

## Memo to NICE re: CG53 revision

Margaret Williams 29<sup>th</sup> August 2010

In addition to Professor Hooper's formal complaint to the Medical Research Council (MRC) about the PACE Trial on ME/CFS, there is the related matter of the failure of the National Institute for Health and Clinical Excellence (NICE) to pay heed to the same concerns and its failure to consider the available biomedical evidence when it produced its 2007 Guideline CG53 on ME/CFS that was described by the ME Association and others as unfit for purpose.

It may be recalled that a copy of Professor Hooper's complaint "Magical Medicine: how to make a disease disappear" (<http://www.meactionuk.org.uk/magical-medicine.htm>) was sent to Professor Sir Michael Rawlins, Chairman of NICE, and that he refused even to look at it, let alone to consider with due attention the disturbing and fully referenced evidence it contained. In his letter dated 2<sup>nd</sup> March 2009 returning the unopened document to Professor Hooper he wrote: *"I am not prepared to enter into any correspondence on this matter. I am returning your document"*.

Many people held this to be a blatant dereliction of duty by Sir Michael.

All the professional members of the NICE Guideline Development Group (GDG) that produced CG53 provided signed Witness Statements for the Judicial Review of CG53 held in the High Court in February 2009. Those Witness Statements have not yet entered the public domain but it is clear that there were very serious issues about the selection of virtually every professional member of that GDG, at least one of whom is currently facing a formal investigation by the General Medical Council for allegedly knowingly misleading the High Court, which allegedly contributed to a grave miscarriage of justice. If found guilty, a charge of perjury automatically carries a custodial sentence.

NICE was scheduled to re-visit CG53 in August 2010 and is asking the same GDG members to decide whether or not there should be any review at all at the present time (message posted by GDG lay member Richard Eddleston on [LocalME@yahoogroups.com](mailto:LocalME@yahoogroups.com) 26<sup>th</sup> August 2010 and message posted by the Medical Advisor to the ME Association: "ME Association Summary and Statement on Lo et al paper", 25<sup>th</sup> August 2010).

In view of the recent evidence of a strong association between ME/CFS and a family of MLV-related retroviruses -- a link described by Dr Harvey Alter (one of the authors of the Lo et al PNAS study) as a *"dramatic association with chronic fatigue syndrome"* (Los Angeles Times, 14<sup>th</sup> August 2010), it is

timely to question whether the current GDG members are competent to assess the importance of this finding.

This must be in doubt because, despite the fact that the 2002 Report of the Chief Medical Officer's Working Group referred to the evidence showing that numerous infections are involved with the disease, those same GDG members also ignored the already unarguable evidence of viral involvement in ME/CFS and recommended that physicians should not carry out testing for viruses on patients with the disorder, even though none of the GDG members was a virologist.

Will the now-changed policy of the UK Department of Health to impose a lifetime ban on blood donation by people with ME/CFS encourage members of the GDG to reflect on the fact that the psycho-behavioural Guideline they produced in 2007 may have had the effect of jeopardising the safety of the UK blood supply? This seems unlikely, given the extent and scientific calibre of the evidence that the GDG members decided (or alternatively were instructed) to disregard when producing CG53.

Clara Swinson, Director of Health Protection at The Department of Health, has confirmed to the ME Association's Medical Advisor: *"As of 1<sup>st</sup> November 2010, blood donors who report that they have had ME/CFS will be permanently excluded from giving blood in the UK...as ME/CFS is a relapsing condition. It brings practice for ME/CFS into line with other relapsing conditions or neurological conditions of unknown origin. The change to donor selection criteria is being made following a recommendation by the UK Blood Services Standing Advisory Committee on the Care and Selection of Donors"* (correspondence between the ME Association and the interim Chief Medical Officer, Professor Dame Sally Davies, about UK blood donation).

It was argued during the Judicial Review that GDG members ignored the biomedical evidence and placed undue reliance on the psycho-social/behavioural model of the disease.

As recently noted (<http://www.meactionuk.org.uk/Update-on-MRC-complaint.htm>), GDG member Dr Esther Crawley is a supporter of the psycho-social model of ME/CFS and is about to study the effects of the Lightning Process on children (some as young as 8 years old) and young people who suffer from the disorder. The Phil Parker Lightning Process is an intervention that is being used for a variety of conditions, particularly ME/CFS, and is based on neuro-linguistic programming and "life coaching" (<http://www.bristol.ac.uk/news/2010/6866.html>). It is a three-day "training" programme run by practitioners who are trained and licensed only by the Phil Parker organisation. Lightning Process practitioners may charge up to £880 for three-day "training" sessions; the practitioners are not accountable to any professional body and there are no random controlled trials of its efficacy in adults (held by the MRC to be necessary before trials are carried out on children). The "training"

sessions include the participant standing on paper circles with positive phrases written on them, with the participant required to affirm phrases such as *"I have a choice"*; *"I choose the life I love"* and *"I want energy and happiness"*.

Of note is the fact that an advertisement placed by one of the Lightning Process practitioners who had previously identified himself with Dr Crawley's trial (Alastair Gibson) was recently censured by the Advertising Standards Authority for making the misleading and unsubstantiated claim that the Lightning Process was an effective treatment for ME/CFS ([www.asa.org.uk/Complaints-and-ASA-action/Adjudications/2010/6/Withinspiration/TF\\_ADJ\\_48612.aspx](http://www.asa.org.uk/Complaints-and-ASA-action/Adjudications/2010/6/Withinspiration/TF_ADJ_48612.aspx)).

The charity Action for ME (AfME) has twice published data showing negative experiences with the Lightning Process (InterAction magazine, March 2007 and AfME's Patient Survey data published in 2008, which record a worsening of symptoms following the Lightning Process "training" programme), yet AfME continues to support Dr Crawley's trial: *"Action for ME sees no reason to oppose this study"* (published on AfME's Facebook). As noted in "Magical Medicine", AfME's members might wish to consider why a charity that was formed to support people with ME should now work so closely with those who believe them to be mentally ill.

Dr Crawley's study is co-funded by The Linbury Trust, a Sainsbury family trust that has supported the Wessely School since 1991; its published view about ME/CFS is: *"...we can state confidently that CFS ...is not an inflammation of brain or muscle disease....Under names such as neurasthenia, effort syndrome and myalgic encephalomyelitis (ME), chronic fatigue has generated medical debate for more than a century...The Linbury Trust was an early player in this story, and has funded the great bulk of CFS research conducted in the UK"* (A Research Portfolio on Chronic Fatigue, edited by Robin Fox, published by The Royal Society of Medicine 1998). The Linbury Trust's mission statement is that patients with "fatigue" and psychological defects are predisposed to develop ME/CFS because they misattribute their symptoms to a physical cause, prompting them to avoid physical activity and thus become deconditioned, which perpetuates fatigue and psychological disturbance. Many people find it troubling that Dr Crawley has chosen to align herself with an non-medical intervention that claims to be able to cure a serious neuroimmune disorder within three days, sometimes even in one day, and that her views should again be sought over a matter of such importance as a revision of the very Guideline with which she was so intimately involved.

Another GDG member, Dr David Vickers is, like Dr Crawley, a paediatrician; he is Consultant Community Paediatrician in Cambridge and since 1991 has been the Designated Doctor for Safeguarding Cambridge; he is Clinical Lead for Community Paediatrics for his Primary Care Trust and for the Children and Young Peoples' CFS/ME Service in Cambridgeshire and Peterborough.

He also 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 RCPCH considers ME/CFS to be a behavioural disorder; its Report of December 2004 (Evidence-based Guidelines for the Management

of CFS/ME in Children and Young People), in the production of which Dr Vickers was a participant, 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"*.

Dr Vickers' views seem to sit uneasily with the views expressed in the large Cambridgeshire ME Support Group, who strongly supported the urgent need for a Judicial Review of CG53.

Dr Vickers' clinical judgment and competency in an alleged child abuse case were questioned in a recent High Court action. On 23<sup>rd</sup> August 2010 the BBC Panorama programme ("Please don't take our child") revealed that his evidence as an expert witness was rejected by the High Court in the case of baby William Ward, whose parents fought and won a lengthy legal battle to disclose Dr Vickers' name publicly. Vickers had told the police that without an explanation for the baby's fractured leg, the cause of his injury was that it was inflicted. The case against the Wards relied on the view of Dr Vickers and others, namely, that if no obvious explanation could be found for an injury, then child abuse was likely. The parents were arrested and charged by the police and were threatened with having their child taken away from them by Cambridgeshire social workers and both parents were suspended from their jobs. However, the Judge did not accept Dr Vickers' argument, stating: *"There is no cogent evidence that these parents injured their son"* (Parents win legal battle to name doctor who accused them of child abuse. Patrick Sawyer; Telegraph, 22<sup>nd</sup> August 2010).

There has never been any "cogent evidence" that ME/CFS is a somatoform disorder either, but that has not prevented Wessely School psychiatrists and those UK agencies which they advise (including the MRC, the Department for Work and Pensions and NICE, as well as the medical and permanent health insurance industry for which they work) from ruthlessly and callously treating it as such, nor Professor Wessely from recently stating (*verbatim*): *"i can say that i remain very content and indeed proud of the contribution i and many of my colleagues have made in improving the management of this condition"* (<http://livingwithchronicfatiguesyndrome.wordpress.com/2010/08/29/conversing-with-professor-simon-wessely-part-2/>).

It may be worth recalling that Wessely also boasted that his team influenced the NICE Guideline (R&D annual reports by NHS organisations in England for 2007: South London and Maudsley NHS Trust: Section 2A) and that he is on record in a BMJ podcast on 5<sup>th</sup> March 2010 as asserting: *"We're not going to go doing more and more tests to find out what was the virus because, frankly, even if we found it there's nothing we're going to do about it"* (<http://podcasts.bmj.com/bmj/2010/03/05/chronic-fatigue-syndrome/>). Many people believe that this was a reprehensible thing for Professor Wessely to say about people who are desperately sick and in whom multi-system abnormalities have been found, including high levels of inflammatory markers, immune system dysfunction, abnormal brain scans, abnormal muscle structure and function and abnormal cardiovascular function.

It is essential that NICE should start paying attention to the biomedical evidence and stop supporting what many regard as cargo cult science (which in the case of ME/CFS seems to be the creation of policy-based evidence instead of evidence-based policy). Cargo cult science is a term used to describe work that has the semblance of being scientific but -- whilst following the apparent

precepts of scientific investigation – is lacking intellectual honesty; it is flawed research that fails to produce genuine results.

Whilst no-one reasonably objects to the prudent monitoring of escalating NHS costs, NICE seems to have become the draconian arm of the Department of Health to the extent that its *raison d'être* now seems to be only to save money, not to alleviate human suffering.

Recently NICE confirmed that: *“Clinical Guidelines represent the view of NICE, and are arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement”* and the Chief Medical Officer separately confirmed: *“Once NICE guidance is published, health professionals (and the organisations who employ them) are expected to take it fully into account when deciding what treatments to give people”* (<http://tinyurl.com/3xe49ow>), so it is essential that NICE does not continue to dismiss the now-extensive biomedical evidence about ME/CFS and does not allow itself to be inappropriately influenced by those with vested commercial interests (for example, the medical and permanent health insurance industry which, in the case of UNUMProvident, now advises and influences the UK Department for Work and Pensions about ways to reduce the number of those eligible for sickness/disability benefit payments).

NICE was set up in 1999 under the New Labour Government ostensibly to establish good practice in the NHS in England and Wales and it seems to be failing in its duty to people with ME/CFS by dismissing the large body of biomedical science that has been published about it and instead promoting ideologically-driven and harmful interventions that, in apparently favouring commercial interests, actually prevent physicians from adhering to the first tenet of medicine: *first do no harm*.