

Sensationalism versus Science?

Malcolm Hooper and Margaret Williams

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The long-promised article by Michael Hanlon on the “war” surrounding the neuroimmune disorder myalgic encephalomyelitis (ME) was published today in the Sunday Times Magazine together with a photograph of Professor Sir Simon Wessely (“This man faced death threats and abuse. His crime? He suggested that ME was a mental illness”). Whilst the article focuses on the unacceptable actions of very few alleged sufferers and not on legitimate challenges mounted by scientists, it may be of interest to reproduce the questions which Hanlon sent to Professor Malcolm Hooper on 31st January and also Professor Hooper’s reply, since that reply provides the backdrop to the on-going “war”.

First, though, it must be said that much of Hanlon’s article is factually wrong. For example, Hanlon begins his article with the assertion that “Professor Sir Simon Wessely lives on the front line of science”, which immediately reveals a lack of understanding in that Sir Simon does not live on the front line of biomedical science but on the front line of psychiatry, a discipline with no biomarkers of disease. Indeed Sir Simon ignores, actively denies or dismisses the evidence of biomedical scientists that demonstrates whole-body inflammation in ME and does not accept that it has now been shown to be an autoimmune disease.

Hanlon goes on to state that Sir Simon “has done a lot of work for the military, helping to treat traumatised war veterans”, when there is irrefutable published evidence that Sir Simon has for decades denied the very existence of Gulf War Syndrome.

Hanlon then states that ME “affects about 600,000 people in Britain”, an assertion not supported by the 2002 Report of the UK Chief Medical Officer, which found there to be about 250,000 sufferers in the UK, of which 25% are severely affected, being house or bed-bound. However, conflating “chronic fatigue” with ME would certainly increase the numbers of alleged sufferers, but lacks scientific credibility.

Hanlon states that “The primary symptoms of the disease is fatigue”; this, again, is inaccurate, because the primary symptom of ME is post-exertional muscle fatigability, this being the cardinal symptom of ME and quite different from fatigue or tiredness.

Hanlon goes on to state that “Most doctors who treat ME...believe that ...cognitive behavioural therapy and exercise therapies provide the best hope for many sufferers to get better” but Hanlon does not explain that in general in the UK, the only doctors who treat ME are psychiatrists or those who work for the permanent health insurance industry, who adhere to their own now-disproven theory that ME is a behavioural disorder and thus does not qualify for insurance payments, neither does he mention the findings in a survey of 2,338 ME sufferers that “Graded exercise was reported to be the

treatment that had made most people worse” or the further findings that 93% of respondents found GET to be unhelpful, with 82% reporting that their condition was made worse (<http://www.meactionuk.org.uk/magical-medicine.htm>).

Hanlon claims that these doctors are in the majority without telling his readers the reason, which is that for over 25 years, as well as acting as advisors on ME/CFS to Departments of State and the insurance industry, Sir Simon and his colleagues have flooded the literature with their own beliefs, to the extent that any doctor who opposed them would be in real jeopardy of losing his/her job and of being labelled naïve and unable to deal effectively with suggestible patients (Simon Wessely. Psychological Medicine 1990:20:35-53). It takes a courageous clinician to risk running such a gauntlet.

Whilst not mentioning the PACE trial by name, Hanlon refers to “a ground-breaking paper” which he claims shows that CBT and exercise therapies provide the best hope for many sufferers to get better, a trial over which Sir Simon is known to swoon: “For those who appreciate these things, the trial is a thing of beauty” (Health in mind and body. Simon Wessely. The Journal of the Foundation for Science and Technology, Volume 20, Number 7, December 2011) even though the Investigators themselves acknowledge that it was “only moderately effective”.

Hanlon mentions a new initiative - the UK CFS/ME Research Collaborative launched on 22nd April 2013 - of which Dr Esther Crawley seems to be in charge, but he does not mention that the Collaborative Charter stipulates that membership is open only to those who agree to the Collaborative’s insistence that “(3.2.3) Members will be required to sign a declaration that they will not take part in the harassment or abuse of researchers. Neither will they take part in orchestrated campaigns against those conducting peer-reviewed research”. Does this mean that the charities who have signed up to the Collaborative will be prevented from legitimate disagreement with the aims and objectives of the Collaboration? The press release hosted on the website of Action for ME states categorically that “Predisposing factors include female sex, functional somatic syndromes, and prior mood disorders” even though the Medical Research Council itself now acknowledges that there is evidence of inflammation in the brain and spinal cord. Will any legitimate disagreement continue to be construed as “harassment”?

Could these stipulations be the reason why, at the recent US FDA Stakeholder meeting held on 25th-26th April 2013 at which the PACE trial was discussed by world-renowned biomedical experts, Dr Peter Rowe said: “ ... and here is where I need my uniformed colleagues to provide me with some help because anyone who ventures into discussion of the PACE Trial probably needs an armed guard [.....] I suspect that most of my clinician colleagues in the room would agree with this comment and that is that if all you've been able to do with your treatment is change your fatigue score by three points on a thirty-three point scale over a year, that that's the kind of thing that would have made us hang up our licenses and our office headings and quit CFS in frustration, we usually do better than that ...”. Dr Rowe was followed by Dr Christopher Snell, who also alluded to the parody being played out in the

UK at the expense of severely sick people: " ... so both Peter and I will need an armed guard when we leave, because I'm also going to talk a little bit about the PACE Trial...".

Hanlon had the opportunity to provide balance by using comments from informed commentators whose opinion he had canvassed: he opted instead to quote an unfortunate patient who is a self-admitted alcoholic who had been struck off the Veterinary Register and who has a conviction for indecent assault on a 12-year old girl. This person is hardly representative of the quarter of a million sufferers with ME in the UK: was this a deliberate attempt by Hanlon to smear the entire ME patient population?

Perhaps the most telling sentence in Hanlon's article is this: "As for the 2009 XMRV paper, Wessely snorts with derision". It is this derision and absolute triumphalism over the XMRV debacle that personifies the way people with ME have been - and still are - treated. Indeed, the Wessely School have advised that the first duty of the doctor is to avoid legitimisation of symptoms (The MRC's own summary of the CIBA Foundation Symposium on CFS held on 12-14th May 1992).

In 1994, one of the world's most renowned ME/CFS clinicians, Dr Daniel L Peterson from the US, went on record: "In my experience, it is one of the most disabling diseases that I care for, far exceeding HIV disease except for the terminal stages" (Introduction to Research and Clinical Conference, Fort Lauderdale, Florida, October 1994; published in JCFS 1995:1:3-4:123-125).

In 1995, Professor Mark Loveless, Head of the AIDS and ME/CFS Clinic at Oregon Health Sciences University said in his Congressional Briefing that an ME/CFS patient: "feels effectively the same every day as an AIDS patient feels two weeks before death; the only difference is that the symptoms can go on for never-ending decades".

In 2004, Dr William Reeves, Chief of the ME/CFS research programme at the US Centres for Disease Control, (CDC) reported that ME/CFS patients "are more sick and have greater disability than patients with chronic obstructive lung or cardiac disease, and that psychological factors played no role" (Press Release, AACFS, 7th October 2004).

Also in 2004, a randomised clinical trial found "In comparison with other chronic illnesses such as multiple sclerosis, end-stage renal disease and heart disease, patients with (ME)CFS show markedly higher levels of disability" (Am J Occup Ther 2004:58:35-43).

On 15th October 2009, Professor Nancy Klimas, then Professor of Medicine, Microbiology and Immunology at the University of Miami, famously said in the New York Times: "I hope you are not saying that (ME)CFS patients are not as ill as HIV patients. I split my clinical time between the two illnesses, and I can tell you that if I had to choose between the two illnesses I would rather have HIV"

Wessely has long trivialised a devastating disorder from which people die,

referring to it as a “myth”: the recent tragic deaths from ME of three young women in the UK, all in their 30s (Sophia Mirza, Lynn Gilderdale and Emily Collingridge) should shame all “non-believers”, including Sir Simon.

As one eminent UK consultant physician -- who bravely stands firm against the doctrine of Sir Simon --commented on Hanlon’s article: “No-one has apparently perceived the whole psychiatric paradigm as dogma, not science”.

Professor Hooper’s reply to Hanlon’s questions, sent to him on 5th February 2013, is reproduced below:

Dear Mr Hanlon

I notice that your couple of questions has multiplied to six which I will deal with in numerical order as best I can, although I am but one of very many national and international opponents of the PACE trial.

1. Is it true, as Peter White asserts, that after the 2011 publication of the PACE trial you wrote several hundred pages of criticism to both the Lancet and the GMC?

No; it is not true. You have been misinformed.

In February 2010, before the PACE trial paper was published in The Lancet, together with many others I wrote “MAGICAL MEDICINE: HOW TO MAKE A DISEASE DISAPPEAR -- Background to, consideration of, and quotations from the Manuals for the Medical Research Council’s PACE Trial of behavioural interventions for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis, together with evidence that such interventions are unlikely to be effective and may even be contra-indicated”. It is a 442 page report and was sent to the Medical Research Council, who dismissed most of it but conceded some of it. I also sent it to Professor Sir Michael Rawlins, Chairman of NICE, whom I know personally, having worked with him in the past, but who returned it unread.

In March 2011, after publication of the PACE trial paper in The Lancet and the accompanying Comment by Bleijenberg and Knoop, I submitted a formal complaint amounting to 46 pages to The Lancet; the senior editor confirmed in writing that the Comment was erroneous and should be corrected, but the rest of the complaint was dismissed after interventions by Professor Peter White.

On 26th April 2010 I lodged a formal complaint to the GMC about Dr William Trevor Hamilton, chief medical officer of three insurance companies, because we have evidence that he knowingly misled the High Court in the Judicial Review of the NICE Clinical Guideline on CFS. He was reprimanded by the GMC who, for the record, are still willing to pursue the matter.

2. What, in essence (and not several hundred pages please!) was your objection? To the existence of the trial itself? To its findings? To the way it was conducted?

The PACE Trial -- which cost £5 million -- I have described as a travesty of science and a tragedy for patients; the conclusions were flawed; the primary outcome measures were dropped; ratings that would qualify a participant as sufficiently impaired to enter the trial were deemed by the Principal Investigators to be “within the normal range” when recorded on completion of the trial; there were significant conflicts of interest in that all three PIs work for the insurance industry (whose managers insist that claimants undertake a course of CBT and GET -- called “rehabilitation” -- which, if people are too ill to do so or if they know from their own experience that it makes worse and therefore decline, payments are stopped on the basis that claimants do not want to get better); the PIs intentionally studied a heterogeneous population and it was conceded only after publication of selective results in The Lancet that the Investigators did not purport to be studying ME but simply chronic “fatigue”; there was a failure to control the trial; there was downgrading of what constituted serious adverse events; there were many changes to the entry criteria; data was not reported and objective outcome measures were dropped; methods of scoring were changed so as to produce only minimally statistically better results that were blatantly misreported in The Lancet.

3. What is your relationship, if any, to the ME campaigner Margaret Williams?

I am inclined to respond that this is none of your business, nor of your readers. However, the truth is that we have known each other and worked together for many years on issues surrounding ME and GWS. Margaret Williams formerly held a senior clinical post in the NHS. Together with an established team of clinicians and medical researchers, our aim is to expose and prevent the injustice perpetrated on patients with ME/CFS in the UK by those whose job is to help, not abuse or denigrate them. We are concerned about the current situation in the UK for people with ME/CFS and their carers who are seeking recognition of the extensive sound science that underlies the biomedical basis of the disease, the provision of an accurate diagnosis, a therapeutically useful intervention and appropriate care of patients. ME/CFS is a devastating chronic multi-system, multi-organ disease which can be life-threatening; those who neither accept nor understand this should not be working in the field.

4. Do you have ME yourself?

No.

5. What sparked your involvement in this area?

I am Chief Scientific Advisor to the Gulf Veterans Association and President (since 2000) of the National Gulf War Veterans and Families Association. I was increasingly being consulted by Gulf War veterans who had been diagnosed with ME accompanied with other “acronyms of ignorance” such as MUS (medically unexplained symptoms) and MUPS (medically unexplained physical symptoms), which led to my involvement with the wider issues surrounding ME/CFS.

6. Do you support the continuing research into ME by people like White and Wessely and Crawley? Or do you think it should be stopped?

I do not support the work of Professors Peter White and Michael Sharpe, nor of Professor Sir Simon Wessely (in his case, not only with ME/CFS but with Gulf War Syndrome and his involvement with military health), nor of Dr Esther Crawley. There are several others, collectively known as “the Wessely School” in Hansard.

I do think it should be stopped. I believe their work on ME/CFS to be seriously flawed, as it disregards the underlying pathology of the disease and may not even be looking at ME/CFS but at chronic fatigue that can have many origins. The cardinal feature of ME is profound post-exertional malaise, also described as post-exertional neuroimmune exhaustion, ie. it is characterised by an inability to produce sufficient energy on demand.

In particular, the Wessely School’s long association with the insurance industry is a matter of concern, as noted by the report of Parliamentarians in 2006:

“At present, ME/CFS is defined as a psychosocial illness by the medical insurance companies. We recognise that if ME/CFS remains defined as psychosocial then it would be in the financial interests of the medical insurance companies.

“There have been numerous cases where advisors to the DWP have also had consultancy roles in medical insurance companies, particularly the company UNUMProvident.

“Given the vested interest private medical insurance companies have in ensuring CFS/ME remains classified as psychosocial illness, there is blatant conflict of interest here.

“This Group finds this to be an area for serious concern and recommends a full investigation by the appropriate standard body” (http://erythos.com/gibsonenquiry/Docs/ME_Inquiry_Report.pdf).

Those parliamentarians who expressed this concern included the former Chairman of a House of Commons Science and Technology Select Committee and former Dean of Biology at the University of East Anglia; a member of the Home Affairs Select Committee; a Minister of State for the Environment; a former President of the Royal College of Physicians; the Deputy Speaker of the House of Lords, and a former Health Minister and Honorary Fellow of the Royal College of Physicians. To date, nothing whatever has been instituted to remedy this unacceptable situation.

I hope this reply will help you to compile a factual and fully representative article, which I look forward to reading.

Yours sincerely

Professor Malcolm Hooper