

The involvement of the PACE Trial Principal Investigators and the Director of the Clinical Trials Unit with the Department for Work and Pensions

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Following publication of the PACE Trial results and mindful of the fact that the Department for Work and Pensions (DWP) was a co-funder of the trial, it may be salutary to reflect afresh on the involvement of Principal Investigators Professors Peter White and Michael Sharpe and the Director of the Clinical Trials Unit (Professor Simon Wessely) with the DWP.

The extracts below are from recent DWP/Atos Healthcare Training Programmes for medical practitioners carrying out assessments on State benefit claimants with ME/CFS.

They graphically illustrate the pervasive influence of the Wessely School's biased beliefs about ME/CFS at the Department for Work and Pensions and the degree of involvement of Professors White, Sharpe and Wessely (a depth of involvement which may indicate that in setting up the PACE Trial, they were not open-minded clinicians seeking to help patients but rather that the PACE Trial was mounted (to quote an influential expert in appraisal of biases in medical research): ***"not to answer a question, but in order to demonstrate a pre-required answer"*** (Why most published research findings are false. J.loannidis; PloS Medicine 2005:2:8:e124 – note that this article by Ioannidis is the most down-loaded in the journal's history).

MEDICAL SERVICES provided on behalf of the Department for Work and Pensions

Training and Development: Continuing Medical Education Programme: Chronic Fatigue Syndrome – Guidelines for the Disability Analyst Version 4; April 2009. Updated by Dr Peter Ellis. Version 1 written by Dr Tony Fisher.

"The authors and Medical Services gratefully acknowledged the contribution of the authors (Professor S Wessely, Professor PD White and Professor M Aylward) of the enclosed articles

and their kind permission to reproduce them in this module. In addition the author would like to express his gratitude to Dr P Dewis for his helpful comments and suggestions”.

For more information on Professor Mansel Aylward and his stance on ME/CFS, see pages 428 ff at <http://www.meactionuk.org.uk/magical-medicine.htm>

Together with (then) Dr Aylward, Dr Peter Dewis from the Disability Living Advisory Board authored the Disability Handbook before Dewis became Chief Medical Officer at UNUMProvident in July 2000 after 16 years at the Department of Social Security (now the DWP). In 2002, Dewis wrote about the patients whose claims management posed difficulties for UNUMProvident; in the company’s Report “Trends in Health and Disability”, he stated:

*“I have commissioned a number of papers from **leaders within the medical profession whose disciplines are particularly relevant to those people...whose claims most frequently pose us difficulties in their management.***

“A paper from Michael Sharpe has reviewed the developments, not only in chronic fatigue syndrome, but also the range of disorders where the symptoms experienced by individual patients appear to be out of proportion with the physical findings or objective evidence of disease.

“Mansel Aylward who is Chief Medical Adviser to the Department of (sic) Work and Pensions has set out the current trends in government strategy relating to both health and social security.

“My intention would be for this report to be repeated on an annual basis and so become an authoritative and informative document on the current state of medical thinking on those issues which are of greatest importance to us.

*“Dr Lipsedge (and) Dr Sharpe have identified the importance of cognitive behaviour therapy of (sic) influencing the outcome in ...chronic fatigue syndrome. **This again represents a challenge in ensuring that people are directed towards this approach**”.*

Thus the interest of the DWP and the insurance industry in ME/CFS is clear: it is a disorder that poses “difficulties” for them, so it seems it must be “eradicated”, preferably by those who already work for these agencies. It appears that it is those commercial interests, not the plight of sick people, which

are paramount. It also seems that, as part of the triple strategy of the “CFS” clinics and the NICE Clinical Guideline on “CFS/ME”, the PACE Trial was the ideal vehicle to remove the “difficulties”.

Extracts from the DWP Medical Services Training and Development on Chronic Fatigue Syndrome Guidelines:

“This training has been produced as part of a Continuing Medical Education programme for Health Care Professionals (HCPs) approved by the Department for Work and Pensions Chief Medical Adviser to carry out assessments”.

*“...it must be remembered that **some of the information may not be readily understood without background medical knowledge and an awareness of other training given to Health Care Professionals**”.*

*“**The series is designed to encourage consistency in our approach to complex conditions**, provoke reflection on our own perception with regard to them, **and foster awareness of current medical thinking**” (ie. the Wessely School’s thinking).*

*“**Chronic fatigue syndrome (CFS) is a disorder, or group of disorders, which continue to cause considerable difficulties for clinician and disability analyst alike** (no mention of difficulties caused to patients). **Since the terms ‘myalgic encephalomyelitis’ and ‘post-viral fatigue syndrome’ both carry implications relating to causation, the generic term CFS is preferred**”.*

*“**The purpose of this module is to encourage Health Care Practitioners working in disability analysis to adopt a common approach to this difficult and complex illness**”.*

In the first self-assessment exercise, Medical Services assessors are instructed to read the questions and then tick one of the boxes, one of the questions being: “**Most cases of chronic fatigue** [sic] **are attributable to abnormal illness behaviour**”. “Chronic fatigue” is not the same as “CFS/ME”, but even if applied to “chronic fatigue”, this is a Wessely School assertion that is not supported by clinical evidence: when carefully examined and diagnosed, patients with many organic illnesses have chronic fatigue, including patients with cancer, COPD, thyroid disease, multiple sclerosis, Parkinson’s Disease, liver disease, TB, and many viral illnesses, none of which disorders can be categorised as “abnormal illness behaviour”.

The training programme then presents a case study: *“Mrs D is a 42-year old woman. You have been asked to assess her and provide a report for a non-medical decision maker. She has completed a claim form herself, amplifying it with several additional pages of hand-written text and a pamphlet describing features of ‘ME’ ”.*

Such loaded wording immediately introduces denigration, disparagement and bias into the training programme for DWP assessors.

The Guidelines for DWP assessors state that anhedonia (loss of any pleasure/interest in life) is commonly present in CFS, which is erroneous, as it is not present in ME/CFS. In 1991, John Wiley & Sons published “Post-Viral Fatigue Syndrome” edited by Professors Rachel Jenkins and James Mowbray; in her own contribution, Professor Jenkins, a Principal Medical Officer at the Department of Health and Director of the WHO Collaborating Centre for Mental Health at the Institute of Psychiatry, made it clear on page 242 that there is no anhedonia in ME.

The DWP Training Guidelines on CFS continue: *“At one end of the scale are the (uncommon) cases where there is a very clear history of the sudden onset of fatigue after a proven viral infection, such as Epstein Barr virus; at the other, cases strongly associated with current or pre-existing psychiatric disorder. **In fact, most patients with CFS will also meet the criteria for a current psychiatric disorder**”* (citing Simon Wessely and Trudie Chalder).

“From the point of view of the disability analyst, by the time an individual has reached the stage of requiring a functional assessment the diagnosis is likely to have been in place for some time and behaviour patterns firmly established in the minds of the claimant and his medical attendant”.

The claimant’s medical attendant may be entirely correct in his/her management, but this implied criticism has long been a feature of the Wessely School’s dismissal of “naive” clinicians who do not subscribe to their own beliefs about ME/CFS: for example:

“Suggestible patients with a tendency to somatise will continue to be found among sufferers from diseases with ill-defined symptomatology until doctors learn to deal with them more effectively....It has been shown (by whom?) that some patients have always preferred to receive, and well-meaning doctors to give, a physical rather than a psychological explanation...such uncritical diagnoses may reinforce maladaptive behaviour” (Old wine in new bottles: neurasthenia and ME. Simon Wessely. Psychological Medicine 1990:20:35-53) and *“The prognosis may depend on maladaptive coping*

strategies and the attitude of the medical profession” (The psychological basis for the treatment of CFS. Wessely S. Pulse of Medicine, 14 December 1991:58).

The DWP Guidelines continue:

“It will almost always be appropriate to assess the claimant’s mental state, and in the case of IB PCA (Incapacity Benefit Personal Capability Assessment) and ESA (Employment and Support Allowance), to complete a mental health/function assessment”.

“The combination of cognitive behavioural therapy (citing Wessely and Chalder) and graduated exercise (citing Peter White) is at present the mainstay of treatment”, “treatments” which have been shown to be ineffective in numerous international reports and in surveys carried out by ME/CFS charities, as well as in the UK FINE and PACE Trials themselves.

The Training Programme then instructs DWP assessors to read only a heavily psychiatrically biased reading list (with no mention of any of the biomedical evidence on ME/CFS), including “Occupational aspects of the management of Chronic Fatigue Syndrome: A National Guideline” (2006) in which Professors White, Sharpe and Chalder were instrumental; the NICE Guideline CG53 (2007) which recommends only CBT/GET as the primary intervention, and the 1996 report on CFS of the DWP Chief Medical Adviser’s “Expert Group” which included Dr John LoCascio (Medical Director of UNUMProvident insurance company), Professor Anthony Pinching, Dr Peter White, and Dr Charles Shepherd, (Medical Adviser, ME Association).

This “Expert Group” advised that: **“The Chief Medical Adviser** (at that time, Dr Mansel Aylward) **is very anxious to ensure consistency of medical advice which is based on the prevailing consensus of informed expert opinion on this subject** (ie. on the advice of Simon Wessely, Peter White and Michael Sharpe, again with no mention of the substantial biomedical evidence-base). *“The following interests and disciplines were represented: academic research into CFS, clinical interest in the field (from psychiatry, neurology, infectious diseases and general practice), occupational medicine, the insurance industry...and the Disability Living Allowance Board”.*

Key recommendation of this “Expert Group” were: *“The sooner appropriate management was started, the better the prognosis”* and *“Activity should be increased in a managed, step-wise manner”.*

The “Expert Group” agreed that: ***“Recovery should not necessarily be equated as getting back to the same condition as before the illness”*** (which seems to be a portender of the PACE Trial results). “Recovery” is defined in The Penguin English Dictionary as *“To regain health after sickness”*, which means restoration of full health after sickness; the term “recovery” is not open to idiosyncratic interpretation by the DWP or its “Expert Group”.

The “Expert Group” recommended that its report to the DWP’s Chief Medical Adviser should be widely available to all those with an interest in CFS (ie. throughout the NHS).

At the end of the Training Programme, assessors were asked to tick more boxes and informed that *“If the objectives have been achieved, you should have no difficulty in responding correctly”*: one of the tick-box choices was: *“The combination of cognitive behavioural therapy and antidepressants should be the mainstay of treatment”*.

The signed, completed form (together with the person’s GMC or NMC registration number) was to be returned to the *“Medical Manager at your Medical Services Centre”*.

The 2010 version

The Foreword to the DWP Medical Services 2010 version (Training and Development: Chronic Fatigue Syndrome [CFS] and Fibromyalgia Learning Set Continuing Medical Education) states: *“The training has been produced as part of a Continuing Medical Education programme for Health Care Professionals (HCPs) approved by the Department for Work and Pensions to carry out assessments”*.

For the DWP Medical Services to conflate “CFS” and fibromyalgia is in breach of the WHO ICD-10 classification which classifies FM as a separate disorder from “CFS/ME” at M79.

This version is particularly prescriptive and has become even more didactic: it ensures that only one message about ME/CFS and FM (the Wessely School’s message) is delivered and received:

“A Learning Set is dedicated to the sharing of team knowledge, and must be conducted using internal sources only. External speakers are not acceptable at these events”. (This is knowledge control, which is unacceptable ethically, morally and academically).

“This Learning Set is designed to encourage competency based on the subject of CFS and FM and the functional effect of these conditions on the claimant”.

“The learning aims are defined and the ‘manager’ of the Learning Set is encouraged to ensure that these are kept prominently to the fore-front throughout the event, keeping them in view of all participants”.

“The only absolute givens are that the essential content is adhered to and the Learning Set aims achieved”.

There is a requirement to ensure that *“verification of the learning aims have been satisfied”*.

Although nominally a DWP Training and Development Programme for assessors, the DWP Medical Services Guidelines state: *“It is also necessary to demonstrate that the outcomes of the Learning Set satisfy the requirements of the Continuing Professional Development Programme for Atos Healthcare”*.

This sounds disturbingly like cult indoctrination and it is little wonder that so many people with ME/CFS report that their assessment(s) by DWP and Atos-trained assessors are traumatic experiences.

In February 2011, the BMJ published an article by Margaret McCartney about Atos Healthcare (Well enough to work? Increasing numbers of people previously deemed medically unfit to work are being taken off state benefits after assessments by a doctor. BMJ 2011:342:d599).

McCartney’s article was enlightening: Atos Healthcare is a *“French information technology firm, which is subcontracted to the Department for Work and Pensions to provide work capability assessments. In November last year (2010) Atos announced a three year extension to its contract with the department, worth £300 million, to ‘support the UK government’s welfare reform agenda’. Atos is the sole contractor....A quick glance at internet discussion forums suggests widespread dissatisfaction from people who have been assessed”*.

“The adverts for Atos, however, consist of a smiling, badged professional saying, ‘Getting home on time has become part of my daily routine’. The lack of on-call duties and the 9-5 office hours were also the major advantage plugged at the evening, where nurses and doctors working for Atos helped to promote joining the company”.

From her attendance at an Atos recruitment evening, McCartney reported:

“The message from the recruitment evening was quite clear. We were told: ‘You are not in a typical caring role.... We don’t call them patients... We call them claimants’. Training is provided for each type of benefit examination. Its length...depends on experience but is generally up to five days of classroom training, followed by sessions accompanied by a trainer that are audited afterwards”.

“Full time doctors can earn £54,000 as basic salary plus various benefits including private healthcare. Sessional doctors work a minimum of four sessions a week....The application forms for sessional doctors state that ‘10 DLA domiciliary visits per week would earn £40,211.60 per annum. Five LCWRA cases (limited capacity for work related activity) per session, for six session per week, would earn £62,883.60 per annum”.

“From the recruitment evening, it was clear that the medical examination consisted of a computerised form to be filled in by choosing drop-down statements and justifying them”.

“Is the current method of assessment fit for purpose? There is a queue of people who think not. ‘Citizens Advice Scotland (CAS) is extremely concerned that many clients are being found fit for work...despite often having severe illness and/or disabilities. Our evidence has highlighted the cases of many clients with serious health conditions who have been found fit for work, including those with Parkinson’s disease, multiple sclerosis, terminal cancer, bipolar disorder, heart failure (and) strokes’. The report found that clients often ‘felt hurried in their assessment and that the healthcare professional was ignoring the answers they were providing to the questions in the assessment. There was a general feeling that the assessor made little eye contact with the claimant and spent most of the assessment entering information into their laptop’. This tallies with the recruitment evening, when it was made clear that efficiency with entering details into the computer system was a stipulation of employment”.

“The Department for Work and Pensions says... ‘It’s unfair to suggest that the system isn’t working....If a decision is overturned at appeal, it does not necessarily mean that the original decision was inaccurate...’. However, this doesn’t really deal with the problem that the healthcare

professionals doing the assessment are not...forwarding sufficient evidence to enable reliable decisions”.

“At the meeting I asked how it was possible to know the variation in symptoms that a patient may have during a one-off assessment. I was told that this could be ‘difficult’ but this was....a ‘functional assessment’ ”.

“The Citizens Advice Bureau...wants ‘better accuracy’ in reports. But how can this be achieved when funding is devolved to Atos with no routine access to detailed specialist or general practice based information and opinion?”.

Returning to the DWP’s Medical Service 2010, its “Learning Aims” are:

- (i) to define CFS and FM (perhaps more accurately, to “re-define” them as functional disorders)
- (ii) to consider *“possible causes and functional effects of these conditions”*
- (iii) to *“consider current management and treatment guidelines (ie. NICE CG53)*
- (iv) to *“consider benefit issues in children and adults with CFS or FM”* and
- (v) to *“consider effects of these conditions on work/occupation and effect of work on these conditions”*.

“It is essential that the Learning Set achieves its learning aims and covers the essential content....It is recommended that all attendees are reminded of the purpose of the Learning Set, the responsibilities of all those present and the learning aims reinforced”.

During training discussions, participants must explore the following factors:

- *“Ways in which relevant functional problems can present in a claim”* (neither ME/CFS nor FM is a functional disorder)
- *“The likely functional effects of CFS and FM”*
- *“Attitudes amongst the team towards the condition”*

· “The claimant’s perceptions of their disability and barriers to recovery” (such a “barrier” is cited as belonging to a support group).

“The challenge for the facilitator is to ensure that all participants are engaged and prepared to commit to the consensus conclusions” -- in other words, 100% commitment and absolute adherence to the Wessely School model of “CFS/ME” is obligatory on the part of all DWP/Atos Healthcare assessors dealing with patients with ME/CFS.

Would such indoctrination be part of a training programme to assess those with other classified neurological conditions such as multiple sclerosis or Parkinson’s Disease?

These DWP training programmes for assessors are extremely disturbing because, as Jason et al have pointed out in a compelling article looking at kindling as the underlying mechanism for the symptomatology seen in ME/CFS, these patients have evidence of extremely serious pathology (An Aetiological Model for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. Neuroscience and Medicine 2011:2:14-27).

Jason et al posit that kindling occurs when an organism is repeatedly exposed to an initially sub-threshold stimulus resulting in hypersensitivity and spontaneous seizure-like activity, and that in ME/CFS patients, chronically repeated low-intensity stimulation due to an infectious illness might cause kindling of the limbic-hypothalamic-pituitary axis and that, once this system is charged or kindled, it can sustain a high level of arousal with little or no external stimulus, which in turn could lead to hypocortisolism seen in ME/CFS patients, and that seizure activity may spread to adjacent structures of the limbic-hypothalamic-pituitary axis in the brain, which might be responsible for the varied symptoms that occur in ME/CFS patients.

Jason et al cite impressive supporting evidence, for example, Broderick, Fletcher and Klimas et al *“applied network analysis to cytokines in patients with ME/CFS and healthy controls, and outcomes were consistent with a latent viral infection (ie. attenuated Th1 and Th17 immune responses, an established Th2 inflammatory milieu, and diminished NK cell responsiveness)...Chronic cortisol deficiency can cause over-production of the pro-inflammatory cytokine interleukin-6 (IL-6), which has been associated with symptoms of ME/CFS. Lower cortisol, as well as an over-active sympathetic nervous system, could be responsible for the ejection fraction decreases (fraction of blood pumped out of the ventricles per heartbeat) and lower cardiac output among patients with ME/CFS....Because of the Th2 shift, the body would not have an effective defence against viral or intracellular infections....”*.

“Baraniuk et al suggested that patients with ME/CFS had unusual proteins in the cerebrospinal fluid, and the aggregation of these abnormal proteins...could cause small amounts of bleeding in the brain (by) causing small punctures in the blood vessels and then small amounts of blood leak into the brain. Other proteins suggest a protease-antiprotease imbalance, increased free radical production, vasoconstriction of the blood vessels, inflammation, and altered rates of cell suicide. Baraniuk et al suggest that inflammation, haemorrhagic elements, increased cell death, and free radical production could be by-products of damage (by these) abnormally folded proteins impeding blood flow and ultimately puncturing blood vessels in the brain”.

“Biswal, Kunwar and Natelson found significant cerebral blood flow reductions in nearly every region of the brain assessed....Neary et al tested whether patients with ME/CFS have reduced oxygen delivery to the brain during and after exercise challenge. They found that in addition to significant exercise intolerance, patients in comparison to controls (have) reduced prefrontal oxygenation, suggesting altered cerebral oxygenation and blood volume in the brain....Neurotropic viral infections could be responsible for the appearance of lesions in the brain and the presence of focal epileptiform seizure activity”.

Referring to the work of Light et al, Jason notes that *“Light et al maintain that exercise could send a continuous signal of muscle sensory fatigue to the central nervous system causing dysregulation of sympathetic nervous system reflexes....About 90% of the ME/CFS patients could be distinguished from control subjects using just 4 of the genes measured...The researchers concluded that ME/CFS patients might have enhanced sensory signal for fatigue that is increased after exercise. These finding all indicate persistent changes in cell membrane function”.*

Referring to his earlier (2009) work, Jason notes that it: *“suggests that being over-extended and going beyond energy reserves can be an impediment to improving functionality and fatigue levels”*and it concludes that *“specific environmental cues”* may trigger ME/CFS. He is clear: *“We need studies based on systems biology that explain the illness, in combination with more details about the environmental contributors to the illness”.*

None of these proven pathologies can be ascribed to deconditioning or to abnormal illness beliefs that are reversible with cognitive restructuring and aerobic exercise.

Just as Peter Dewis of UNUMprovident sees a challenge in ensuring that people are directed towards the Wessely School’s behavioural approach, a far greater challenge faces the ME/CFS community in directing agencies of State such as the DWP, NICE, the MRC and the NHS away from the Wessely School’s inflexible approach to a chronic, inflammatory neuroimmune disorder.

For those involved at the highest level in directing the DWP's policy towards people with ME/CFS to have been the ones involved with the PACE Trial could be seen to indicate an unacceptable level of bias and commercial collusion against extremely sick and vulnerable people for whose disorder there exists an abundant biomedical evidence-base which continues to be systematically ignored by the PACE Trial Principal Investigators and those they advise.