

Communication with NICE about the revision of the Clinical Guideline 53

Margaret Williams 12th March 2017

Dear Professor Baker,

The attached Open Memo (below) addressed to you is about to be distributed via various internet channels, so I wanted to assure you that it is in no way an *ad hominem* attack on you personally.

It is simply a last-ditch attempt to prevent more harm being done to the many thousands of ME sufferers in the UK whose life has been wrecked by an utterly devastating neuro-inflammatory disease which has nothing whatever to do with “chronic fatigue” or with “*aberrant illness beliefs*” or with “*hypervigilance to normal bodily sensations*” as reiterated by those who were so influential in the production of the original Guideline CG53.

Over the last 30 years I have accumulated a huge library of books, articles and international conference reports on ME/CFS, resulting in a vast database. Despite frequent claims that little is known about it, on looking at this published evidence, I am always struck at the enormous amount that is actually known about the disease.

For example, there has been much discussion about the recent findings by Naviaux et al that ME/CFS patients are in a hypometabolic state, but evidence of this was presented by Tavio et al from Aviano, Italy, at the AACFS International Conference on (ME)CFS in San Francisco in 1996, which is 21 years ago.

Those findings were publicly dismissed by Dr Simon Wessely but they were replicated in 1998 by D. di Giuda and D. Racciatti et al from Rome, who found brainstem hypoperfusion in 83.9% of (ME)CFS patients studied and who concluded that their study confirmed previous reports of brain perfusion impairment in (ME)CFS patients and provided objective evidence of central nervous system dysfunction.

What is so disturbing is that in the UK, the disproportionate influence of the psychosocial lobby has succeeded in ensuring that this enormous knowledge-base of multi-system dysfunction has been suppressed, dismissed and ignored; had that lobby not achieved this suppression of the evidence, their own beliefs would long ago have been exposed as null and void, as has now finally happened.

That they were able to achieve such control has been due in no small measure to the instrumental role played by the Science Media Centre (of which Professor Sir Simon Wessely is a founder member and whose advisory board includes James Gallagher, the BBC's Science Editor). The SMC's active campaign against the acceptance of ME/CFS as a neuroimmune disease is undeniable and has been documented by Professor Malcolm Hooper (www.meactionuk.org.uk/MW/2013/role-of-science-media-centre-and-insurance-industry.pdf).

Indeed, I was personally told by the medical editor of a major broadsheet that they would not publish anything about ME/CFS unless they received it from the Science Media Centre which, sadly, gives undue weight to the psychosocial voice, so - despite the internet - the wealth of evidence showing significant pathology is not easily available in the UK.

In 2003 Carruthers et al published “Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols. A Consensus Document” (JCFs: 2003: 11(1):7115) and an Overview published in 2005 confirmed the compelling research evidence of physiological and biochemical abnormalities which identify ME/CFS as a distinct, biological, clinical disorder with autonomic, endocrine and immune dysfunction, stating categorically that it is not synonymous with psychiatric disorder. The Overview draws specific attention to the dangers of “*unwisely*” prescribed graded exercise because of the evidence of suboptimal cardiac function and because patients have different physiological responses to exercise than healthy controls. It also points out that the standard battery of tests is inadequate to reveal the many abnormalities present.

You will doubtless be aware that the UK psychosocial lobby refuses to accept any of this evidence and disparages the world-class experts from thirteen countries who compiled the Consensus and who, collectively, have 400 years of clinical experience of ME/CFS and who have diagnosed and treated approximately 50,000 patients with ME/CFS.

The crushing impact of ME/CFS was emphasised by Dr Julie Gerberding, Director of the US CDC, when on 3rd November 2006 she announced the CDC’s Toolkit to draw attention to the “*tremendous impact*” of (ME)CFS and to patients’ “*courage*” and to their “*incredible suffering*”, and she emphasised the underlying biological nature of the disease. This is very different from the message in the UK, which is that “CFS/ME” is a behavioural disorder and if patients would only co-operate and engage in “*cognitive restructuring*” and graded aerobic exercise, they could recover. Nothing is further from the truth.

It is notable that the interventions of CBT and GET which were part of the CDC Toolkit have now been archived (<http://www.cdc.gov/cfs/toolkit/archived/html>) and that the National Institutes for Health (NIH) have advised that the Oxford criteria used in the PACE trial are flawed: “*Specifically, continuing to use the Oxford definition may impair progress and cause harm...Thus, for needed progress to occur we recommend that the Oxford definition be retired*” (<http://annals.org/article.aspx?articleid=2322804>). Their conclusions were based on comprehensive reviews of over 9000 peer-reviewed research papers and testimony from expert researchers and clinicians.

I’m sure you will have seen the latest open letter about the PACE trial to the editors of Psychological Medicine, a letter which has 101 international signatories, but in case you missed it, here is the link: www.virology.ws/2017/03/13/an-open-letter-to-psychological-medicine-about-recovery-and-the-pace-trial/

Without doubt you have a very difficult task ahead of you and I can only wish you strength and courage in “*standing up for science*” (this, ironically, being the citation in the award of the inaugural John Maddox prize in 2012 to Simon Wessely).

With kind regards

Margaret Williams

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OPEN MEMO TO PROFESSOR MARK BAKER AT NICE

Margaret Williams 12th March 2017

Now that it has been agreed that the NICE Clinical Guideline on “CFS/ME” (CG53) that was published in August 2007 is to be removed from the static list and reviewed this year, it may be helpful for everyone involved to consider a few relevant facts.

As you have worked for NICE since 2009 and as you are now the Centre for Guidelines Director, you will, of course, be familiar with the following points but, given their importance and given the extent to which they were ignored in the production of the original Guideline, it seems prudent to draw renewed attention to them.

As NICE is funded by – and is accountable to – the UK Department of Health, it should go without saying that NICE adheres to DH published policy, but it would appear that in the production of CG53 there was no such adherence.

Relevant Facts

1. “The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century” was launched in September 2001 by the Chief Medical Officer (DH 2001). The programme was to be mainstreamed throughout the NHS between 2004 and 2007. The underlying purpose of The Expert Patient Programme (EPP) was, of course, to get patients with chronic diseases to police their own behaviour and thereby reduce their dependence on State resources (From 1984 to 2004: Double think, social movements and health policy: Ruth McDonald, National Primary Care R&D Centre, University of Manchester, 2004) but the nominal aim was self-explanatory: it was to empower patients in decision-making about the chronic illness with which they lived and, being “user-led”, the sharing of expertise between clinicians and patients would lead to a better quality of life for those living with chronic diseases. It was recognised

that such patients are well-informed about their condition and therefore partnerships between patients and professionals were essential.

This did not happen in the production of CG53. Even though NICE received over 11,000 pages of submissions about this particular Guideline and despite ostensible patient representation on the Guideline Development Group (GDG), the voice of the expert patient was over-ruled. The Chairman of the GDG, Professor Richard Baker, failed in his remit to uphold Government policy by permitting influential members of the GDG to refuse to accept the WHO classification of ME/CFS as a neurological disorder as directed by NICE itself: on 10th September 2002 the Communications Director (Anne-Toni Rodgers) of NICE Special Health Authority issued a Communications Progress Report which, at section 2.7.1.5 was clear: ***“The ICD-10 classification is used for the recording of diseases and health related problems... The WHO produces the classifications and ICD-10 is the latest version...the classification codes are mandatory for use across England”***.

Given that the DH accepts that ME/CFS is a neurological disorder (letter dated 11th February 2004 from Lord Warner, Parliamentary Under Secretary of State, Department of Health; confirmed on 2nd June 2008 by Lord Darzi, Parliamentary Under-Secretary of State, Department of Health: *“My Lords, I have acknowledged that CFS/ME is a neurological condition... as I said earlier, (it) is a neurological rather than a mental condition”*), will you personally ensure that the revised Guideline makes it clear that NICE also accepts the WHO classification of ME/CFS as a neurological disorder?

2. On 21st March 2002 in the BBC Radio 4 programme *“You and Yours”*, the issue of patient /professional co-operation was discussed in relation to the then-recent Report of the UK Chief Medical Officer on “CFS/ME”. The interviewer said: *“Now the government says it wants patients to sit alongside clinicians and become amateur experts and contribute to a whole range of treatments. But putting theory into practice has proved problematical... Tony Britton from the ME Association thinks the use of expert patients for some conditions is vital”*.

One of the reporters, Margaret Collins, said: *“The theory then is fine, it is putting the concept of the ‘expert patient’ into practice that’s the real challenge. When the Independent Working Group on CFS/ME was set up to improve the quality of care and treatment, clinicians and patients could not agree and several resigned....The clinicians felt that there was sufficient evidence for the treatments they wanted to recommend. Dr Peter White resigned over evidence about the treatment”*.

Peter White responded: *“We need to know what treatments work for our patients in general rather than specifically what particular patients know works for them. That’s the way we can reassure our other patients that there is evidence that a particular treatment works...We are talking about a hierarchy of evidence that is most convincing. If I wanted to persuade someone who is sceptical about what I have to say, the best way to do that is to show scientifically repeatedly that what I say is true....I think the ‘expert patient’ programme will work best when there is consensus about the way forward....When it is a chronic condition for which there is no immediate chance of a cure, when the programme is properly resourced... to get the*

patients who are going to provide the evidence...then the 'expert patient' programme could work well". (Plainly, Peter White was saying that only if the 'expert patient' concurred with his own views would a partnership be possible).

The interviewer then introduced Anne-Toni Rodgers from NICE and asked her: *"From NICE's point of view, wouldn't academics and researchers...have their own agenda – that's the real world, and patients perhaps will have theirs, and that's perhaps how never the twain will meet?"* Anne-Toni Rodgers replied: *"We are trying very hard to study our guidelines process to prevent that happening....One way we have actually focused in supporting patients in this relationship is by establishing something called a 'Patient Involvement Unit'...we fund it (and) we are very clear about patients that we want involved in clinical guidelines... so then we have a broad understanding of the condition....When you have lived with a condition for 20 years, you often know more about it".*

The interviewer then said *"But that's what the doctors object to....So the doctors get in the way – they say they don't agree with patients....When push comes to shove, doctors are going with their own scientific instincts, aren't they, rather than whatever patients may tell them",* to which Dr Rona McDonald, Assistant Editor, BMJ, replied: *"I am afraid that that actually may be the case, even though it's one that I absolutely abhor myself....The whole problem is that the patients have never been included from the start"* (Transcript by Doris M Jones, 19.04.2002).

3. In March 2008, the British Medical Association published its report "Public and Patient Involvement (PPI) in the NHS" which called for active involvement of the public who fund it and the patients who use it. The BMA found that public and patient involvement was at risk of being seriously weakened and offered recommendations on the necessary structures and processes that would ensure that PPI is robustly established as an integral and collaborative process in the NHS in order to develop productive partnerships between patients, the public, health professionals and policy makers.

Given the requirement for the active involvement of the "expert patient", will you ensure that in the current revision, NICE accepts the voice and the experience of the expert ME/CFS patient? What the expert ME/CFS patient has consistently said is that the behavioural interventions recommended in the original Guideline do not work and, given the indisputable evidence that people with ME/CFS (as opposed to chronic fatigue) are in a hypometabolic state, graded aerobic exercise may be actively harmful.

4. On 6th January 2011 Frances Rawle PhD, Head of Corporate Governance and Policy at the Medical Research Council, wrote to Professor Malcolm Hooper confirming about CBT/GET that, prior to the PACE Trial: *"there was insufficiently strong evidence from randomised controlled trials to support their effectiveness"*. This was a surprising admission, because the NICE Guideline that advocated CBT/GET was published in 2007, which was four years before the initial results of the PACE Trial appeared. Given Dr Rawle's confirmation that in 2007 there was insufficiently strong evidence, NICE should not have recommended such

interventions for national implementation, as further confirmed by the House of Commons Health Select Committee, First Report of Session 2007-08, Volume I:29, whose members were unequivocal that NICE should not recommend interventions when the evidence is weak.

Indeed, in the absence of sufficiently strong evidence, in the 2007 Guideline the interventions of CBT and GET should have been sanctioned only for use in research and should not have been promoted for national implementation.

As is now undeniable, it cannot be credibly disputed that the PACE Trial failed, so there is still no robust evidence that the interventions promoted in CG53 are appropriate or effective.

The fact that currently there is no effective treatment for ME/CFS should be admitted and should not be the reason for the recommendation of interventions that have been shown to be harmful.

Will you personally ensure that, in the current revision, any recommendations you make will be supported by transparent evidence of effectiveness?

4. In 2006 NICE received The Clinical Guideline Development Programme: A Review by the World Health Organisation: May 2006, in which the WHO said: *“The Report contains a series of recommendations on how NICE could further develop the Guideline development process”*.

Two key recommendations with which the WHO required NICE’s compliance would seem to be relevant to the current situation:

Key recommendation 1: *“NICE should develop several types of clinical guidelines, rather than continue to use the current ‘one size fits all’ approach”*.

Key recommendation 12: *“NICE should strengthen collaboration with national and international groups”*.

In its response of January 2007 to the WHO recommendations NICE said:

Key recommendation 1: *“We are reviewing our scoping process in 2007 with the aim of producing more focused guidelines. When updating full guidelines, we will focus on the key points of the pathway where guidance is most needed”*.

Key recommendation 12: *“NICE already has strong collaborative links with national professionals and stakeholder organisations and research groups. It is involved in several international projects and initiatives...It is a member of the Guidelines International Network (G-I-N)...It has established links with other guidelines organisations in Europe and has regular exchanges with similar North American organisations. These links...need to be balanced with the institute’s primary responsibility to prepare and disseminate its guidance”*.

Given that there is no literature bearing the imprimatur of UK Royal Colleges acknowledging that the PACE results are inaccurate due to multiple deviations from its published protocol, will you ensure that the current revision of CG53 concurs with key recommendations of the WHO and that NICE will pay requisite heed to the international biomedical evidence which demonstrates what patients have been saying for decades, namely that CBT and GET do not help patients with ME/CFS and that GET in particular is likely to cause iatrogenic harm?

GET cannot help overcome chronic inflammation and it was ten years ago that Nancy Klimas, President of the International Association for CFS/ME and Professor of Medicine and Immunology, University of Miami, said: *“Unquestionably, the name CFS has done harm both to patients who are dismissed as merely chronically fatigued and to the credibility of professionals who are attempting to understand and treat a complex illness that involves neuroinflammation, autonomic and immune perturbations, and hormonal dysregulation”*, the substantial published evidence of which NICE comprehensively ignored.

As the Guidelines Development Manual requires equal weighting of the evidence, will you personally ensure that the “expert patient’s” voice is given equal weight to the well-orchestrated voice of one particular group of professionals with confirmed vested interests and will you personally ensure that the evidence upon which NICE’s revised Guideline is predicated is seen to be fact, not fiction?