

## OFF THE PACE: CMIs, BPS, PACE, GUIDELINES and CONSEQUENCES



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### **Abbreviations used in the article:**

**CMI** – *Chronic Multisystem Illness*  
**NICE** - *National Institute for Health and Care Excellence*  
**DWP** – *Department for Work and Pensions*  
**CFS** – *Chronic Fatigue Syndrome*  
**ME** - *Myalgic encephalomyelitis*  
**BPS** - *Biopsychosocial*  
**CBT** – *Cognitive Behavioural Therapy*  
**GET** – *Graded Exercise Therapy*  
**MRC** – *Medical Research Council*

### **Chronic Multisystem Illnesses, CMIs.**

These illnesses/conditions are complex chronic multisystem conditions which are ill-defined and often are assigned a somatoform disorder, psychiatric, “all in the mind” label by psychiatrists. The most influential of these belong to the “Wessely School” headed by Professor (now Sir) Simon Wessely they occupy influential positions that direct Government and Military Health policy, NICE guidelines, and benefit payments by the DWP and Insurance Agencies.

### **BioPsychoSocial, BPS, model/theory/paradigm**

This model developed in the 1970s as a response to the perception in psychiatry that there was a large and growing gulf between psychiatry, mental health and science-based biomedicine that has been successful in developing effective treatments for many serious life threatening and fatal illnesses previously assigned a psychiatric/psychological diagnosis, e.g. Parkinson’s disease, multiple sclerosis etc. Miles and Shands, 1959 [https://en.wikipedia.org/wiki/Biopsychosocial\\_model](https://en.wikipedia.org/wiki/Biopsychosocial_model) provides a useful article. Criticism of the BPS is long standing and voiced by eminent psychiatrists. This is an area of current controversy but the overall view emerging is that the BPS theory has “run its day”, “The BPS model has failed to achieve what it set out to achieve .... more and more commentators are speaking about it critically, calling for an alternative”, Bennning, 2015, Ghaemi, 2009, 2011.

Others regard the model as having no sound foundation in any theory, McLaren, 2001 equates it with fraud. Others see it as anti humanistic, Ghaemi cited above.

The BioPsychoSocial, BPS, is the real issue behind the adoption of CBT/GET as the foundation for NHS policy. The claims by some psychiatrists, especially the 'Wessely School' who have great influence with policy makers Government, NHS, benefit agencies (DWP and Insurance Companies) have been extensively canvassed and grossly exaggerated leading to the uncritical adoption of CBT/GET and untruthful claims about "the best evidence base" stated in the current NICE Guidelines and the policy towards claims submitted to the DWP and Insurance Companies.

"The biopsychosocial model has played a significant role in shaping the UK government's approach to disability and welfare over the last two decades, yet some important claims made about the value and benefits of biopsychosocial approaches have been based upon poor quality evidence and misleading claims. Even as awareness of these problems grows, many aspects of the biopsychosocial model are so advantageous to those wishing to justify cuts to state disability benefits that they are unlikely to be abandoned. While it may be that explicit references to the biopsychosocial model will now be avoided. The tactic of using the positive language of empowerment to promote policies which will cut the incomes of members of society living with ill health and disability looks likely to continue. So long as cuts to disability spending can go on being sold in this manner they will be a .....target for a Government committed to finding £12 billion of welfare savings." Faulkner, 2016.

In further comments Faulkner sees a wider concern, "It is not just in the political sphere that the biopsychosocial model has caused problems. While there can be an assumption that medical researchers are more trustworthy than politicians, and that the interventions they promote as being 'evidence-based' will benefit patients, results from medical research can be exaggerated and misrepresented. When the biopsychosocial model encourages researchers and medical, stand to see the management of patients' cognitions and expectations as a routine part of medical practice this can be seen as legitimatising the manipulation of the information provided about prognosis, treatment efficacy and recovery rates. There seems to be a belief that informed consent is not required for this psychosocial treatment. It should not be surprising that presuming certain groups of patients deserve to be manipulated in this way will be stigmatising, and risks creating a culture of cynicism and distrust as knowledge of what has occurred spreads."

### **ME and the PACE TRIAL**

ME/CFS has been a battleground in the BPS controversy, in which the late arrival, 1988, of CFS, Chronic Fatigue Syndrome reinforced the somatoform argument and intensified the debate. ME had been listed by the WHO in neurology, ICD 10-G 93.3 since 1969 and the term CFS was later, 1988, included only in the alphabetical list of synonyms for already listed illnesses. This allowed ME to become ME/CFS – a description favoured by patients- or CFS/ME favoured by those promulgating the somatoform view of the illness. This allowed psychiatry to dominate many sick people and insist on them receiving the favoured treatment, CBT/GET, (cognitive behavioural therapy/graded exercise therapy). This diagnosis belittles patients and carers leaving, them 'devoid of any significant support, medical, social or physical. It has resulted in much cruel behaviour from doctors and other medical staff, much suffering for patients and, in some cases, hastened their death, Sophia Mirza, <http://www.sophiaandme.org> . Lynn Gildersdale [https://en.wikipedia.org/wiki/Lynn\\_Gilderdale](https://en.wikipedia.org/wiki/Lynn_Gilderdale)

**The PACE TRIAL** was funded by UK Medical Research Council, MRC, [Department of Health](#) for England, Scottish Chief Scientist Office, and uniquely for a clinical trial - the [Department for Work](#)

and Pensions, DWP. This indicates how the BPS model has dominated UK health policy and the vested interests that lie behind this expensive study, £6 Million.

The PACE Trial, White et al 2011, was judged, shortly after its publication, to be, A Travesty of Science; A Tragedy for Patients; Tantamount to Fraud; Hooper, 2012. Release of the data from the trial, was strongly resisted by the authors, publishers, editor, the university holding the data, QMUL, and only happened after an FOIA judgement that took 5 years to obtain.

An important unanswered question is why was there such resistance to publication of data that formed part of a publicly funded scientific study? What did they fear? What were they wanting to hide?

Extensive papers followed showing that there were multiple breaches of research design, including patient selection, numerous changes in the design protocol, some *post hoc*, shameless manipulation of the data, and advising participants of the success of the proposed treatment BEFORE conclusion of the trial.

“It was doomed to failure from the start”, Goldin, 2016; and has changed the understanding of ME both clinically and socially. Rehmeyer, 2016. Several analyses have confirmed that the claimed results for CBT and GET as effective treatment of ME/CFS were deeply misleading and wrong. The investigators had been engaged with a ‘null’ field; the results were not significant – an abject and costly, £6 million, failure, Vink 2016; David Tuller, 2011-2017 has published a collection of his papers/responses, >3000 words, to the PACE in his Virology blog, <http://www.virology.ws/mecfs/> . This includes the call for retraction of the initial paper and others depending on the data therein, the unwillingness to identify the “experts” who reviewed the paper before publication and the intransigence of the editor to withdraw this deeply flawed paper which dishonours the reputation of the Lancet. One letter was signed by 45 internationally known academics, for a useful summary see [http://me-pedia.org/wiki/PACE\\_trial](http://me-pedia.org/wiki/PACE_trial)

Other significant papers, identifying major deficits in the PACE study include an editorial by Geraghty, 2017, who concluded after consideration of design factors and patient doctor conflicts (some pointing to cruelty) that, “these therapies are non-curative and should be downgraded to adjunct support-level status.”

Faulkner, 2016 speaking from the perspective of welfare reform is devastating and comprehensive in his comments. “Medical research ..... used to justify assertions of political power and any attempt to reform the state's relationship with those with disabilities and ill health should be founded upon a rigorous examination of the available evidence. Researchers need to be honest and clear about the limitations of their research and their ability to accurately measure **subjective** symptoms.

Spandler and Allen, 2017, describe the consequences of the psychiatric framing of ME and show how hermeneutics (interpretation of data and statements) and epistemic injustice (not believing, belittling and dismissing patients’ experience of the illness) has contributed to much abuse and suffering for patients.

“...ME and mental health activists struggle for a fuller acknowledgement of their suffering and a greater awareness of the negative consequences of psychiatric framing on their lives.....ME activists demand medical legitimization of their illness, .....[and] demand that their experience, knowledge and perspectives are taken more seriously. In other words, they .....demand epistemic legitimization, recognition and justice. This is why the notion of epistemic injustice is key to understanding the ongoing oppression and discrimination of ..... people with CFS/ME ..... It is also why some commentators have argued for a truth and reconciliation process in psychiatry

to provide restorative justice .....This kind of process could begin to acknowledge and apologise for, the harm caused to people with CFS/ME ....”

“The PACE trial shows the danger of allowing researchers with an interest in reporting positive results to use **subjective**, self-report outcome measures for a **non-blinded** trial. While the more objective outcome measures from the PACE trial indicated that the biopsychosocial interventions tested were not useful to patients, results were released in a way which led to a range of excited claims being made about them leading to recovery for patients.”

“The bold claims of those who have built their careers upon the development and provision of biopsychosocial interventions will have personal incentives to make exaggerated claims about the value of their work, even if doing so risks distorting the beliefs and actions “of others and robbing patients of the ability to make informed decisions about the treatments to which they are being asked to consent. The bold claims made by medical researchers about the value of the biopsychosocial model of disability has allowed the British state to claim authority over the psychosocial aspects of disabled people's lives, and use their supposed expertise to justify cuts to disability welfare payments.”

The biopsychosocial reforms, and the DWP's biopsychosocial disability assessments, have also led to inaccurate claims about claimants being fit for work, and now we have seen the culture of cynicism and distrust spread to others being affected by the biopsychosocial model. The satirical response of a campaigning group to the assessments carried out by Atos for the DWP, which routinely classed seriously sick and disabled people as ' fit for work', could be equally applied to the claims made about recovery in the PACE trial.”

Until the serious and ongoing problems distorting medical research in this area have been overcome, it is important to avoid assuming that civil servants and medical researchers have a better understanding of how people with disabilities should live their lives than disabled people themselves.”

Criticism of the BPS is long standing and voiced by eminent psychiatrists. This is an area of current controversy but the overall view emerging is that the BPS theory has “run its day”, failed, is a placebo, no longer applicable, and at best only an adjunct to treatment in cases where depression occurs.

The BPS model/conception/theory was introduced to move away from a perceived, rigid and mechanistic scientific approach to the treatment of **mental health** and was then extended by some psychiatrists. The ‘Wessely School’, in the UK, began to claim that this theory could apply to other conditions that were clearly different from mental health disorders, Wessely et al.,1999.

These conditions are clearly associated with chronic multisystem illnesses for which no agreed biological understanding had yet emerged, and were not, at the time, the subject of major biomedical research programmes. They covered all fields of medicine.

**Gastroenterology – IBS, Non-ulcer dyspepsia**

**Gynaecology – PMS, chronic pelvic pain**

**Rheumatology – Fibromyalgia**

**Cardiology – Atypical or non-cardiac pain**

**Respiratory medicine – hyperventilation**

**Infectious Disease – PVFS- ME-CFS [LYME?]**

**Neurology – Tension Headache**

**Dentistry – TMJ dysfunction, Atypical facial pain**

**ENT – Globus syndrome**

**ALLERGY - MCS**

Whilst Lyme disease is not listed here, CFS is mentioned 13 times in a response to the Lyme Guidelines and indicates an attempt to treat this illness in a similar manner.

Wessely had his mind set on destroying ME as a meaningful clinical term. Describing it as “a fad”, an idea/belief, misled, Williams, 2007, and discounting the Royal Free outbreak, as an example of mass hysteria, McEvedy and Beard 1970, despite excellent clinical research by Ramsay, 1988, and others that claimed it was of viral origin and treated it as such.

These psychiatrists should have known better in the light of the failures of previous psychiatric diagnoses, for what are now readily recognisable biomedical conditions, e.g. diabetes, Parkinson’s disease, multiple sclerosis, that are amenable to effective treatment. The Wessely School have taken their model for mental health and applied it *mutatis mutandum* to a series of multisystem organic disorders. A fundamental category error. This is why ME patients protest when told they have a mental health problem and need CBT/GET, not investigations or directed medical treatment.

The terminology of the ‘Wessely School’ psychiatrists has generated a number of “acronyms of ignorance”, including MUS, multiple unexplained symptoms, PUPS, persistent unexplained physical symptoms, MUPS, multiple unexplained physical symptoms, PUS, persistent unexplained physical symptoms. First Gulf War veterans, GW-1, were ‘diagnosed’ with MUS, Lee, 2000, when in reality they were poisoned with a combination of anticholinesterase agents, organophosphates, the nerve agent sarin and pyridostigmine bromide and in some cases multiple vaccines some of them experimental see extensive RAC reports.

The publication by NHS Choices <https://www.nhs.uk/conditions/medically-unexplained-symptoms/> shows how the Government are still ‘buying into the BPS model’ of the illness and committed to using these acronyms of ignorance.

The PACE trial has exposed this fallacy at great cost to patients and carers and the Exchequer. The all embracing claims of the BPS theory, adopted as dogma by National Governments, national health systems in many countries, DWP, and insurance companies; reduced research funding for many chronic complex diseases, offered cheap (talking) medicine in place of targeted therapy. Much less attention is paid to accurate clinical diagnosis, examination and investigatory tests that were severely restricted, see NICE Guidelines for ME/CFS, CG53, 2007. It is no longer credible to view the illness in this way.

## **CONSEQUENCES**

**NICE Guidelines:** The current NICE Guidelines were endorsed following the publication of the PACE trial which was initially welcomed by NICE. The exposure of the extensive flaws in the paper and the analysis of the original trial data by independent scientists that provides possible evidence of deliberate fraud has led to the withdrawal of the current Guidelines and the “wheels



have been set in motion” for new Guidelines to be constructed. This process is slow possibly up to 3 years and disappointingly the current Guidelines will remain until this process is complete.

**Medical Education and Reference Systems:** The advent of Chronic Fatigue Syndrome, CFS, as an alternative name for ME, 1988, played into the hands of psychiatrists supporting the BPS model and CBT/GET treatment for ME. The impact was extensive and CFS/ME was moved in medical textbooks from neurology to psychiatry. ME appeared in Davidson’s Textbook of Clinical Medicine, 1962 and later in the WHO neurology ICD 10 G 93.3 since 1969. The move to psychiatry appeared in later general textbooks e.g. Kumar and Clark, 2016. However, attempts continued to engineer this deception with the result that the joint name ME/CFS or CFS/ME was adopted. Although this name was used in all the protocols for the PACE trial, Hooper, 2010. Prof Peter White wrote after its publication that they “did not purport to be studying ME but CFS as operationally defined.”

This let the ‘cat out of the bag’-. It seems the PACE study was designed to totally discredit ME as a biomedical illness (an attempt at deception?).

Nonetheless, the idea seems to be gaining ground that ME and CFS are distinct illnesses/conditions. THEY ARE NOT. There are other ICD 10 codes for Chronic Fatigue otherwise unspecified, ICD 10 53.82 and weakness 53.1, and neurasthenia (earlier used to describe ‘shell shock) F.48.8. The response to the Lyme disease Guidelines seems to fall into this error as does Prof Julia Newton, who at a recent, showing of film, ‘UNREST”, about ME, stated she did not see CFS patients, only those with ME. Such a dichotomy is NOT POSSIBLE, CFS and ME, still less CFS or ME are both WRONG - the terms are synonymous.

The IoM report was charged with finding an alternative name for CFS/ME getting rid of CSF/ME. It supported ‘retiring’ the Oxford definition. This unfortunately destroyed ME as a name at the same time- a case of ‘throwing out the baby with the bath water’. Their alternative name SEIDS, Systemic Exertion Intolerance Disease has not won acceptance. ME still seems the best choice –on both historical (use by patients and doctors) and clinical grounds. This matter clearly needs to be resolved when the new Guidelines are being considered.

A useful summary of the recent IOM report summarises the principal findings.

- New diagnostic criteria are more focused on core symptoms than some other definitions.
- A new name for the disorder – ‘Systemic Exertion Intolerance Disease’ (SEID). The committee points out that the name ‘CFS’ perpetuates misunderstanding of the illness and dismissive attitudes from health care providers and the public.
- A new code for the disorder in the International Classification of Diseases (ICD-10), not linked with ‘chronic fatigue’ or ‘neurasthenia’ as at present. [This is already the case at present.]

<http://www.meresearch.org.uk/news/institute-of-medicine-report/>

There is no doubt that in many people’s mind, in the UK and USA, CFS should be dropped completely and straightway. The term ME, myalgic encephalomyelitis, muscle pain with inflammation of the brain and spinal cord, is a meaningful term that is accurate. Inflammation is a major feature of ME that has been identified in post-mortem tissue, Cader et al., 2009, brains scans, [http://me-pedia.org/wiki/Brain\\_imaging](http://me-pedia.org/wiki/Brain_imaging) and raised CRP values and prostaglandin metabolites, Kennedy et al 2005. In keeping with its multisystem label, other major biological systems are also affected the cardiovascular, immune (autoimmune), gastrointestinal and endocrine systems as indicated in the comprehensive Canadian and International Consensus Criteria.

The mental health diagnosis of a somatoform disorder provides a route into easy cheap medicine that is welcomed by both the NICE, the DWP and Insurance Agencies since it reduces the costs of care. In this way our current over stretched health system has come to neglect such conditions/illnesses. Some authorities have tried to justify these attitudes by supporting studies such as the PACE trial which were initially welcomed by NICE and the DWP, in response to the sycophantic torrent of publicity and misinformation distributed by the Science Media Centre, SMC, which is guilty of deliberately misleading the public, politicians and the media by its operations. Their work needs to be assessed and, in the light of their role in the PACE debacle, terminated, Hooper, 2013.

### **A Public Enquiry in to the Medical Abuse of ME Sufferers, MAIMES.**

This has been called for by Dr Sarah Myhill in the light of the total failure of the PACE trial, [http://www.drmyhill.co.uk/wiki/Medical\\_Abuse\\_In\\_ME\\_Sufferers\\_\(MAIMES\)](http://www.drmyhill.co.uk/wiki/Medical_Abuse_In_ME_Sufferers_(MAIMES)). A challenging video at <https://www.youtube.com/watch?v=IOXCjZPboFw> . I would encourage your support.

The final irony is that Wessely, 2001, had already made clear that CBT/GET interventions:-- Was (sic) safe, sensible and modestly effective common sense ways to reduce disability and enhance control

### **Not remotely curable Not the answer**

Had these comments been recognised, Maes and Twisk, 2009, CBT/GET is, "ineffective, non-evidence-based and potentially harmful", then the wasted money spent on the Fatigue Clinics, £8.2 million, PACE trial, 2011, £5 million and FINE trial, 2010 ~£1 million could have been used to support biomedical research which is now discovering a better understanding of ME and identifying some effective treatments.

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