS.

Dr Alastair Santhouse is a Consultant Liaison Psychiatrist who works with Simon Wessely (the foremost proponent of the psycho-social model of "CFS/ME") at the Chronic Fatigue (*sic*) Research and Treatment Unit, Kings College Hospital, London. His Head of Service is Professor Trudie Chalder. Santhouse failed to declare that his employer (Trudie Chalder) is in receipt of part of a £2 million MRC grant for the PACE trial that is investigating CBT/GET for "CFS/ME", nor did he declare that his employer's research papers constituted 11% of the NICE "evidence-base" in alleged support of CBT/GET. His employer would thus be a prime beneficiary of a NICE recommendation of CBT/GET for "CFS/ME". In 2004, Santhouse published "The 10 chronic fatigue syndrome commandments" (Doctor, 26<sup>th</sup> February 2004) in which he stated: "*CFS is the accepted name among professionals but many patients still prefer the name ME. Attribution of illness to a purely physical cause appears to predict a poorer response to treatment. The best research evidence is for CBT and/or a graded exercise programme*". In 2005, Wessely wrote a Foreword for Santhouse ("Fatigue as a Window to the Brain"; Psychological Medicine 2005:337:a2331). It is noted that Santhouse sponsored Simon Wessely's cycle ride to Paris in 2007. It may also be noted that Santhouse is on record as asserting: "*Psychiatry is the noblest branch of medicine*" and that he states of himself: "*At times I am carried away by the nobility of my calling*" (BMJ 2008:337:a2331).

Dr Julia Smedley is an Occupational Health Physician whose main interest is in occupational risks to healthcare workers. Her publications include "A survey of the delivery and uptake of influenza vaccine among healthcare workers" (Occup Med 2002:52:271-276); "Respiratory illness in agricultural workers" (Occup Med 2002:52:451-459); "Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity and health service use among residents" (BMJ 2006:333:1241) and "Influenza immunisation: attitudes and beliefs of UK healthcare workers" (Occup Environ Med 2007:64:223-227). Wessely School psychiatrist Professor Michael Sharpe is very active in the world of Occupational Health and Insurance Medicine and his views permeate the world of Occupational Medicine (i.e. that ME is a "pseudo-disease" that can be "cured" by CBT and that ME sufferers who "*refuse to accept the stigma of mental illness remain the undeserving sick of our society and health service*").

As the Guideline Development Manual stipulates that GDG members must be disease-specific experts, it will be interesting to hear NICE's explanation to the Judge as to why Dr Smedley was deemed to have more clinical expertise in the disorder in question than, for example, Dr William Weir, Dr Jonathan Kerr, Dr Abhijit Chauduri, Professor Julia Newton or Dr Charles Shepherd.

However, Dr Smedley was involved with the production of the Department of Health's NHSPlus Report "Occupational Aspects of the Management of Chronic Fatigue Syndrome: A National Guideline" published in October 2006, whose Guideline Development Group included Professor Trudie Chalder and whose "external assessors" were psychiatrists Professor Michael Sharpe and Professor Peter White. This National Guideline was based on the behavioural model of "CFS/ME" and made exaggerated claims for the effectiveness of CBT/GET in returning people with "CFS/ME" to employment. This exaggerated claim was based on six studies, three of which were co-authored by Trudie Chalder and one was co-authored by Peter White. The National Guideline was severely criticised to the extent that 25 UK ME/CFS organisations signed a joint Statement condemning it as unfit for purpose. Its conclusions were comprehensively discredited by an authoritative American systematic review, which concluded: "*No specific interventions have been proved to be effective in restoring the ability to work*" (SD Ross et al. Arch Intern Med 2004:164).

Dr David Vickers, Clinical Lead, children and young people with CFS/ME service, was the second paediatrician on the GDG (the other being Dr Esther Crawley). It is notable that both Drs Crawley and Vickers are known supporters of the psycho-social model of "CFS/ME" and that the UK's senior paediatrician whose 25 years' experience afforded him unique expertise in paediatric ME/CFS and who was a member of the 1994 UK Task Force on ME/CFS but who does not support the psycho-social model (Dr Nigel Speight) was not permitted to be on the GDG. Dr Vickers holds the post of Registrar to the Royal College of Paediatrics and Child Health (RCPCH). In his Application Manifesto for the post of Registrar, Vickers wrote: "*The most important role is supporting the President and other Senior Officers*". The views of the RCPCH bear little relationship to children and young people with ME/CFS. The College's view of ME/CFS is that it is a behavioural disorder. The RCPCH report, in the production of which Dr Vickers was a Delphi participant ("Evidence-based Guidelines for the Management of CFS/ME in Children and Young People", published in December 2004) emphasised behavioural interventions: "*Children and young people with CFS/ME should be considered for graded exercise or activity programmes*" and contributors referred to the "*emotional dimensions of the illness*" and stated: "*The overarching aim of CBT is to help patients modify their behaviour for their own benefit*".

Gillian Walsh is a nurse who is the Network Co-ordinator for the Manchester "CFS" Centre. She, as is Miss Bavinton, is involved with Human Givens Therapy and whilst she was on the GDG was working towards a diploma from the Human Givens Institute. She has a private Human Givens practice in Manchester, which is described as her "*helping*

*career*". She uses the letters " M.FETT" after her name, which stand for the "Fellowship of Eclectic Talking Therapists". This is explained as being a "*professional body for ethical counsellors and hynotherapists who use techniques as best suits the client*". She is referred to as "*an experienced counsellor and psychotherapist*" and helps patients to reach their goals and aspirations. She is also a reflexologist (with a Diploma from the Centre for Advanced Reflexology) and a hypnotherapist. Her employer at the Manchester CNCC is liaison psychiatrist Dr Damien Longson, chairman (replacing Professor Anthony Pinching) of the CFS/ME Clinical Network Co-ordinating Centres Collaborative. He is also the Lead for audit of these Centres, in collaboration with GDG members Dr Esther Crawley and Dr Fred Nye, together with Professor Peter White.

Carol Wilson is Lead Occupational Therapist for the Cornwall CFS/ME Service and is CFS/ME Network Co-ordinator for South West Peninsula. The Lead consultant of the Cornwall CFS/ME Service is Professor Anthony Pinching.

Dr Philip Wood has been a consultant immunologist at Leeds since January 2002. He failed to declare that he was a member (2004-2006) of the CFS/ME Service Investment Programme (whose Clinical Lead was Professor Anthony Pinching and whose Programme Director was Patrician Noons). He also failed to declare that he was a member (2004 – 2006) of the CNCC Collaborative. His main interest is in adult and paediatric allergy, but he has an interest in "chronic fatigue" (note: this is not the same as ME/CFS). He has published one study on allergic disease in children (Eur J Pediatr 2005;164:741-747). He is a clinician in the Leeds & West Yorkshire CFS/ME Service, whose 2008 booklet "Goal Setting" says the following: "*CFS/ME is a diagnosis that does not fit under one specific medical speciality. Complex referrals may be seen initially by a physician and liaison psychiatrist. Unfavourable prognosis is associated with prolonged duration of symptoms (and) untreated beliefs around the need for purely physical treatment. The Leeds & West Yorkshire CFS/ME Service finds that if the practitioner can demonstrate why a diagnosis has been made, then that patient will start to engage in taking some responsibility in managing the effects of CFS/ME. The Leeds & West Yorkshire CFS/ME Service has three components: 1) Medical assessment by Dr Philip Wood; 2) Biopsychosocial assessment and considerations of interventions in liaison psychiatry led by Dr Hiroko Akagi and 3) Therapy Services, led by Sue Pemberton, occupational therapist. We all need goals to move forward in our lives. Without specific goals we can feel demotivated. This can have an impact on how we feel about ourselves. Setting and working towards a goal releases energy. How do you feel when you have no goals? The therapist within the team will help you with goal setting*". The "Useful Books" list contains only books by Wessely School members (Trudie Chalder's "Coping with Chronic Fatigue", which has nothing to do with ME/CFS; "Overcoming Chronic Fatigue" by Trudie Chalder & Mary Burgess; and a book by psychiatrist Michael Sharpe, co-authored by Frankie Campling, a Wessely School supporter). Bearing in mind that many ME/CFS sufferers are professional people, such a superficial approach is an affront to their intelligence and cannot help people deal with

vertigo, cardiomyopathy, pancreatitis, dysautonomia, adrenal insufficiency or vasculitis, all of which are well-documented key features of ME/CFS.

None of these GDG “experts” had anything to offer people with ME/CFS, but everything to offer the pre-determined agenda of the NICE Guideline CG53 to recommend CBT/GET across the nation. None of them is a “*disease-specific*” expert as required in the Manual, but no expert dissenting voices were permitted to be GDG members. The result is the recommendation of inappropriate behaviour-modifying interventions for people with a serious multi-system disorder who are unable to benefit from the recommended interventions.

It is the case that the Wessely School were unsuccessful in obtaining their intended outcome (i.e. that ME does not exist as a nosological disorder and that CFS – onto which they patronisingly tagged ME to read CFS/ME – is a somatoform disorder) in both the 1994 National Task Force Report and also in the 2002 Chief Medical Officer’s Working Group Report on CFS. Indeed, it is reported that Peter White was jubilant when he believed he had been successful in covertly removing from the latter Report the provision for children to receive home tuition (after it had been agreed), and that he argued against the need for the final meeting before the Report’s publication. However, it is reported that the chair (Professor Allen Hutchinson) was persuaded to permit the final meeting (which Peter White believed had been cancelled), at which the provision for home tuition that Peter White had removed was re-instated. It is a matter of record that five Wessely School members were so incensed that they did not get their own way that they “walked out” and refused to sign up to the final Report. Those five members were psychiatrists Professor Peter White; Professor Elena Garralda and Dr Anthony Cleare; Trudie Chalder (fatigue therapist), and Dr Alison Round (a community physician and co-author with GDG member Dr William Hamilton).

It seems irrefutable that, having been thwarted twice in the past, in the production of the NICE Guideline on “CFS/ME”, the Wessely School were ruthlessly determined to be successful to the extent that every single professional member of the GDG was carefully selected and could be relied upon to support the somatoform model of “CFS/ME” and the recommendation of CBT/GET.

NICE’s explanation for this unequivocal bias is eagerly awaited. That NICE deliberately and intentionally excluded every single ME expert in the UK from membership of the Guideline Development Group is a scandal that will hopefully be exposed under the spotlight of a High Court Judicial Review.

There were many other failures of the GDG to adhere to the Manual which the Judge may choose to address at the High Court Hearing, not least the GDG’s failure to identify and define the disorder to which the Guideline purports to relate.

## Conclusion

No-one could have summed up the situation better than Hayley Klinger in a letter to The Times Online on 11<sup>th</sup> December 2008: *“Despite thousands of medical research papers showing immunological, neurological, endocrine, cardiac and gene expression involvement in ME, it is thought of as an illness of fatigue and even called chronic fatigue syndrome by the media and some doctors”*.

And as Hilary Patten so aptly wrote in a letter to The Sun on 12<sup>th</sup> December 2008: *“American research has proved ME is caused by a viral and bacterial infection. But over here, health guidelines drawn up by psychiatrists, only allow psychological interventions for sufferers. It is an absolute scandal”*.